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Rohypnol [1]

Dole sweeps up 8 states

By Bob Minzesheimer
USA TODAY

AI

NEW YORK — Sen. Bob Dole took a giant step toward the GOP presidential nomination by winning all eight primaries held Tuesday.

"I think it's over," said House Speaker Newt Gingrich after hearing that Dole had won Gingrich's home state Georgia, Tuesday's biggest prize. "I think he's the nominee."

Dole's hopes for the nomination were further strengthened by reports that former Tennessee governor Lamar Alexander and Sen. Richard Lugar will drop out today. Both had been pressured by GOP leaders to clear the way for Dole.

"We've proven the pundits wrong," Dole said Tuesday night. "The Republican Party is not spinning apart, but coming together."

Dole leads in polls in New York, which votes Thursday.

"New York could do it. It could demoralize every other candidate in this race," Dole said.

But neither of Dole's top rivals, Pat Buchanan and Steve Forbes, showed signs of quitting what's left of the race.

The campaign moves south on March 12 and to the Midwest on March 19.

Sweeping winner-take-all contests Tuesday in New England, Maryland and Colorado, Dole now has 273 convention delegates, more than three times as many as any other candidate. But 996 are needed to be nominated in August.

"I know they call this Junior Tuesday but it seems pretty superior to us," a beaming Dole declared.

Buchanan, who hoped to "crack open the South" in Georgia, failed to win more than a third of the voters in any of Tuesday's primaries. Buchanan admitted, "It's an uphill battle everywhere," but said he'll fight all the way to the San Diego convention.

Forbes, who hoped for an upset in Connecticut and a strong showing in Colorado, got neither. Forbes, who is paying his own way, said he's in "for the duration" and predicts he'll win New York, although polls show him far behind.

In the busiest day of the primary season so far, Republicans in Minnesota and Washington state also held caucuses.

The Minnesota caucus didn't affect the delegate-selection process. Washington, where Buchanan is strong, won't report caucus results for days.

Today, Dole campaigns in Texas to pick up the endorsement of Gov. George W. Bush.

U.S. backs 'strong action' by Israel

By Lee Michael Katz
USA TODAY

AI

The U.S. Tuesday gave Israel its support for retaliation against the radical Palestinian group Hamas, blamed for 57 deaths in a wave of bombing attacks over the last 10 days.

Secretary of State Warren Christopher said "there is an understanding that Israel needs to take strong action to defeat the terrorism ... so deadly to its citizens."

Israel rejected Hamas' latest cease-fire offer, and stepped up its offensive.

Soldiers raided a West Bank village, contained 1 million Palestinian residents by closing borders and raided academic and charitable groups in areas linked to violence.

President Clinton will dispatch bomb detection equipment to Israel and terrorism experts to train and equip Israeli and Palestinian officials.

Clinton, fearing outrage over the bombings could torpedo Mideast peace talks, told Israelis in a TV address, "We stand with you today to bring this horror to an end and bring those responsible to justice."

He also warned that Palestinian leader Yasser Arafat "must do everything possible to end this campaign of terror."

GOP presidential hopeful Bob Dole said unless Arafat takes "serious anti-terrorism actions," \$340 million in pledged U.S. aid to his government may be jeopardized.

Arafat ordered his police to raid a West Bank teacher's college suspected of terrorism.

Christopher called his Syrian counterpart Farouk Shara to stress the need to fight terrorism. He also singled out Iran as "deeply involved" in aiding the Hamas bombers.

► Anger and fear, 7A

'Date rape' pill banned from USA

By Claudine Kriss
USA TODAY

AI

U.S. customs officials said Tuesday they will immediately begin seizing all imports of the sedative Rohypnol, which is often associated with date rape.

"Rohypnol has been called a party drug of today," said Customs Service commissioner George Weise. "Well, the party is over."

The announcement came after Treasury Secretary Robert Rubin banned the drug from the country.

Hoffmann-La Roche, which makes the drug in South America, Mexico, Europe and Asia, said it will work with officials to end "illegal diversion and illicit use of Rohypnol," known as roofies or the forget pill.

The powerful compound, 10 times stronger than Valium, causes a drunk, sleepy feeling that lasts up to eight hours.

Officials in Florida are investigating cases where women were sexually assaulted after being given the drug.

People entering the USA were allowed to bring in small amounts for their own use, but that will no longer be allowed.

A study indicated 101,000 tablets were brought into the USA at Laredo, Texas, during a three-week period last July.

Field shrinking as Lugar, Alexander set to leave

COVER STORY

Lifelong goal finally coming within reach

'If he had just ordinary grit ... he'd be under a white cross in Italy,' says friend

By Walter Shapiro
USA TODAY

The talk all day was of a sweep. But as the returns began to roll in Tuesday, Bob Dole still had too many disappointments under his belt to take anything for granted.

He sat quietly watching the evening news on four TV screens in his Senate suite, smiling and giving a thumbs-

up sign with his left hand only to please the photographers. Even as he walked from his office to do the obligatory TV interviews, the no-more-doldrums candidate refused to exult. "We're still watching Georgia," where it was still close, he told reporters who wanted something more quotable, less Bob Dole-like. "Doing all right there, I think," he added, as much for himself as for history.

It was left to House Speaker Newt Gingrich, once a potential rival in the presidential race, to put the needed spin on the primary results. Gingrich, who had been watching the returns, said Dole "walked over and shook my hand and said he was really happy to be carrying Georgia." And then with typical understatement, "Thanks for your vote."

Gingrich tried to explain Dole's emotional caution on what was the biggest victory night in his three tries for the party's presidential nomination.

"This is a guy who's run for president several times, been national chairman, been vice presidential nominee," Gingrich said. "I don't think he's going to take anything for granted until the inauguration."

Please see COVER STORY next page ▶

Continued from 1A

Still, Dole was laughing, even cracking jokes, through much of his campaign day. And at 2:15 p.m., when an aide hurried onto the Senate floor to give him the first exit polls, Bob Dole had to smile. He was ahead in every state.

Those numbers stood for more than a primary sweep or his latest

COVER STORY

political resurrection. They represented a lifelong journey that carried him from the hospitals in which he recuperated after World War II to the Senate to disappointments in his attempts for the White House.

Now, after firing his pollster in frustration over his New Hampshire primary defeat, Dole was back on top with visions of a San Diego coronation dancing in his head.

Dole is still a long way from moving into 1600 Pennsylvania Avenue, though he did tell a business group in New York Tuesday morning that the recent marathon budget negotiations "gave me my first real look at the White House. It was exciting."

Pat Buchanan, accustomed to the role of underfunded underdog, will be at his back all the way to the convention. And Steve Forbes, said campaign chairman Malcolm Wallop, also is a good bet to stay in the race.

Dole may again be hailed as Mr. Inevitable, but he is more than 700 delegates short of the 996 needed for nomination. And even after San Diego Dole must still face that other Comeback Kid, President Clinton.

Not since Franklin Roosevelt triumphed over polio to win the White House in 1932 has any presidential candidate overcome a life filled with so much adversity. Until the last few days, Dole has been reluctant to talk about the World War II wounds that crippled his right arm and force him to constantly hold a pen in his right hand to give it definition.

"On April 14, 1945, two days after the death of Franklin D. Roosevelt, our commander in chief," Dole began Monday as he tried to tell the Nassau County Republicans the story

of his war in Italy.

"I was wounded. But that's not the point," Dole said, still groping to adjust to the tell-all demands of 1990s politics. "The point is that it was pretty bad. And it took 39 months to recover. Before I could feed myself, or dress myself, or do a lot of things that we don't think about."

Dole in politics has long been something of a Rodney Dangerfield clone, never quite getting the respect he craved. As Jerry Ford's running mate in 1976, he was widely criticized for railing against "Democrat wars" in a vice-presidential debate with Walter Mondale.

Dole said he first thought about running for president himself the day after Ford's defeat as a way of countering his Republican critics, who blamed his "hatchet man" image for the loss.

The less said about Dole's abortive 1980 race for the GOP nomination the better. Then, just inches from grasping the brass ring in 1988, Dole stumbled in New Hampshire by failing to respond to a last-minute fusillade of negative ads from George Bush. The final nail in the coffin came when Dole snapped at Bush on TV the night of the primary to "stop lying about my record."

After he lost New Hampshire in 1988, Dole had no strategy, no way to rebound. He spent the last wan days of the campaign visibly depressed, bitterly joking aboard his campaign plane, "Maybe we should fly around until we see a crowd and land."

But four years later, it was a different Dole who fought back the tears at a Senate dinner honoring Bush after his defeat in the 1992 election, or who openly cried at President Nixon's funeral in 1994.

Having survived prostate cancer, Dole sensed that his generation — the fighting men of World War II — was passing from the stage and that he would never get another chance at the presidency.

As Kim Wells, an old friend from Kansas, put it Tuesday, Dole's roll through the primaries "must be emotionally gratifying for him. But that's the story of Bob Dole. If he had just ordinary grit and determination, he'd be under a white cross in Italy.

He was given up for dead on a battlefield. He was given up as politically dead in his 1974 Senate race. He was dead again in 1980."

This time around the Dole team always boasted a what-if-New-Hampshire-turns-sour strategy. Endorsements were part of the game, but equally important was the primary calendar. South Carolina, where Dole reigned his stalled engines last Saturday, was seen as the gateway to the South. The same organization the late Lee Atwater constructed to stop Dole in 1988 was now employed to knock some of the bluster out of Buchanan.

Dole's secret strength lies in the way he's tailored his positions to fit the agenda of social conservatives, whose support he could not afford to lose to Buchanan. Many in the Senate, where Dole is known as a voice of moderation, would not recognize this born-again candidate who hit all the hot button issues from opposition to "filth" in the arts to the "liberal activists" who are ruining the nation's courts.

"I have a flawless record on standing up for the unborn, which is not going to change when I become president of the United States," he told the Christian Coalition in South Carolina. "In fact, the first time this was an issue was in my race in Kansas in 1974."

More than anything, this last point represented a stretch by Dole. Richard Ben Cramer, in his book *What It Takes* — a vivid portrait of Dole that is treated like holy writ by his staff — paints a far different picture of that post-Watergate 1974 Senate election race.

Dole's opponent, a doctor-turned-congressman who had performed a few abortions to save the life of the mother, was far ahead in the polls when the senator turned on him in the final seconds of a campaign debate and snapped, "Why do you do abortions? And why do you favor

abortion on demand?"

Afterwards, as Cramer recounts, Dole was so depressed by his own false charges that he confided to an aide, "I'm just not sure it's worth it."

But in dire straits on the eve of the South Carolina primary, Dole reached into his nearly empty ammunition pouch and dredged up this same 20-year-old episode as something to brag about in demonstrating his fidelity to the anti-abortion cause.

Even after winning more primaries in a single day than he had in the entire 20 years he has sought the presidency, Dole is far from the perfect candidate.

His age troubled primary voters in New Hampshire. Dole can still lapse

into congressional jargon at the slightest provocation. "We will veto Bill Clinton in November" is an example he used as an applause line Tuesday night.

Monday, at a raucous Republican rally in Franklin Square, N.Y., Dole reveled in the cheers of the troops gathered by Sen. Alfonse D'Amato.

Dole is widely expected to sweep almost all New York's 31 congressional districts on Thursday. But even his fervent supporters admit that their standard-bearer is not the ideal candidate for a TV age.

Nassau County Republican Chairman Joseph Mondello talked about the hundreds of people who had called him to say, "In person, (Dole) comes across rather well." Mondello added, "Television does not give a great sense of who Bob Dole is."

But the TV age did not produce the qualities that have led Dole to the gateway of the Promised Land. His character was forged the hard way, though suffering, determination and strength of will.

Few people achieve their long-frustrated ambitions when they are 72 years old. But then, if Bob Dole were not an exception to every rule, he would not have come nearly as far as he has.

Contributing: Judi Hasson and Richard Wolf in Washington.

Business Groups Ready to Fight On Health Care

By LAURIE MCGINLEY

Staff Reporter of THE WALL STREET JOURNAL
WASHINGTON — Business groups are mobilizing to fend off controversial provisions that might weigh down new health-insurance legislation.

House leaders, as they prepare to plunge into the knotty issue, are working on a proposal that may include medical savings accounts, antitrust relief to doctors and overhaul of medical malpractice laws, according to Republican aides. But proponents of the bill are afraid that including these provisions would make it more difficult to get the legislation enacted.

Groups including the Business Roundtable, the National Association of Manufacturers, the Healthcare Leadership Council, the American Association of Health Plans and the Association of Private Pension and Welfare Plans are urging the House to produce a "clean" bill protecting workers from losing health-insurance coverage because of a change in job status or a pre-existing medical condition.

Such a bill is being championed in the Senate by Chairman Nancy Kassebaum of the Labor and Human Resources Committee and Sen. Edward Kennedy, the panel's ranking Democrat.

"From a procedural standpoint, we'd be happier if they didn't clutter up the insurance-portability bill with those provisions," said Paul Huard, senior vice president of the NAM.

Pamela Bailey, president of the Healthcare Leadership Council, which represents managed-care companies, hospitals and pharmaceutical companies, said that although her group supports some of the provisions House leaders would like to include in the bill, those issues should be handled separately. On insurance reform, she said, Congress should "focus on elements on which there is bipartisan agreement. The last thing any of us want is to see is this legislation going down to defeat, because the political support is so broad it would be a tragedy to lose this."

Many of the groups appeared at a news conference yesterday to express support for the Kassebaum-Kennedy bill and the two senators' strategy to fend off amendments on the floor; the bill is tentatively scheduled for floor debate on April 18 or 19. Many of the employer groups said they would oppose the bill if it included provisions imposing new, costly restrictions on managed-care companies or eliminating caps on benefits paid over a lifetime.

But in interviews later, the business officials also said they were concerned about the potential political impact of some of the items the House may include in its version of insurance overhaul. For example, a provision to provide tax incentives for the creation of medical savings accounts is staunchly opposed by many Dem-

California Firms to Help Connect Schools to Internet

By a WALL STREET JOURNAL Staff Reporter
MOUNTAIN VIEW, Calif. — Sun Microsystems Inc., Hewlett-Packard Co., Pacific Telesis Group and more than 800 other companies and universities plan an electronic barn-raising: they will try to connect California's 13,000 elementary and secondary schools to the Internet.

The organizers of NetDay96 don't expect to get all the schools wired that day, but they may be able to make a good start. As of Tuesday, 13,644 volunteers had signed up, mostly on a site on the Internet's World Wide Web. The site has a map showing which schools need help, and allows volunteers to sign up online. On Saturday, the volunteers will show up at the schools to lay cable and telephone lines and do other work.

The event has drawn a number of endorsements, including one from President Clinton. If the organizers reach their goal, California would be the only state where every school is linked to the Internet.

"We are doing what the government said it couldn't," said John Gage, head of Sun Microsystems' science office, and a key organizer of the event.

ocrats, including Sen. Kennedy and President Clinton.

Nevertheless, an aide to Rep. Dennis Hastert (R., Ill.), who is coordinating the House effort, said strong GOP support for medical savings accounts means it's unlikely that a health bill could pass the House without such a provision. And other aides said that many House members are eager to take another crack at passing antitrust and medical malpractice changes, which are important pieces of the Republican health agenda. But passing the provisions in the House may set up a confrontation with the Senate that will make it difficult to work out differences and pass compromise legislation acceptable to the White House.

U.S. Places Ban on Import Of the Sedative Rohypnol

WASHINGTON (AP) — The U.S. banned the importation of the sedative Rohypnol, saying the pill is a growing threat to teenagers and young adults and has no legitimate therapeutic use.

The pills are manufactured overseas and used legally in about 60 nations for insomnia. Until yesterday, travelers to the U.S. could bring a three-month supply for personal use.

But Treasury Secretary Robert E. Rubin said the Customs Service now will seize any amount of the drug, also known as "roofies," that is brought into the country by travelers, in commercial shipments or by mail.

The Drug Enforcement Administration is taking steps to reclassify it as a Schedule 1 drug with no accepted medical use in the U.S. As such, it will be grouped with heroin, methaqualone and LSD.

Rohypnol, a sedative 10 times more potent than valium, often has been associated with date rape, the Treasury said, citing numerous news reports about women claiming to have been assaulted after their drinks had been spiked. The drug creates a drunken, then sleepy feeling that peaks after two hours and lasts about eight.

THE WALL STREET JOURNAL
WEDNESDAY, MARCH 6, 1996

Tax Report

A Special Summary and Forecast Of Federal and State Tax Developments

AI ESTATE-TAX CUTS sought by business groups draw icy reception from Treasury.

A coalition of more than 80 business groups urged President Clinton last week to reconsider his opposition to large-scale relief from estate and gift taxes. But the Treasury isn't convinced. Officials say congressional proposals to slash estate and gift taxes would benefit the rich at a very high cost to the nation.

The federal estate tax now hits only about 25,000 estates each year, or slightly more than 1% of all Americans who die annually, Treasury officials say. GOP proposals for broad relief, if enacted, would result in exempting nearly half the estates that now pay. Thus, Treasury opposes broad relief, but it does favor allowing easier payment terms for businesses hit by the tax. "Helping families pay estate tax over time at a low interest rate is our first priority," says Leslie B. Samuels, Treasury's top tax-policy official.

"Further relief for the 1% of estates that pay estate tax would be costly in this budget environment," Mr. Samuels says.

THE INTERNET may offer new ways to cheat on taxes.

The marvels of the electronic era may have a dark side: aiding and abetting tax fraud. And that prospect has Treasury officials worried. "Not only does the Internet afford the opportunity for desirable cultural, economic and other activity, it also creates possible opportunities for tax avoidance," says Joseph Guttentag, Treasury's international-tax counsel.

The concern is over development of electronic-payment systems that allow anonymous transfers of funds over the Internet. These systems, one official explains, create "the possibility for extensive transactions outside of normal banking channels." Mr. Guttentag says the government will "maintain tax toll booths on the information superhighway."

LAW FIRMS and debt-collection agencies will help the IRS collect back taxes.

Late last year, Congress inserted a provision in the IRS's budget calling for a \$13 million pilot program to hire law firms and debt-collection agencies to help rake in unpaid taxes. The idea drew strong objections from some lawmakers, IRS officials and outside tax specialists. Critics fear private agencies might violate taxpayer privacy and other rights. But the critics lost, and the IRS yesterday said it has begun soliciting bids for the work.

The IRS seeks firms to find and contact taxpayers by phone or mail—not in person—and remind them of their unpaid taxes as well as available payment alternatives. The IRS plans to award three to five contracts to work on 25,000 to 40,000 cases each over one year. Firms will get very little information about the taxpayers they are pursuing. Payments will go to the IRS, not outsiders. Cases will include individual and businesses now or formerly in Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington and Wyoming.

If taxpayers have moved, contractors will have to try to find and contact them.

THE WALL STREET JOURNAL
WEDNESDAY, MARCH 6, 1996

CHAIRMAN ARCHER of the House Ways and Means Committee plans a series of hearings starting March 20 and continuing through late this year on overhauling the tax code. The March 20 hearing will focus on problems with today's law. Later hearings will analyze the possible impact of proposed changes. Archer wants to replace the entire code with a broad-based consumption tax.

JUDGE MARY ANN COHEN takes over as chief judge of the U.S. Tax Court in June. Judge Cohen, 53 years old, succeeds Lapsley W. Hamblen Jr., 69, who has been chief judge for four years.

HOME PRICES a decade from now would be about 10% lower if Washington enacts a flat tax such as the one proposed by Robert Hall and Alvin Rabushka of the Hoover Institution. That is the median forecast of 18 economists, lawyers and tax analysts surveyed at a recent Brookings Institution conference.

OPPOSITION GROWS to a proposed new tax on short-term securities sales.

Senior Treasury officials yesterday joined Wall Street groups in opposing a recent proposal by Sen. Bingaman. As part of a large package of proposals, the New Mexico Democrat suggested a tax on sales of securities held less than two years. This "securities transfer excise tax," to be paid by the seller, would diminish gradually over the holding period of the security. All the tax rates work out to less than 0.5% of the value of the security at the time of the sale.

Sen. Bingaman calls his plan a tax on "short-term churning" of securities. It wouldn't apply to new issues. But a Treasury official said in an interview yesterday the proposal, if enacted, "could reduce liquidity of capital markets." Also, he said, enactment "would disadvantage" frequently traded securities such as Treasury bills and "thus raise Treasury's financing costs."

Micah Green, executive vice president of the Public Securities Association, a bond-market trade group, labels the idea "bad economic policy" and predicts it would lead to "less investment, fewer jobs and a weaker economy."

BRIEFS: An accountant in the Washington, D.C., area called the IRS about an estate-tax issue. He says the IRS representative asked him: "Are you the decedent?" . . . Clinton political guru James Carville, in his new book modestly titled "We're Right, They're Wrong," includes a section on the flat tax called: "Flat Earth, Flat Taxes."

—TOM HERMAN

LEVEL 1 - 1 OF 29 STORIES

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SECTION: Variety; Pg. 1E

LENGTH: 654 words

HEADLINE: FYI;
'Date-rape' drug

BYLINE: Dave Matheny; Staff Writer

BODY:

Rohypnol, a potent sedative-hypnotic drug, has made its way to Minnesota. Rohypnol is a sleeping pill used in Mexico but not approved for use in the United States. It has been abused primarily by young people who combine the drug with alcohol. Because of its amnesialike effects it also is being used as a date rape drug, according to a drug alert issued by the Minnesota Department of Human Services.

In southern Minnesota, abuse of the drug has been suspected in several cases in which some is placed in alcoholic beverages of young women who are subsequently exploited sexually. Victims have no recall of the events following sedation. Rohypnol has a bitter taste when added to a beverage and is about 10 times more potent than Valium. For more information on this drug, call the Minnesota Prevention Resource Center at 427-5310 (metro) or (800) 247-1303.

- Hazelden Foundation

Saddam happens

Five years ago today, the Gulf War suddenly became real, as Allied jets swept into Iraq. We're indebted to "War Slang" by Paul Dickson (Pocket Books hardcover; \$ 25) for the following information. There is something appealing about slang that grows up around particular pursuits or disciplines, especially hazardous ones: It reflects how we adapt to hardship and even to the possibility of being killed.

Dickson includes sections on specialized slang from the Civil War up through the present. Here are a few from the Gulf War:

- Diver: CNN reporter Charles Jaco, known for diving off camera during Scud alerts.

- Homer: A member of the Iraqi army (based on bumbling Homer Simpson).

- Little Hollywood: Area near the swimming pool of the Dharhran hotel, from which TV correspondents frequently delivered their live reports, often wearing

helmets, flak jackets and goggles, while the camera crews wore T-shirts. Mysterious blue domes seen in the background actually were pool cabanas and storage sheds.

- Poor man's defense: The Iraqi tactic of filling the sky with randomly aimed gunfire, as was seen over Baghdad almost nightly.

- Saddam Happens: Bumper sticker seen on the back of a tank.

- Speed bumps: At first, the handful of U.S. troops on the Saudi Arabian side of the border, facing the massed Iraqi forces on the other side; if the Iraqis had attacked, the Americans saw themselves as little more than speed bumps. Later the term was applied to Iraqi soldiers. (By the time the war ended, Iraqi troops had been killed by Allied forces at a ratio of about 1,000 to one. In fact, the Pentagon later said that more Americans would have died if the troops had remained stateside during the same period, largely from road accidents.)

- W.T.O.: The Washington Theater of Operations - an ironic reference.

In a subsection titled "Murphy's Laws for Grunts," Dickson includes a list of 29 laws. A sampling:

- When in doubt, empty your magazine.
- If the enemy is in range, so are you.
- Tracers work both ways.
- The easy way is always mined.
- Dave Matheny

This week

Thinking about the warm

One way to take the edge off of winter is to go to a big indoor place where they pretend it's some other season - summer, for example. Actually, the annual Minnesota Sportsmen's Boat, Camping and Vacation Show isn't just for warm-weather activities, but that's what comes to mind for most folks: Boats, RVs, hunting and fishing stuff is what it's about. As usual there are displays and demonstrations, including a live trout pond and stage shows.

- What: 1996 Minnesota Sportsmen's Boat, Camping and Vacation Show
- When: Today, 5 to 10:30 p.m.; noon to 10:30 p.m. tomorrow through Friday; 10 a.m. to 10:30 p.m. Saturday; 10 a.m. to 6:30 p.m. Sunday.
- Where: St. Paul Civic Center, St. Paul.



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- Admission: \$ 6 adults, \$ 2 children under 12; preschoolers free.

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LEVEL 1 - 3 OF 29 STORIES

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HEADLINE: After mickey came roofie: Illegal drug used in date rapes;
Sedative slipped into drinks creates nightmares for some

BYLINE: JULIO LABOY; Orange County Register

DATELINE: SANTA ANA, Calif.

BODY:

SANTA ANA, Calif. - It started out as a casual get-together for a 25-year-old student but ended in rape, humiliation and the harrowing revelation that a drug used in date rapes is knocking on the nation's door.

The drug, Rohypnol, is described by law enforcement as a sedative 10 times more powerful than Valium and is manufactured by the F.Hoffmann-La Roche & Co. pharmaceutical firm, based in Basel, Switzerland. Not approved for use in the United States, it has been a legal prescription drug for several years in most of the world and is available in Europe and Latin America.

The sale and introduction of the drug into interstate commerce in the United States is illegal; virtually the only people who can possess it legally in this country are those who have prescriptions written in other countries.

On the street, users call the small, white pills "'roofies'" and "'Roche. '" The substance has also been referred to as "'the date rape drug'" and "'the Quaalude of the '90s,'" after another often abused sedative. Rohypnol is drawing the attention of narcotics experts across the country.

It is being smuggled into the United States, usually in its original wrapping, through Colombia and Mexico, according to Bob Nichols, an assistant state prosecutor in Fort Lauderdale, Fla., where illegal use of roofies in this country first became noticed.

Nichols has been involved in five sexual-battery cases connected to roofies in the last five months.

"I don't know why it's suddenly on the scene. It's been around awhile," Nichols said. "The pattern with the rapes is that



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The Houston Chronicle, January 1, 1996

high school and college kids and gang members are slipping it into drinks at nightclubs and pick-up joints. '' That is what one Orange County, Calif., woman, an English major at the University of California, San Diego, believes happened to her Sept. 29.

The student attended a concert that night with a male friend.

The two were not romantically involved, she said.

She had three glasses of wine that night. At least one glass of wine was consumed in the parking lot of the San Diego theater where the concert was taking place.

That's when the student started feeling strangely. She doesn't remember the concert. She doesn't remember how she got home.

She doesn't remember getting into bed. The last thing she does recall is waking up the next morning naked and in a pool of vomit.

''I was so sick when I woke up,'' she said. ''I could hardly hold

my head up. I couldn't remember anything. I noticed there was vomit on the bed and stuck on my hair. I was lying in it. I could have choked on it and died. He was naked and I was naked. He said we made love. ''

The woman was crushed. Their relationship had never been an intimate one, she said. The Orange County Register, which generally doesn't publish the names of sexual-abuse victims, is withholding her name from publication.

The woman, who works as a part-time language teacher and as a waitress, believes that her companion slipped a roofie into her wine that night and that it erased her memory, an effect described by pharmacologists and in medical reports.

Struggling to overcome the nightmare, the woman is seeing a therapist and is taking a vacation out of the country to escape the everyday reminders of that ill-fated night. She agreed to share her story because, she said, ''I didn't do anything wrong. ''

She wants to turn a negative experience into a positive one.

She wants to warn other young women about roofies.

''My friends had no clue about this drug,'' she said. ''This stuff is scary. You can't be cautious enough. ''

She called a rape hot line after spending two lonely days knee-deep in guilt and self-doubt. She then went to a therapist at Kaiser Permanente in San Diego.



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"Some people were saying I got drunk. But I didn't. I just had wine," the student said. "I was telling (the therapist) that I couldn't believe it. I was crying. I was confused. As I started telling her my story she said, 'Hold on. I know what this is. ' ' "

The student learned from the therapist that her situation resembled a drugging, and that an epidemic of similar cases had arisen in the past six months.

"She said they all were feeling sluggish and drunk on dates that ended in rape," the student said.

That's when the student first heard about roofies.

"We have seen many date-rape cases," Kaiser Permanente spokesman Jim McBride said. "Many of those patients report being drugged. Our therapists believe these stories are credible. It's real. It's happening. ' ' "

The woman then notified the San Diego Police Department.

Investigators are looking into the matter.

Police Sgt. Joanne Archambault of the sex-crimes unit said she cannot comment on rape cases because of privacy reasons, but confirmed that the student's report had been taken.

"Recently, lots of girls have been coming in saying they were drugged or passed out after having one or two drinks," Archambault said. "We even talked to the Poison Control Center about it. ' ' "

Orange County drug counselors and law-enforcement officers are bracing for the arrival of roofies, which typically cost \$ 1 to \$ 5 for a single, 2-milligram pill. The pill is also taken by cocaine users who want to parachute down less harshly from a cocaine high.

"I would assume that because of the movement of things in the San Diego-Los Angeles-Orange County corridor, that yes, it may be here," said Bill Edelman, division manager in charge of alcohol and drug programs at the Orange County Health Care Agency. Reports of Rohypnol abuse have surfaced in Florida, Texas and other parts of the Southwest, he said.

Jennifer Trenshaw, health educator at the University of Southern California Health Center, had a word of advice for people, especially women: Don't leave your drink unattended, and don't accept a drink from a stranger.



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LANGUAGE: ENGLISH

LOAD-DATE: January 3, 1996



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LEVEL 1 - 4 OF 29 STORIES

Copyright 1995 The Dallas Morning News
THE DALLAS MORNING NEWS

December 17, 1995, Sunday, BULLDOG EDITION

SECTION: NEWS; Pg. 40A

LENGTH: 1655 words

HEADLINE: Police suspect illegal sedative used in date rapes

BYLINE: Julio Laboy, Orange County Register

DATELINE: SANTA ANA, Calif.

BODY:

SANTA ANA, Calif. - It started out as a casual get-together for a 25-year-old student but ended in rape, humiliation and the harrowing revelation that a drug used in date rapes is knocking on the nation's door.

The drug, Rohypnol, is described by law enforcement as a sedative 10 times more powerful than Valium and is manufactured by the F. Hoffmann-La Roche & Co. pharmaceutical firm, based in Basel, Switzerland. Not approved for use in the United States, it has been a legal prescription drug for several years in most of the world and is available in Europe and Latin America.

The sale and introduction of the drug into interstate commerce in the United States is illegal; virtually the only people who can possess it legally in this country are those who have prescriptions written in other countries.

On the street, users call the small, white pills "roofies" and "Roche." The substance has also been referred to as "the date rape drug" and "the Quaalude of the '90s," after another oft-abused sedative. Rohypnol is drawing the attention of narcotics experts across the country.

It is being smuggled into the United States, usually in its original wrapping, through Colombia and Mexico, according to Bob Nichols, an assistant state prosecutor in Fort Lauderdale, Fla., where illegal use of roofies in this country first was noticed.

Mr. Nichols has been involved in five sexual-battery cases connected to roofies in the last five months.

"I don't know why it's suddenly on the scene. It's been around awhile," Mr. Nichols said. "The pattern with the rapes is that high school and college kids and gang members are slipping it into drinks at nightclubs and pick-up joints."

That is what one Orange County, Calif., woman, an English major at the University of California, San Diego, thinks happened to her Sept. 29.

The student attended a concert that night with a male friend.



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The two were not romantically involved, she said.

She had three glasses of wine that night. At least one glass of wine was consumed in the parking lot of the San Diego theater where the concert was taking place.

That's when the student started feeling strange. She doesn't remember the concert. She doesn't remember how she got home. She doesn't remember getting into bed. The last thing she does recall is waking up the next morning naked and in a pool of vomit.

"I was so sick when I woke up," she said. "I could hardly hold my head up. I couldn't remember anything. I noticed there was vomit on the bed and stuck on my hair. I was lying in it. I could have choked on it and died. He was naked and I was naked. He said we made love."

The woman was crushed. Their relationship had never been an intimate one, she said. The Orange County Register, which generally doesn't publish the names of sexual-abuse victims, is withholding her name from publication.

The woman, who works as a part-time language teacher and as a waitress, thinks that her companion slipped a roofie into her wine that night and that it erased her memory, an effect described by pharmacologists and in medical reports.

Struggling to overcome the nightmare, the woman is seeing a therapist and is taking a vacation out of the country to escape the everyday reminders of that ill-fated night. She agreed to share her story because, she said, "I didn't do anything wrong."

She wants to turn a negative experience into a positive one. She wants to warn other young women about roofies.

"My friends had no clue about this drug," she said. "This stuff is scary. You can't be cautious enough."

She called a rape hotline after spending two lonely days knee-deep in guilt and self-doubt. She then went to a therapist at Kaiser Permanente in San Diego.

"Some people were saying I got drunk. But I didn't. I just had wine," the student said. "I was telling the therapist that I couldn't believe it. I was crying. I was confused. As I started telling her my story she said, Hold on. I know what this is." "

The student learned from the therapist that her situation resembled a drugging and that an epidemic of similar cases had arisen in the past six months.

"She said they all were feeling sluggish and drunk on dates that ended in rape," the student said.

That's when the student first heard about roofies.

"We have seen many date-rape cases," Kaiser Permanente spokesman Jim McBride said. "Many of those patients report being drugged. Our therapists believe

these stories are credible. It's real. It's happening."

The woman then notified the San Diego Police Department.

Investigators are looking into the matter.

Police Sgt. Joanne Archambault of the sex-crimes unit said she cannot comment on rape cases because of privacy reasons, but she confirmed that the student's report had been taken.

"Recently, lots of girls have been coming in saying they were drugged or passed out after having one or two drinks," Sgt. Archambault said. "We even talked to the Poison Control Center about it."

Orange County drug counselors and law-enforcement officers are bracing for the arrival of roofies, which typically cost \$ 1 to \$ 5 for a single, 2-milligram pill.

"I would assume that because of the movement of things in the San Diego-Los Angeles-Orange County corridor, that yes, it may be here," said Bill Edelman, division manager in charge of alcohol and drug programs at the Orange County Health Care Agency. Reports of Rohypnol abuse have surfaced in Florida, Texas and other parts of the Southwest, he said.

Jennifer Trenshaw, health educator at the University of Southern California Health Center, said she advised people, especially women, not to leave their drinks unattended and not to accept drinks from strangers.

The UCSD student who says she was raped remembers going to the bathroom twice during the concert. She left her drink with her date.

The student described all the classic circumstances and side effects of a roofie mixed with alcohol, Mr. Edelman said.

"It's a sedative. It's a drug that can be enhanced when it is combined with alcohol or opiates," Mr. Edelman said.

Rohypnol, the brand name for Flunitrazepam, is used in other countries to treat anxiety and insomnia and to sedate surgery patients, according to pharmacologists and drug-information centers.

Patients on the drug appear drunk. When it's combined with alcohol, the effects can be deadly.

"These guys using this to get girls are like those people who like to do things with dead bodies," Mr. Edelman said. "It's sick."

Maybe we need to think about a campaign about how this drug is used in bars."

Al Wasilewski, a spokesman for the pharmaceutical company's U.S. division, said the drug is being illegally mailed into the United States. He also said that some Mexican pharmacies near the U.S. border are illegally selling the drug over the counter. He said Hoffmann-La Roche has never sought approval to market the drug in the United States.



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"It's a legitimate product sold for legitimate use in those countries where it's registered," Mr. Wasilewski said. He disagreed with law-enforcement officials who have described the drug as being 10 times more powerful than Valium but acknowledged that taken in equal doses, Rohypnol will act more quickly and more powerfully than Valium.

"They are two different drugs designed to do two different things," Mr. Wasilewski added. "It was about a year ago when we began to see just more than sporadic abuse of Rohypnol."

Hoffmann-La Roche has initiated studies to learn more about how the drug is being abused, where it's coming into the United States, and where in the country it is most likely to be found. The company is trying to track its movement throughout the country and recently helped set up a task force with members drawn from federal and local law-enforcement agencies, academics and drug-counseling centers, Mr. Wasilewski said. The company has also disseminated alerts to the health-care industry and police departments.

Hoffmann-La Roche has divisions in Mexico City and Bogota, Colombia, where Rohypnol is manufactured for the Latin American market.

"We're doing everything that is possible for Roche to get this product off the streets," Mr. Wasilewski said. "We're confident that the diversion of Rohypnol is not occurring internally from our sites in Mexico and Colombia."

Dr. Jim Adams, associate professor of molecular pharmacology and toxicology at USC's School of Pharmacy, said Flunitrazepam can make someone lose control of motor and neurological functions.

Respiration is also affected. When it's mixed with alcohol, he said, a coma can easily follow. Vomiting also can occur, and if a victim is unconscious, he or she runs the risk of drowning in the discharge.

The drug reacts with brain cells to quickly diminish nervous system operations, said Dr. Edward Newton, a consultant to the Los Angeles Regional Poison Control Center. The area the center serves includes Orange County.

"It depresses neurological activity in the brain," Dr. Newton said. "People do die if they take too much."

It is difficult to determine a lethal dose of Rohypnol because reactions to sedatives differ among individuals, and when taken alone it is not difficult to manage, according to the Up Front Drug Information and Education Center in Miami. An overdose is more likely when Rohypnol is mixed with alcohol or other drugs. The speed with which the overdose will take place depends on how much alcohol a person has consumed.

A roofie will sedate its user quickly. Sedation occurs 15 to 30 minutes after ingestion and lasts about eight hours, USC's Ms. Trenshaw said. If an overdose occurs, the need for medical care is urgent.

An added problem with Rohypnol is that it causes amnesia for most of the sedation period, especially during a patient's first consumption. That makes prosecution of abuse cases difficult, Ms. Trenshaw said.



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LANGUAGE: ENGLISH

LOAD-DATE: December 18, 1995



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LEVEL 1 - 5 OF 29 STORIES

Copyright 1995 Denver Publishing Company
Rocky Mountain News

December 10, 1995, Sunday

SECTION: NEWS/NATIONAL/INTERNATIONAL; Ed. F; Pg. 95A

LENGTH: 374 words

HEADLINE: New drug takes hold among teens
Florida, Texas report surging use of Rohypnol, sold legally in 60 countries
but not U.S.

BYLINE: Mireya Navarro; The New York Times

DATELINE: MIAMI

BODY:

A prescription drug sold abroad is becoming the fastest-growing abused drug among young people in Florida and has found its way to a dozen other states, law-enforcement officials say.

Manufactured by Hoffmann-La Roche, the Swiss pharmaceutical company, and sold by prescription in about 60 countries as Rohypnol, the pills are not made or approved for use in the United States.

Federal Drug Enforcement Agency officials say police in Florida, Texas and other southern states are reporting an increase in smuggled shipments from Colombia, a Hoffmann-La Roche distribution site for other Latin American countries, and from Mexico, where some pharmacies sell Rohypnol over the counter.

The DEA has reported Rohypnol seizures in at least 13 states but says its distribution and abuse has been concentrated in Texas and Florida, where some law enforcement officials say the pills threaten to become "the Quaaludes of the '90s."

Lee P. Brown, the White House drug-policy director, said Friday that Rohypnol is an emerging drug that his office is tracking closely but that "it has, by no means, become a national problem."

In Florida, drug counselors say Rohypnol has found a thriving market among teen-agers who have made it the latest addition to the drug scene at nightclubs and in schools.

School officials say Rohypnol has become almost as widely used as marijuana and LSD.

In Texas, where Hoffman-La Roche is financing an epidemiological study to examine why Rohypnol is being abused, researchers say it is taken mostly by people who find it more potent than other sedatives.



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Rohypnol is a benzodiazepine, a class of sedatives that includes Valium. The drug induces muscle relaxation, short-term amnesia and sleep.

LANGUAGE: English

LOAD-DATE: December 12, 1995



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LEVEL 1 - 7 OF 29 STORIES

Copyright 1995 The New York Times Company
The New York Times

December 9, 1995, Saturday, Late Edition - Final

SECTION: Section 1; Page 6; Column 1; National Desk

LENGTH: 1313 words

HEADLINE: In South, Drug Abusers Turn to a Smuggled Sedative

BYLINE: By MIREYA NAVARRO

DATELINE: MIAMI, Dec. 8

BODY:

A prescription drug sold abroad is becoming the fastest-growing abused drug among young people in Florida and one that has found its way to a dozen other states, law-enforcement officials say.

Manufactured by Hoffmann-La Roche, the Swiss pharmaceutical company, and sold by prescription in about 60 countries as Rohypnol, the pills are not made or approved for use in the United States. But Drug Enforcement Administration officials say the police in Florida, Texas and other Southern states are reporting an increase in smuggled shipments from Colombia, a Hoffmann-La Roche distribution site for other Latin American countries, and from Mexico, where some pharmacies sell Rohypnol over the counter.

The Federal Drug Enforcement Agency has reported Rohypnol seizures in at least 13 states but says its distribution and abuse has been concentrated in Texas and Florida, where some law enforcement officials say the pills threaten to become "the Quaaludes of the '90s."

Lee P. Brown, the White House drug policy director, said today that Rohypnol was an emerging drug that his office was tracking closely but that "it has by no means become a national problem."

But in Florida, drug counselors say Rohypnol has found a thriving market among teen-agers who have made it the latest addition to the drug scene at nightclubs and in schools. School officials in South Florida say Rohypnol, considered a bargain at \$5 or less a pill, has become almost as widely used as marijuana and LSD among students.

Officials in Dade County, where the sedative first surfaced in 1989, have become concerned enough that they have begun routine testing for Rohypnol in cases where the driver appears drunk but registers low alcohol levels. The medical examiner's office will soon begin to test for Rohypnol in cases in which women say they might have been raped but do not remember.

In Texas, where Hoffman-La Roche is financing an epidemiological study to examine why Rohypnol is being abused, researchers say it is mostly taken by users of other drugs who find it more potent than other sedatives. Cocaine



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The New York Times, December 9, 1995

addicts say Rohypnol helps them come down more smoothly from their high; heroin users say it offsets their withdrawal symptoms.

Known among American users as "roofies," from the mispronunciation of the brand name, and sometimes as "roach" or "rope," Rohypnol is a benzodiazepine, a class of sedatives that includes Valium. Marketed in 1- or 2-milligram dosages, it induces muscle relaxation, short-term amnesia and sleep. Its effect, felt within 15 to 20 minutes and lasting eight hours or more, is similar to that of alcohol in that it helps loosen inhibitions before sedation takes hold.

Frequent users can develop tolerance and get addicted, requiring treatment. In Miami, officials at the Up Front Drug Information Center said its hot line had received calls from teen-age girls who said they had grown dependent on Rohypnol and wanted help.

When combined with alcohol or other drugs, drug experts say, it can cause respiratory depression and death. Kurt Cobain, the grunge rock singer, collapsed and slipped into a brief coma a month before his suicide last year after ingesting Rohypnol with champagne in a hotel room in Rome.

While in Europe and Latin America Rohypnol is mainly known as a sleeping aid and pre-surgery anesthetic (although it is also abused), many here learned of its existence in startling ways. Drug information hotlines started to hear from parents wondering about the pills they had just found in their child's pocket. Teachers called paramedics because a student had passed out.

At Miami Palmetto Senior High School, the school newspaper reported, a junior was taken to the hospital when a friend noticed she missed her mouth while eating nachos.

Now, 20 percent of the patients at the adolescent drug abuse program at Jackson Memorial Hospital say they have taken Rohypnol, doctors there said. In Dade County schools, 21 cases of Rohypnol possession or use have been reported to police since they began tracking the drug five months ago.

In Broward County, north of here, prosecutors say they handled two rape cases recently and are investigating two others where men gave the drug to women and then sexually assaulted them. In one case, the pill was slipped into the woman's drink while she visited the defendant. The man then bragged he had done the same to a dozen other women.

"When they wake up, they're completely naked and the defendant is sitting next to them in his underwear," said Assistant State Attorney Bob Nichols, adding that both defendants pleaded guilty and went to prison. "These girls are all in therapy because they can only imagine what happened."

Since Dade County began testing drunk drivers for Rohypnol, 35 drivers have tested positive for the drug, making roofies the most popular among caught drivers after marijuana and cocaine, said Dr. Lee Hearn, director of the toxicology laboratory at the county's medical examiner's office.

"Police are reporting that they stop them for driving really badly and when they open the door, they fall out," he said.

Its low price and harmless look, bubble-wrapped like so much medicine, may



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explain some of the drug's popularity, drug counselors and police said. At Miami Palmetto High, Rene C., a 16-year-old junior, said he liked it because "it gets you drunk." Maria B., an 18-year-old senior, said she only took roofies on special occasions to feel relaxed.

"You don't hear anything bad about it, like heroin or crack, where people die or anything," she said.

They were able to obtain Rohypnol from both classmates and friends, the students said. In Florida, Rohypnol is mainly smuggled through the mail and delivery packages or in luggage, DEA officials say. In Texas, the drug comes in through border crossings, often legally. A recent survey by the University of Texas College of Pharmacy in Austin found that 43 percent of those declaring prescription drugs in customs forms at the border brought Rohypnol. Only Valium was declared more frequently.

The Food and Drug Administration generally allows people to bring drugs sold abroad but not approved here but only for their personal use, defined as a three-month supply. But once in, the drug is considered illegal by law enforcement officials. They said Rohypnol was a controlled substance and its possession punishable by both fines and prison.

D.E.A. officials have reported seizures of more than 50,000 pills at a time in both Texas and Louisiana, and they say they are concerned about the involvement of cocaine and marijuana traffickers in Rohypnol's distribution. So are drug counselors, who say they worry that it may be used by dealers to hook children on other drugs.

"We feel South Florida is a test market for this drug," said James Hall, of Up Front Drug Center here.

Alfred J. Wasilewsky, a spokesman for Hoffmann-La Roche's affiliate in the United States, said the company was working on altering Rohypnol's dosage to try to make it less attractive. He said the presence of similar products in the market dissuaded the company from seeking approval to sell the drug in the United States.

In South Florida, school officials have added roofies to their group counseling and classroom discussions. In Texas, the state's Commission on Alcohol and Drug Abuse is about to send out 10,000 fliers on the drug to school nurses and has added a question about Rohypnol to its survey of 100,000 4th to 12th-graders about drug use, which is given every other year.

But the Miami Palmetto Senior High School principal, Leonard Glazer, noted that alcohol, not roofies, remained the biggest problem in schools.

"I think we tend to overlook that in the high school scene, alcohol is the introducer," he said. "Once your inhibitions have been lowered by alcohol, you're more likely to experiment."

GRAPHIC: Photo: The fastest-growing abused drug in Florida is the Rohypnol pill, made by Hoffmann-La Roche.



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The New York Times, December 9, 1995

Map: "A CLOSER LOOK: Abusing a Sedative"

Siezes by law-enforcement agencies of the prescription sleeping pill Rohypnol, which is not approved for sale in the United States, have risen sharply in certain states. Map of continental U.S. shows states where the greatest quantities of Rohypnol have been siezed, along with other states where the drug has been siezed. (Source: Drug Enforcement Administration)

LANGUAGE: ENGLISH

LOAD-DATE: December 9, 1995

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LEVEL 1 - 9 OF 29 STORIES

Copyright 1995 The Tribune Co. Publishes The Tampa Tribune

The Tampa Tribune

December 2, 1995, Saturday, FINAL EDITION

SECTION: NATION/WORLD, Pg. 14

LENGTH: 500 words

HEADLINE: Menace of the "date rape drug"

BODY:

It is hard to fathom how the drug scene in America could degenerate any further. Recently a Detroit woman was reported to have sold her 15-year-old son to a drug dealer in exchange for crack cocaine. Police say the boy spent six months as a sex slave and drug runner before being rescued.

That little horror is just one more in an endless series of degradations involving crack. But a new drug is making the rounds now, with its own peculiar brand of evil. Rohypnol, known on the street as "roofies," is not just a drug of the slums, although it is used there by gang members. It is also traded in bars, dance parties and other gatherings of young people. Police in California call it "the date rape drug."

Rohypnol, the brand name for flunitrazepam, is used in other countries to treat anxiety and insomnia and to sedate surgery patients. It is illegal to possess it in the United States without a foreign prescription. In a story in the Orange County Register, a spokesman for the Swiss manufacturer, the F. Hoffmann-La Roche & Co. pharmaceutical firm, said the drug must be getting into the United States through the mail or across the border from Mexican pharmacies.

Local police also report the drug's appearance in our area. Pinellas County sheriff's investigators recently arrested three men in Seminole who had 38 of the tablets, along with other drugs, guns and \$ 22,000 in cash. "We're starting to see it hand over fist," said Lt. Michael Platt of the Pinellas narcotics-intelligence unit.

The drug is diabolically well-suited for rape, because it can be slipped into someone's drink at a bar, and within 15 to 30 minutes that person slips into a state of amnesia lasting up to eight hours. "It's like, "I think I got raped, but I don't remember," " Platt said.

The victim is in danger of more than sexual assault, though. When combined with alcohol, the drug can be fatal.

If being young weren't cruel and complicated enough these days, now young women have to worry about whether some creep is slipping a knock-out pill into her drink at a party. Counselors advise people to refuse a drink offered by a stranger, and never to leave one's drink unattended.



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The Tampa Tribune, December 2, 1995

This is a law enforcement problem, of course, but it is more than that. Here the women's rights movement and the most ardent social and religious conservatives ought to find common ground. The level of decadence and disregard for human worth required to drug and rape a young woman ought to arouse the wrath of every rational person.

It would be simple if the manufacturer could just stop making the drug, but that seems unlikely. Washington ought to press researchers to consider other ways of accomplishing the same medicinal results, perhaps altering the formula or form of the drug. Shipping and dispensation should be more rigorously controlled too.

Still, the problem is not so much with the manufacturer. America's drug problem is just one more symptom of the moral breakdown of much of society.

TYPE: EDITORIAL; EDITORIALS

LOAD-DATE: December 4, 1995



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LEVEL 1 - 12 OF 29 STORIES

Copyright 1995 The Scotsman Publications Ltd.
The Scotsman

November 14, 1995, Tuesday

SECTION: Pg. 2

LENGTH: 1960 words

HEADLINE: Fresh drug menace surfaces

BYLINE: Severin Carrell Home Affairs Correspondent

BODY:

FEARS are growing that a potent sleeping tablet blamed for drug deaths in Europe and the United States may be replacing temazepam among users and addicts in Scotland.

Drugs agencies and police have received reports that heroin addicts and regular drugs users in Greenock, Glasgow, Dundee and Stirling have begun abusing Rohypnol, a strong sedative used mainly for insomnia, in conjunction with other substances and alcohol.

Batches of the drug, known to users as Wallbangers or Roofies, have been seized by Strathclyde police for the first time.

About 2000 have been impounded in two recent hauls.

One English force has also begun investigating counterfeit Rohypnol imports.

Rohypnol has caused controversy in the Netherlands, Germany, and the US over drugs deaths, illness due to breathing problems and acts of violence by users who had taken the stronger, two-milligramme tablet which is sold in Europe.

One of the world's largest pharmaceutical firms, Roche, has voluntarily stopped making the stronger tablet and replaced it with much lower dosage, one-milligramme pills similar to those sold in the United Kingdom.

Dr Donald Uges, a specialist in forensic toxicology and drug analysis from Groningen in Holland, said the drug became popular among Dutch football hooligans as it promoted aggression and among drug addict prostitutes as it sedated them before sex.

Heroin addicts take it to boost the effects of poor quality heroin, and cocaine users use it to smooth out withdrawal.

He added doctors and drug addicts had stopped using or dispensing the drug recently because it was so dangerous if taken with other drugs or alcohol.

"You won't be happy when Rohypnol is in your country," Dr Uges told The Scotsman yesterday.



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"Rohypnol is even worse and more dangerous than temazepam."

The drug was withdrawn from National Health Service lists in 1985 after the Government began its "selected list" of the cheapest generic drugs. But its use in private prescriptions has remained high, with boxes of 30 costing pharmacists £ 4.08.

Rusty Murray, chair of a voluntary drug users group in Dundee, said he knew of about 20 to 30 addicts and users in the city who took Rohypnol regularly, plus others in areas of Glasgow.

They acquired purple, diamond-scored, one-milligramme pills from doctors by buying them on private prescription, took them personally or sold them off to other users or dancers at raves for £ 3 or £ 4 each - securing a substantial profit.

Despite fears the tablets would be ground down and injected, like temazepam tablets, most swallowed them in quantities of up to 10 or 15 at a time.

Illegally imported European- strength pills sold for up to double that price.

He said: "Once people get the feeling for them, they will just take off. You will find they will become more and more known because doctors won't be prescribing temazepam."

The Scottish Drugs Forum has learnt that drugs workers in Inverclyde had found the different strengths on sale in the area, selling for as little as 50p each. They came on sale early this year, and had begun showing up in Stirling.

Dave Liddell, the agency's director, said it was too soon to predict if Rohypnol would replace temazepam after the clampdown on its availability and ban on gel-filled capsules by ministers in October.

But he added: "It's something we view with concern. In some senses, there's an inevitability about something replacing temazepam. There is no surprise in relation to this, unless we get to grips with reducing the overall demand for drugs."

LANGUAGE: ENGLISH

LOAD-DATE: November 14, 1995



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LEVEL 1 - 13 OF 29 STORIES

Copyright 1995 Star Tribune
Star Tribune

October 24, 1995, Metro Edition

SECTION: Variety; Pg. 1E

LENGTH: 538 words

HEADLINE: FYI;
Kissing Keanu and telling

BODY:

Noting that after 25 takes of a kissing scene with Keanu Reeves for "Bram Stoker's Dracula," Winona Ryder "reportedly left the set in tears," YM (Young and Modern) magazine has harvested the following smooching critiques:

"Keanu's so sure of himself, but I was back there spraying Binaca and hoping that I wouldn't offend him." - Sandra Bullock, costar in "Speed."

"He was pretty scruffy . . . but he had a sexy smell." - Ione Skye, costar in "River's Edge."

"Kissing scenes are pretty complicated, but we tried to enjoy them." - Aitana Sanchez-Gijon, costar in "A Walk in the Clouds."

"He's a very good kisser. . . . He's definitely blessed." - Lori Petty, costar in "Point Break."

- San Francisco Chronicle

'Spanish fly' becomes real

Rohypnol, an illicit sedative-hypnotic drug most commonly abused in Florida and Texas, has made its way to Minnesota. It is used for medicinal purposes in other parts of the world, but not approved in the United States. Primary users are adolescents who combine it with alcohol and other drugs. Because of its amnesia-like effects, it is also being used as a "date rape" drug, according to a drug alert issued by Carol Falkowski, research coordinator for the Chemical Dependency Division of the Minnesota Department of Human Services.

In southern Minnesota, abuse of the drug has been suspected in several cases in which a drug was placed in alcoholic beverages of young females who are subsequently exploited sexually, said Falkowski. Victims have no recall of events following sedation. Rohypnol has a bitter taste when added to a beverage and is about 10 times more potent than Valium. For more information on



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Star Tribune, October 24, 1995

Rohypnol, call the Minnesota Prevention Resource Center at (800) 247-1303.

- Hazelden Foundation

Today Costumed guides will lead visitors by candlelight through Historic Fort Snelling. The living-history players will be preparing for winter.

When: 7 to 9 p.m. today

Where: Historic Fort Snelling, Hwy. 5 and 55, near the Minneapolis-St. Paul International Airport.

Admission: Adults, \$ 6; seniors, \$ 5; ages 6 to 15, \$ 4.

Call: 725-2413

Same space, whole new place

The old Rupert's in Golden Valley has been remodeled and reincarnated as the Metropolitan, an elegant room to rent for events and concerts. The Metropolitan, on Interstate Hwy. 394, is owned by upscale Twin Cities restaurateurs, the D'Amico Brothers. The space underwent a \$ 1 million renovation. It seats 730 people for concerts at tables on various tiers.

A site for wedding and bar mitzvah parties, it also will be open to the public for the "Live at the Met" concert series in the next few weeks. October Project, an arty pop band featuring poetic singer Mary Fahl, will kick off the series tonight. Lowen & Navarro, an adult-pop duo, will do the Met Nov. 21, and jazz vocalist Dee Dee Bridgewater will sing there Nov. 26.

What: October Project.

When: 8 p.m. today.

Where: The Metropolitan, 5418 Wayzata, Blvd., Golden Valley.

Admission: \$ 14 to \$ 20.

Call: 989-5151.



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GRAPHIC: Photograph

LANGUAGE: ENGLISH

LOAD-DATE: October 25, 1995

LEVEL 1 - 14 OF 29 STORIES

Copyright 1995 Sentinel Communications Co.
THE ORLANDO SENTINEL

October 3, 1995 Tuesday, METRO

SECTION: LOCAL & STATE; Pg. C5

LENGTH: 494 words

HEADLINE: ST. CLOUD MAN DIES FROM ILLEGAL DRUG;
POLICE SAID THE 20-YEAR-OLD OVERDOSED ON THE ILLEGAL SEDATIVE SMUGGLED FROM
SOUTH AMERICA.

BYLINE: By Henry Pierson Curtis of The Sentinel Staff

DATELINE: KISSIMMEE

BODY:

A St. Cloud man may be one of the first victims in Florida to die from an overdose of an illegal sedative smuggled from South America.

Stacy McCormack died sometime Sunday after swallowing more than a dozen tablets of Rohypnol, a drug commonly called "roofies," Kissimmee police said.

The sedative is 10 times more powerful than Valium and is becoming known as the "Quaalude of the '90s," a reference to the drug widely abused in the 1970s. Rohypnol has become increasingly popular in the past few years among high school students mixing it with beer for a cheap high, drug abuse authorities said Monday.

Spokesmen for the Florida Poison Information Centers said Monday that no Rohypnol-related deaths had been reported previously to offices in Miami, Tampa and Jacksonville. It's possible that previous fatalities have not been reported by medical examiners to the statewide network, they said.

"We've just been lucky that kids who take it are just slumped over their desks in school and not driving. It's just a matter of time (until) we're going to have a couple," said Dr. Susan Sandbeck, deputy director of the Florida Poison Information Center in Miami. "It's fast acting; it's intense. It's a great buzz . . . but all you have to do is get a kid who vomits or get a kid who is driving a car and it's deadly."

McCormack, 20, was found dead about 10:30 p.m. Sunday on a couch in a friend's apartment on Central Avenue in Kissimmee. He had gone to sleep about 7 a.m. after taking "roofies" and watching movies, Kissimmee police Detective Warren Shepard said.

McCormack, who worked construction and had been in robust health, apparently choked on his own vomit after falling asleep, police reported. Several of his friends told police that McCormack began taking Rohypnol several months ago and had taken as many as 14 tablets at one time.



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Orlando Sentinel Tribune, October 3, 1995

The Orange-Osceola Medical Examiner's Office said the cause of McCormack's death will not be known for several weeks - until toxicology tests are completed. The office is investigating a second possible Rohypnol-related death, a spokeswoman said.

The victim of that overdose was a Brevard County woman who died last week in an Orlando-area motel room. Additional information about the death could not be obtained Monday from the Orange County Sheriff's Office.

Rohypnol is the brand name of flunitrazepan, a sedative sold in Europe, South America and Asia by Roche, a Swiss pharmaceutical company. Its sedation lasts about an hour and it is used to calm patients for minor surgery in physicians' offices, pharmacists said.

In interviews Monday, several people said Rohypnol sells for \$5 a tablet in Orlando-area nightclubs. Authorities said it began appearing in mid-1989 in South Florida and that most shipments appear to come from Colombia.

Rohypnol abuse can cause hallucinations, slowed reflexes and altered depth perception. Overdoses can cause respiratory arrest or death from aspirating vomit.

LANGUAGE: ENGLISH

LOAD-DATE: October 4, 1995



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LEVEL 1 - 15 OF 29 STORIES

Copyright 1995 Times Publishing Company
St. Petersburg Times

October 1, 1995, Sunday, City Edition

SECTION: LARGO-SEMINOLE TIMES; Pg. 1

DISTRIBUTION: LARGO-SEMINOLE TIMES; NORTH PINELLAS TIMES; CLEARWATER TIMES;
CITY TIMES

LENGTH: 645 words

HEADLINE: Police say new drug is popular with youth

BYLINE: JANE MEINHARDT

BODY:

Smuggled into the Pinellas County area via connections used by cocaine and marijuana dealers, a dangerous sedative known on the street as ruffies, roofies and forget-me pills is the latest rage.

Authorities are seizing more and more of the drug Rohypnol throughout the county, especially in the past several months.

"The volume is indicative of an upward trend," said Pinellas Sheriff's Lt. Michael Platt. "It's very popular with the rave and alternative lifestyle people. We have specific intelligence that there is a large volume of Rohypnol in Pinellas and Hillsborough . . . doses in the thousands."

Six doses of Rohypnol were seized last week during an undercover investigation of street-level drug dealing in Dunedin. A Seminole man arrested in early September outside a St. Petersburg mall had several doses of the drug in his backpack.

Thirteen cases involving one to 10 doses of Rohypnol have been submitted to the Pinellas County forensic laboratory this year. Surveys show high school students who use drugs list Rohypnol - along with ecstasy and LSD - as a drug of choice. Authorities seized 20 doses of the drug recently during a raid at a rave - an all-night dance, - in Tampa.

"The people who use this drug are not your crack-cocaine type," Platt said. "They are designer drug users who probably use pot, alcohol and LSD. It's a club-oriented drug, which makes it very dangerous because they're drinking with them."

The drug is made in South America and Mexico for use as a sleeping aid and a sedative before surgery. It is not sold in the United States. Rohypnol is a benzodiazepine, the same class of drug as Valium. However, it is much more potent.



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St. Petersburg Times, October 1, 1995

"It is more hypnotic and amnesic than Valium," said Dr. Sven Norman, director of the Florida Poison Information Center in Tampa. "When combined with alcohol, it is much more powerful. It is a potentially lethal combination.

"We've known about Rohypnol for at least a year, but now it's really making the circles," he said. "Calls about it are coming from nearly everywhere."

Often referred to as the Quaaludes of the '90s, Rohypnol can cause deep sedation or respiratory arrest. A month before Nirvana lead singer Kurt Cobain committed suicide, he went into a coma after taking about 50 Rohypnol tablets with alcohol.

A Rohypnol-alcohol combination also can loosen inhibitions in a person and cause short-term amnesia, which is the basis for one of the drug's street names, "forget-me pills."

In South Florida, where, authorities say, Rohypnol first began appearing, at least six women were raped in July after being given drinks laced with the drug. State attorneys in Broward County say the cases are difficult to prosecute because the victims can't remember what happened.

Norman identified three groups of Rohypnol abusers: high school students who combine it with alcohol, heroin addicts who use it to enhance the effects of heroin and cocaine addicts who take it to "parachute" down from a high.

In addition to its sedating effects, Rohypnol is popular because of its price. Authorities say the street price of one tablet can range from \$ 3 to \$ 5.

The Swiss drug company Hoffmann-LaRoche makes the drug in Colombia and Mexico, where it is often sold over the counter.

"It is more addictive than Valium," said Dr. Joe Federico, vice president of clinical services at Operation PAR. "At this point, we aren't treating anyone for it, but it's on the street. Depending on the person and amount taken, a tolerance to it and dependence can build up quickly."

Rohypnol is often sold in its original bubble-wrap packaging. The round, flat tablets are white and about the size of an antacid tablet. The tablets are imprinted with the name Roche and the numeral 2 with a circle around it.

GRAPHIC: BLACK AND WHITE PHOTO, courtesy of Pat Pattee, Pinellas County Forensics Lab; the drug Rohypnol, also known as ruffies or roofies

LANGUAGE: ENGLISH

LOAD-DATE: October 3, 1995



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LEVEL 1 - 19 OF 29 STORIES

Copyright 1995 The Dallas Morning News
THE DALLAS MORNING NEWS

June 15, 1995, Thursday, HOME FINAL EDITION

SECTION: NEWS; Pg. 1A

LENGTH: 1065 words

HEADLINE: Dangerous sedative being smuggled across border Mind-altering drug reduces inhibitions, can cause amnesia

BYLINE: Rebecca Howland, Staff Writer of The Dallas Morning News

BODY:

Law enforcement officials say they are alarmed at the growing popularity of a dangerous and potent sedative being smuggled across the Mexican border and now making its way north through the state.

Rohypnol - commonly called Roach, Rophie or the Forget Pill on the street - is a hypnotic or mind-altering drug that reduces users' inhibitions and can cause amnesia, especially when taken with alcohol.

The drug reportedly has been used in gang initiations and date-rape cases in which the woman can't remember the next day what happened, say drug treatment and law enforcement officials.

The drug - which officials say is about 10 times stronger than Valium - is illegal in the United States. But in other countries anyone can get Rohypnol with a doctor's approval, and in some, including Mexico and Colombia, it is often sold over the counter.

The drug is most often seen among males ages 13 to 18 and is

frequently used in gang initiations, officials in South Texas say.

Law enforcement officials and medical experts say use of the drug in South Texas is skyrocketing, and there is increasing incidence of it in Austin, Houston and Dallas. The drug is often sold on the street for 50 cents to \$ 3 a pill, officials said.

Use of the drug has also increased dramatically in southern Florida, especially in Miami, since 1992. Officials there said it is streaming into the United States from Colombia.

Hoffmann-LaRoche, a Switzerland-based pharmaceutical company that manufactures the drug, produces Rohypnol in plants in Colombia and Mexico.

Although selling Rohypnol over the counter is technically illegal worldwide, it happens frequently in the two countries, which do not effectively enforce regulations, officials from the World Health Organization said.



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The drug is used as a sleeping aid to combat severe insomnia or to sedate psychotic patients, said Al Wasilewski, director of public policy and communications for Hoffmann-LaRoche. It is also prescribed to patients about to undergo surgery and who are not going to receive full anesthesia. After taking the drug, the patient would not remember the uncomfortable procedure.

Mr. Wasilewski declined to comment about whether or not Hoffmann-LaRoche would consider discontinuing its production of the drug, although he said the company is "very concerned" about the abuse.

Rohypnol "happens to have that attraction to a certain subset of the population that will abuse anything. . . . It is an unbelievable thing to hear that these drugs which have a good therapeutic use are being abused in this way," Mr. Wasilewski said.

Hoffmann-LaRoche never sought approval from the Food and Drug Administration to distribute Rohypnol in the United States, he said.

"There was already a significant number of similar sedative hypnotics" in the United States, he said. "There was no need to add another one to the pie."

Steve Mithos, the director of program services for the Palmer Drug Abuse treatment center in McAllen, said more than half of the teenagers he sees are "getting roached."

"It's pretty widespread, and in the last six months, it's really grown," he said. "Now, about 15 percent of the kids I see list it as their primary drug of choice, not just something they take once in a while."

Sean, a 19-year-old in treatment for drug abuse in Dallas and who asked not to be identified by his last name, said Rohypnol began "hitting it big" on Dallas' club and party scene last year.

Sean estimated that half of his friends had experimented with the drug or were using it regularly. "It's everywhere," he said.

"If you just go down and see a doctor in Mexico and get a prescription, you can carry five boxes across the border, no problem," he said. "Each box has 50 or 100 pills in it."

Sean estimated he'd taken the pills 10 or 11 times.

"It's real mellow. I just felt like I didn't want to move," he said.

Although Sean described feeling "under control" while on the drug, he recounted experiencing amnesia after mixing the drug with alcohol, and described several "incidents" in which men "took advantage of women sexually because the women didn't know what they were doing."

The drug can also trigger belligerent and aggressive behavior, Mr. Mithos said.

One of Mr. Mithos' patients is on probation for manslaughter, he said.



"The guy doesn't even remember shooting anyone. He's neat, a real nice guy. You wouldn't think he would do something like that, but he was loaded on Roaches."

In Austin and Houston, law enforcement officials say the drug is rapidly growing in popularity and is most often seen in conjunction with "heavier" drugs such as heroin or crack cocaine.

"We're seeing (Rohypnol) all over the place," said Tony Arnold, a forensic chemist for the Austin Police Department.

"People are using the hyperactive drugs, and when they finally burn out, then they use the Rohypnol to go to sleep," Mr. Arnold said, estimating that one out of every five cases he sees involves the drug.

A few months ago, nobody had heard of the drug, Mr. Arnold said.

"At first, most of the cops thought they were 2-milligram Valiums," he said. Hoffmann-LaRoche also produces Valium, a small, blue pill stamped with the number "10" in a circle. Rohypnol differs in color - it is white - and is marked by "2" instead of "10." The numbers refer to the dosage of the active ingredient in milligrams.

Many law enforcement officials in Dallas said that while they had encountered the small white pills several times during the past year, they were not overly concerned that it was getting out of control.

But Martin Pracht, who works for the Drug Enforcement Administration in Dallas, said officials are underestimating the drug's spread.

"Rophies are much more dangerous and potent than what people are giving them credit for," Mr. Pracht said. "You'd be crazy to say this will not be a problem" in Dallas.

"It's just taking a while to get up here and increase in popularity. But it will," he said.

Because the drug has never been legal in the United States, detecting it is difficult, Mr. Pracht said. The drug is not listed in the commonly-used Physician's Desk Reference, and police and medical officers do not know what symptoms to look for.

Customs officials on the border said it is difficult to stop such smuggling because officers search for materials that look like contraband.

GRAPHIC: CHART(S): (DMN) Rohypnol.

LANGUAGE: ENGLISH

LOAD-DATE: July 13, 1995



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LEVEL 1 - 22 OF 29 STORIES

Times Publishing Company
St. Petersburg Times

November 29, 1994, Tuesday, Tampa Edition

SECTION: TAMPA TODAY; TAMPA BAY & STATE; Pg. 5B

DISTRIBUTION: TAMPA TODAY; TAMPA BAY AND STATE

LENGTH: 511 words

HEADLINE: Tranquilizer hooks teens, drug users

BYLINE: SUSAN CLARY

BODY:

It's just a few dollars a hit. But wash it down with a beer and you might do something embarrassing - or downright scary.

You might crumple to the ground. Or urinate on yourself.

Or stop breathing.

Technically, the drug is called Rohypnol. Those more familiar with the little, white pills call them "Roofies."

If you haven't heard of them yet, you will, drug abuse specialists and police say.

"They have become the Quaaludes of the '90s," said Dr. Sven Norman, referring to a sedative that was popular in the 1970s. "One of the reasons they are abusing it is they get the desired effect. It causes drowsiness and a pretty significant intoxication."

Norman, director of the Florida Poison Information Center at Tampa General Hospital, said the center first heard of the drug earlier this year.

Experts say it is popular with three groups. Teenagers use it to intensify the effects of alcohol. Heroin users like it because it enhances the sedating effects of lower-purity heroin. Cocaine abusers use it to parachute down from a binge.

"It is extremely dangerous," Norman said. "When combined with alcohol, it can be life-threatening."

The tranquilizer is a small, white tablet imprinted with the letters RH. Experts say the drug is several times more powerful than Valium. Users call the pills "roofies," "ruffies" or "Roche," (pronounced Ro-shay) after the company that makes them.



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St. Petersburg Times, November 29, 1994

The drug's side effects include hallucinations, respiratory problems, sleep disturbances and anxiety.

While the drug is widely used in South Florida, law enforcement officials in the Tampa Bay area said they have yet to see any cases.

"I'm not saying it doesn't exist around here, but it's not a problem. Not yet," said Lt. Bob Guidara, commander of the Tampa Police Department QUAD Squad.

St. Petersburg police spokesman Bill Doniel said the same is true in his city but noted that new drugs in South Florida often migrate here.

Roofies have become especially popular with high schoolers because they are inexpensive - 50 cents to \$ 8 each. When taken alone, they make users feel very sleepy. The effect is intensified when combined with alcohol.

Rohypnol is manufactured by Roche, a U.S. pharmaceutical company, but is not legal here. It is used in Central and South America to sedate patients for surgery, said Al Wazaluski, a Roche spokesman.

- Information from the Associated Press was used in this report.

TEEN DRUG**NAME:** Rohypnol (Roofies)**WHAT IT LOOKS LIKE:** Little white pills.**PRICE:** Inexpensive - \$ 3 to \$ 5 each.**WHAT IT DOES:** Used alone, roofies make users feel very sleepy. Combined with alcohol, the effect intensifies. Described as 10 times stronger than Valium. Side effects include hallucinations, respiratory problems, sleep disturbances, anxiety and possible addiction.**MANUFACTURER:** Rohypnol is manufactured by Roche, a U.S. company, but is not legal here. Authorities think the drug is being brought in from South America.**LANGUAGE:** ENGLISH**LOAD-DATE:** November 30, 1994

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LEVEL 1 - 23 OF 29 STORIES

Copyright 1994 Phoenix Newspapers, Inc.
THE PHOENIX GAZETTE

November 29, 1994 Tuesday, Final

SECTION: FRONT; Pg. A2

LENGTH: 351 words

HEADLINE: NEW, CHEAP DRUG CATCHING ON WITH TEENS

DATELINE: FORT LAUDERDALE

BODY:

It's just a \$5 hit. But wash it down with a beer and you might do something embarrassing -- or downright scary.

You might crumple to the ground. Or urinate on yourself.

Or stop breathing.

Technically, the drug is called Rohypnol. Those more familiar with the little white pills call them roofies.

If you haven't heard of them yet, you will, drug abuse specialists and police say.

"It will be as popular as crack because it is so cheap," said Dave Marcus, case manager at Spectrum Program Inc., a drug treatment center for adolescents in Pompano Beach, Fla.

In Arizona, however, the drug is unknown, police said.

"We've never even heard of it, but if it gets popular in other areas of the country, it will get here sooner or later," said Lt. Rick Knight, a state Department of Corrections narcotics detective.

High schoolers are particularly fond of roofies because they are cheap and because they make users feel very, very drunk, Marcus said.

The pills sell for \$3 to \$5 apiece. Teenagers generally buy the drug off-campus and take it at weekend parties. Sometimes they pop one in the morning before school, making them incoherent all day.

"It's like the poor man's Quaalude," Marcus said, referring to a sedative drug that was popular in the '70s.

It's not known how many people are abusing Rohypnol, but in Broward County, Fla., nearly one in five clients at two drug treatment centers for adolescents have used them.

Rohypnol is manufactured by Roche, a U.S. pharmaceutical company. The drug is



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not legal in the United States. It is used in Central and South America to sedate patients for surgery, Al Wazaluski, a Roche spokesman, said.

School officials say many teenagers get the drug at parties, where it is given away by a dealer who is looking for customers.

The drug, sold in tablet form, has been described as 10 times stronger than Valium. Used alone, roofies make users feel very sleepy. Combined with beer, the effect is intensified.

The drug also is crushed and snorted to cushion the crash from a cocaine or crack high, said Hollywood Police Sgt. Mark May.

LANGUAGE: ENGLISH

LOAD-DATE: December 13, 1994



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LEVEL 1 - 18 OF 29 STORIES

Copyright 1995 The Tribune Co. Publishes The Tampa Tribune

The Tampa Tribune

June 23, 1995, Friday, FINAL EDITION

SECTION: FLORIDA/METRO, Pg. 6

LENGTH: 359 words

HEADLINE: Radio host blamed for drug mishap

BYLINE: WILLIAM YELVERTON; Tribune Staff Writer

DATELINE: CLEARWATER

BODY:

Prosecutors are holding radio personality Ron Bennington of "Ron and Ron" fame responsible for leaving an illegal drug where his young daughter could find it.

The 10-year-old girl was hospitalized overnight in March. She fell asleep and couldn't be roused after taking medicine from a box marked "children's Tylenol."

An investigation determined the child had taken an undetermined amount of Rohypnol - a powerful narcotic similar to Valium - that was in the Tylenol container.

Pinellas sheriff's spokeswoman Marianne Pasha said Bennington told a deputy someone in Miami had given him the Rohypnol a year ago. His daughter was taken to All Children's Hospital in St. Petersburg for observation but was home the next day, Pasha said.

"Ron felt very bad about the whole situation," Pasha said.

Bennington, 36, who with Ron Diaz has a popular show on WSUN, was charged earlier this month with culpable negligence in the March 6 incident at his Seminole home. He has filed a written plea of not guilty.

Bennington agreed to enter a pretrial intervention program, said Rebecca Graham, assistant county court director for Pinellas State Attorney Bernie McCabe.

The program is a form of probation for first-time, nonviolent offenders. If participants complete the program and stay out of trouble, charges are dropped.

Bennington could not be reached for comment Thursday.

His daughter, Gail, was taken to a Seminole hospital the night of March 6 after her mother couldn't rouse her, Pasha said.



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Julie Bennington told a deputy who was called to the hospital that she feared the girl was having an allergic reaction to children's Tylenol. The mother had told the girl to take the Tylenol earlier that night when she wasn't feeling well.

At the request of emergency workers at the hospital, Julie Bennington telephoned her husband and told him to bring in the box and package, Pasha said.

Ron Bennington was charged June 8. He was not arrested. Instead he was issued a summons. His wife was not charged.

Although Rohypnol, also known as "roofies," "rufies" and Roche, is illegal, Bennington was not charged with a drug offense.

GRAPHIC: PHOTO,
Ron Bennington

TYPE: FOCUS ON FLORIDA

LOAD-DATE: July 3, 1995



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LEVEL 1 - 17 OF 29 STORIES

Copyright 1995 TEXAS MONTHLY, INC.
TEXAS MONTHLY

September, 1995

SECTION: STATE WIDE REPORTER; Pg. 88

LENGTH: 839 words

HEADLINE: A New Low

BYLINE: HELEN THORPE; Edited by David McCormick

HIGHLIGHT:

Across the state, kids are getting seriously messed up on a dirt-cheap downer from Mexico.

BODY:

ROB IS A JITTERY NINE-teen-year-old bean pole who lives in Houston. He doesn't work or go to school, but he spends a lot of time in the city's nightclubs, where he frequently buys a potent sedative called Rohypnol. A single two-milligram pill has more intoxicating power than a six-pack of beer. "I was at Numbers, a club down the street," says Rob, sitting in front of a youth center on Westheimer. "I took two Rohypnol and I was like --" he rolls his eyes, tilts his head, and lets his tongue hang out of his mouth. "I went outside and there were these two cops in the parking lot. I said, 'Excuse me, Mr. Beers, I haven't had any officers tonight.'"

Although Rohypnol is illegal in the United States, it is available by prescription in Mexico, and importing it is no trouble at all: Lately the drug has become a fad among teenagers around the state. Rohypnol is manufactured by the Swiss pharmaceutical giant Hoffman-La Roche and was introduced in the seventies in Europe and South America, where it is prescribed as a means to relax patients before surgery and as a treatment for insomnia. Beginning in the eighties, hard-core drug users in Europe started using it to come down from cocaine or metham-phetamine highs. Now thrill-seeking teenagers in Texas, Florida, and other parts of the South have discovered the drug. To them, it's ideal because it makes them feel drunk but doesn't make them throw up, doesn't show up in the most common urine tests, and is dirt cheap. One pill can cost anywhere from \$ 1 to \$ 5. But the pills are far from harmless; early last year, the late grunge rock star Kurt Cobain slipped into a coma after taking Rohypnol and drinking champagne while on tour in Italy, though he was revived after his stomach was pumped.

So many teenagers have been taking it that the Texas Commission on Alcohol and Drug Abuse (TCADA) issued a warning to drug treatment centers about the pills in May. On the street the drug has many nicknames; teenagers know it as rope, ribs, or roaches. Law-enforcement authorities call it Mexican Valium because of its similarities to that drug, but Rohypnol is estimated to be ten times stronger and has some novel attributes. Another of its many names is "the forget pill," because Rohypnol typically causes complete short-term amnesia. It also reduces inhibitions. Rob says, "You take it -- you black out. The next day



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people tell you what you did, and you're like, 'Wha-a-a-a-t?'" In rare cases Rohypnol can also induce aggression, rages, hallucinations, or psychoses. Many teenagers take it while drinking, which greatly increases the impairment of their motor abilities. Statewide, there have been two suspected fatal overdoses.

Rohypnol first became popular in border towns. According to figures compiled by the TCADA, law enforcement along the border reported 31 cases involving the drug in 1991. Last year there were 197 cases. Nilda Gomez, a drug abuse counselor who works with teenagers in Brownsville, says Rohypnol is everywhere she turns. "What's so surprising is that it used to be fifteen-year-olds who were doing drugs, but now it's thirteen-, twelve- and even eleven-year-olds," says Gomez.

The use of Rohypnol gradually spread north, and today drug counselors in Houston, San Antonio, Dallas, and Austin know of people who have taken Rohypnol. The drug is said to have a moderate to high risk of addiction. Eight months ago Annette, a self-possessed sixteen-year-old, was buying Rohypnol regularly in clubs along Sixth Street in Austin. (Her name has been changed to protect her privacy.) She now lives in Odyssey House, a residential treatment facility in Houston for teenagers. As she sits on a sofa there, wearing a white T-shirt and white cotton pants, her honey-colored hair twisted into a bun, Annette looks like an extra in Beverly Hills 90210. but she recites a family history of abuse and chemical dependency. "I'm the kind of person who wouldn't take one or two," she says of her experiences with Rohypnol. "I would take three or four and drink at the same time. We used to call them 'run-trip-and-falls.'" Sometime last year Annette took enough Rohypnol to obliterate four full days. She came to at her boyfriend's house, with a hospital band around her wrist. "A friend of mine from San Antonio had run away, and she wanted to do some because she'd never tried them. We got a lot. The last thing I remember is my friend turning to me and saying, 'Annette, we need to go.' And then it just goes black.

"Four days later I woke up -- well, not really woke up, because I hadn't been asleep. I had gone to another friend's apartment, and I had had sex with somebody -- this is what they told me -- and I had had a tampon in, and it had gotten stuck up inside me, so I had to go to the emergency room. I lost track of my friend, and she didn't know anybody in Austin."

Clearly, playing drugstore cowboy is no game. Rohypnol is more than an easy way to get wasted -- it's an easy way to waste a life.

GRAPHIC: Picture, Known as "the forgot pill,"-Rohypnol reduces inhibitions and causes short-term amnesia. ANDREW YATES

LANGUAGE: ENGLISH



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LEVEL 1 - 16 OF 29 STORIES

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The Tampa Tribune

September 12, 1995, Tuesday, FINAL EDITION

SECTION: NATION/WORLD, Pg. 8

LENGTH: 508 words

HEADLINE: What are kids doing out at 4 a.m.?

BODY:

It's 4 o' clock Sunday morning. Do you know where your kids are?

That's the wake-up call that the parents of 2,500 mostly teenagers should have gotten this weekend when police and sheriff's deputies busted up a "rave" party in downtown Tampa.

"Rave" clubs are the latest youth fad, drawing young people after bar closing hours to while away the morning dancing, lounging and generally having "fun."

Within minutes of the bust at the Parthenon club, 13 people had been arrested - seven for possessing illegal drugs. Hundreds more appeared to be under the influence of something other than loud music.

The smell of cigarettes, marijuana and alcohol hung in the air. Police confiscated LSD, marijuana, ecstasy and Rohypnol.

LSD, as nearly everyone knows, is a hallucinogenic drug popular during the '60s and currently experiencing a revival. Ecstasy is a powerful and very addictive drug that has been available for years.

And, Rohypnol is one of the newer drugs on the underground market. A sedative similar to Halcion and Valium, it mimics alcohol intoxication. Nicknamed "roofies," the pills sell for \$ 3 to \$ 5 each and are growing in popularity. Rohypnol is the drug Broward County prosecutors say a rapist used earlier this year to sedate women he met in bars and later attacked.

No responsible parent would want a son or daughter trying these dangerous drugs. But one has to wonder how many of these kids have responsible parents.

Among those arrested were 17-year-olds from Tampa, Pinellas Park and St. Petersburg. Police suspect others in the crowd were 16, 15 and possibly even 14. Party-goers interviewed by The Tampa Tribune said they've seen children as young as 12 at some "rave" parties.

Hellooooo. Is an adult present at these kids' homes?

Tampa has a curfew that was supposed to put an end to such shenanigans, but



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everyone knows it is largely ignored. City officials say they are sitting helplessly on their hands until some high court somewhere says curfews are legal. So much for bold leadership.

Courts haven't stopped cities like Phoenix, Washington, D.C., Atlanta, Boston, Buffalo, Dallas, Denver, New Orleans, Newark and Orlando from adopting and enforcing curfews. Indeed, those cities have seen a significant drop in juvenile crimes such as auto thefts ever since the kids were forced to stay off the streets in the middle of the night.

Parents who can't see to it that their kids get home by midnight or shortly after don't get a lot of sympathy here. Certainly parenting is hard work. Saying no, being firm, taking away the car keys isn't easy. But it has to be done to assure the kids' survival.

As for the dance clubs that put on the "raves," the police are well within their jurisdiction to do just what they did at Parthenon over the weekend: shut them down. Police cited faulty wiring and unsafe conditions in order to close the place. They can also go a step further and declare them a public nuisance. This community doesn't need a business that entices kids to stay out all night.

TYPE: EDITORIAL; EDITORIALS

LOAD-DATE: September 14, 1995



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LEVEL 1 - 15 OF 29 STORIES

Copyright 1995 Times Publishing Company
St. Petersburg Times

October 1, 1995, Sunday, City Edition

SECTION: LARGO-SEMINOLE TIMES; Pg. 1

DISTRIBUTION: LARGO-SEMINOLE TIMES; NORTH PINELLAS TIMES; CLEARWATER TIMES;
CITY TIMES

LENGTH: 645 words

HEADLINE: Police say new drug is popular with youth

BYLINE: JANE MEINHARDT

BODY:

Smuggled into the Pinellas County area via connections used by cocaine and marijuana dealers, a dangerous sedative known on the street as ruffies, roofies and forget-me pills is the latest rage.

Authorities are seizing more and more of the drug Rohypnol throughout the county, especially in the past several months.

"The volume is indicative of an upward trend," said Pinellas Sheriff's Lt. Michael Platt. "It's very popular with the rave and alternative lifestyle people. We have specific intelligence that there is a large volume of Rohypnol in Pinellas and Hillsborough . . . doses in the thousands."

Six doses of Rohypnol were seized last week during an undercover investigation of street-level drug dealing in Dunedin. A Seminole man arrested in early September outside a St. Petersburg mall had several doses of the drug in his backpack.

Thirteen cases involving one to 10 doses of Rohypnol have been submitted to the Pinellas County forensic laboratory this year. Surveys show high school students who use drugs list Rohypnol - along with ecstasy and LSD - as a drug of choice. Authorities seized 20 doses of the drug recently during a raid at a rave - an all-night dance, - in Tampa.

"The people who use this drug are not your crack-cocaine type," Platt said. "They are designer drug users who probably use pot, alcohol and LSD. It's a club-oriented drug, which makes it very dangerous because they're drinking with them."

The drug is made in South America and Mexico for use as a sleeping aid and a sedative before surgery. It is not sold in the United States. Rohypnol is a benzodiazepine, the same class of drug as Valium. However, it is much more potent.



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St. Petersburg Times, October 1, 1995

"It is more hypnotic and amnesic than Valium," said Dr. Sven Norman, director of the Florida Poison Information Center in Tampa. "When combined with alcohol, it is much more powerful. It is a potentially lethal combination.

"We've known about Rohypnol for at least a year, but now it's really making the circles," he said. "Calls about it are coming from nearly everywhere."

Often referred to as the Quaaludes of the '90s, Rohypnol can cause deep sedation or respiratory arrest. A month before Nirvana lead singer Kurt Cobain committed suicide, he went into a coma after taking about 50 Rohypnol tablets with alcohol.

A Rohypnol-alcohol combination also can loosen inhibitions in a person and cause short-term amnesia, which is the basis for one of the drug's street names, "forget-me pills."

In South Florida, where, authorities say, Rohypnol first began appearing, at least six women were raped in July after being given drinks laced with the drug. State attorneys in Broward County say the cases are difficult to prosecute because the victims can't remember what happened.

Norman identified three groups of Rohypnol abusers: high school students who combine it with alcohol, heroin addicts who use it to enhance the effects of heroin and cocaine addicts who take it to "parachute" down from a high.

In addition to its sedating effects, Rohypnol is popular because of its price. Authorities say the street price of one tablet can range from \$ 3 to \$ 5.

The Swiss drug company Hoffmann-LaRoche makes the drug in Colombia and Mexico, where it is often sold over the counter.

"It is more addictive than Valium," said Dr. Joe Federico, vice president of clinical services at Operation PAR. "At this point, we aren't treating anyone for it, but it's on the street. Depending on the person and amount taken, a tolerance to it and dependence can build up quickly."

Rohypnol is often sold in its original bubble-wrap packaging. The round, flat tablets are white and about the size of an antacid tablet. The tablets are imprinted with the name Roche and the numeral 2 with a circle around it.

GRAPHIC: BLACK AND WHITE PHOTO, courtesy of Pat Pattee, Pinellas County Forensics Lab; the drug Rohypnol, also known as ruffies or roofies

LANGUAGE: ENGLISH

LOAD-DATE: October 3, 1995



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LEVEL 1 - 13 OF 29 STORIES

Copyright 1995 Star Tribune
Star Tribune

October 24, 1995, Metro Edition

SECTION: Variety; Pg. 1E

LENGTH: 538 words

HEADLINE: FYI;
Kissing Keanu and telling

BODY:

Noting that after 25 takes of a kissing scene with Keanu Reeves for "Bram Stoker's Dracula," Winona Ryder "reportedly left the set in tears," YM (Young and Modern) magazine has harvested the following smooching critiques:

"Keanu's so sure of himself, but I was back there spraying Binaca and hoping that I wouldn't offend him." - Sandra Bullock, costar in "Speed."

"He was pretty scruffy . . . but he had a sexy smell." - Ione Skye, costar in "River's Edge."

"Kissing scenes are pretty complicated, but we tried to enjoy them." - Aitana Sanchez-Gijon, costar in "A Walk in the Clouds."

"He's a very good kisser. . . . He's definitely blessed." - Lori Petty, costar in "Point Break."

- San Francisco Chronicle

'Spanish fly' becomes real

Rohypnol, an illicit sedative-hypnotic drug most commonly abused in Florida and Texas, has made its way to Minnesota. It is used for medicinal purposes in other parts of the world, but not approved in the United States. Primary users are adolescents who combine it with alcohol and other drugs. Because of its amnesialike effects, it is also being used as a "date rape" drug, according to a drug alert issued by Carol Falkowski, research coordinator for the Chemical Dependency Division of the Minnesota Department of Human Services.

In southern Minnesota, abuse of the drug has been suspected in several cases in which a drug was placed in alcoholic beverages of young females who are subsequently exploited sexually, said Falkowski. Victims have no recall of events following sedation. Rohypnol has a bitter taste when added to a beverage and is about 10 times more potent than Valium. For more information on



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Star Tribune, October 24, 1995

Rohypnol, call the Minnesota Prevention Resource Center at (800) 247-1303.

- Hazelden Foundation

Today Costumed guides will lead visitors by candlelight through Historic Fort Snelling. The living-history players will be preparing for winter.

When: 7 to 9 p.m. today

Where: Historic Fort Snelling, Hwy. 5 and 55, near the Minneapolis-St. Paul International Airport.

Admission: Adults, \$ 6; seniors, \$ 5; ages 6 to 15, \$ 4.

Call: 725-2413

Same space, whole new place

The old Rupert's in Golden Valley has been remodeled and reincarnated as the Metropolitan, an elegant room to rent for events and concerts. The Metropolitan, on Interstate Hwy. 394, is owned by upscale Twin Cities restaurateurs, the D'Amico Brothers. The space underwent a \$ 1 million renovation. It seats 730 people for concerts at tables on various tiers.

A site for wedding and bar mitzvah parties, it also will be open to the public for the "Live at the Met" concert series in the next few weeks. October Project, an arty pop band featuring poetic singer Mary Fahl, will kick off the series tonight. Lowen & Navarro, an adult-pop duo, will do the Met Nov. 21, and jazz vocalist Dee Dee Bridgewater will sing there Nov. 26.

What: October Project.

When: 8 p.m. today.

Where: The Metropolitan, 5418 Wayzata, Blvd., Golden Valley.

Admission: \$ 14 to \$ 20.

Call: 989-5151.



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GRAPHIC: Photograph

LANGUAGE: ENGLISH

LOAD-DATE: October 25, 1995

LEVEL 1 - 9 OF 29 STORIES

Copyright 1995 The Tribune Co. Publishes The Tampa Tribune

The Tampa Tribune

December 2, 1995, Saturday, FINAL EDITION

SECTION: NATION/WORLD, Pg. 14

LENGTH: 500 words

HEADLINE: Menace of the "date rape drug"

BODY:

It is hard to fathom how the drug scene in America could degenerate any further. Recently a Detroit woman was reported to have sold her 15-year-old son to a drug dealer in exchange for crack cocaine. Police say the boy spent six months as a sex slave and drug runner before being rescued.

That little horror is just one more in an endless series of degradations involving crack. But a new drug is making the rounds now, with its own peculiar brand of evil. Rohypnol, known on the street as "roofies," is not just a drug of the slums, although it is used there by gang members. It is also traded in bars, dance parties and other gatherings of young people. Police in California call it "the date rape drug."

Rohypnol, the brand name for flunitrazepam, is used in other countries to treat anxiety and insomnia and to sedate surgery patients. It is illegal to possess it in the United States without a foreign prescription. In a story in the Orange County Register, a spokesman for the Swiss manufacturer, the F. Hoffmann-La Roche & Co. pharmaceutical firm, said the drug must be getting into the United States through the mail or across the border from Mexican pharmacies.

Local police also report the drug's appearance in our area. Pinellas County sheriff's investigators recently arrested three men in Seminole who had 38 of the tablets, along with other drugs, guns and \$ 22,000 in cash. "We're starting to see it hand over fist," said Lt. Michael Platt of the Pinellas narcotics-intelligence unit.

The drug is diabolically well-suited for rape, because it can be slipped into someone's drink at a bar, and within 15 to 30 minutes that person slips into a state of amnesia lasting up to eight hours. "It's like, 'I think I got raped, but I don't remember,'" Platt said.

The victim is in danger of more than sexual assault, though. When combined with alcohol, the drug can be fatal.

If being young weren't cruel and complicated enough these days, now young women have to worry about whether some creep is slipping a knock-out pill into her drink at a party. Counselors advise people to refuse a drink offered by a stranger, and never to leave one's drink unattended.



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This is a law enforcement problem, of course, but it is more than that. Here the women's rights movement and the most ardent social and religious conservatives ought to find common ground. The level of decadence and disregard for human worth required to drug and rape a young woman ought to arouse the wrath of every rational person.

It would be simple if the manufacturer could just stop making the drug, but that seems unlikely. Washington ought to press researchers to consider other ways of accomplishing the same medicinal results, perhaps altering the formula or form of the drug. Shipping and dispensation should be more rigorously controlled too.

Still, the problem is not so much with the manufacturer. America's drug problem is just one more symptom of the moral breakdown of much of society.

TYPE: EDITORIAL; EDITORIALS

LOAD-DATE: December 4, 1995



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LEVEL 1 - 3 OF 29 STORIES

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The Houston Chronicle

January 1, 1996, Monday, 3 STAR Edition

SECTION: a; Pg. 18

LENGTH: 995 words

HEADLINE: After mickey came roofie: Illegal drug used in date rapes;
Sedative slipped into drinks creates nightmares for some

BYLINE: JULIO LABOY; Orange County Register

DATELINE: SANTA ANA, Calif.

BODY:

SANTA ANA, Calif. - It started out as a casual get-together for a 25-year-old student but ended in rape, humiliation and the harrowing revelation that a drug used in date rapes is knocking on the nation's door.

The drug, Rohypnol, is described by law enforcement as a sedative 10 times more powerful than Valium and is manufactured by the F.Hoffmann-La Roche & Co. pharmaceutical firm, based in Basel, Switzerland. Not approved for use in the United States, it has been a legal prescription drug for several years in most of the world and is available in Europe and Latin America.

The sale and introduction of the drug into interstate commerce in the United States is illegal; virtually the only people who can possess it legally in this country are those who have prescriptions written in other countries.

On the street, users call the small, white pills "'roofies'" and "'Roche. '" The substance has also been referred to as "'the date rape drug'" and "'the Quaalude of the '90s,'" after another often abused sedative. Rohypnol is drawing the attention of narcotics experts across the country.

It is being smuggled into the United States, usually in its original wrapping, through Colombia and Mexico, according to Bob Nichols, an assistant state prosecutor in Fort Lauderdale, Fla., where illegal use of roofies in this country first became noticed.

Nichols has been involved in five sexual-battery cases connected to roofies in the last five months.

"I don't know why it's suddenly on the scene. It's been around awhile," Nichols said. "'The pattern with the rapes is that



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high school and college kids and gang members are slipping it into drinks at nightclubs and pick-up joints. ''

That is what one Orange County, Calif., woman, an English major at the University of California, San Diego, believes happened to her Sept. 29.

The student attended a concert that night with a male friend.

The two were not romantically involved, she said.

She had three glasses of wine that night. At least one glass of wine was consumed in the parking lot of the San Diego theater where the concert was taking place.

That's when the student started feeling strangely. She doesn't remember the concert. She doesn't remember how she got home.

She doesn't remember getting into bed. The last thing she does recall is waking up the next morning naked and in a pool of vomit.

"I was so sick when I woke up," she said. "I could hardly hold

my head up. I couldn't remember anything. I noticed there was vomit on the bed and stuck on my hair. I was lying in it. I could have choked on it and died. He was naked and I was naked. He said we made love. ''

The woman was crushed. Their relationship had never been an intimate one, she said. The Orange County Register, which generally doesn't publish the names of sexual-abuse victims, is withholding her name from publication.

The woman, who works as a part-time language teacher and as a waitress, believes that her companion slipped a roofie into her wine that night and that it erased her memory, an effect described by pharmacologists and in medical reports.

Struggling to overcome the nightmare, the woman is seeing a therapist and is taking a vacation out of the country to escape the everyday reminders of that ill-fated night. She agreed to share her story because, she said, "I didn't do anything wrong. ''

She wants to turn a negative experience into a positive one.

She wants to warn other young women about roofies.

"My friends had no clue about this drug," she said. "This stuff is scary. You can't be cautious enough. ''

She called a rape hot line after spending two lonely days knee-deep in guilt and self-doubt. She then went to a therapist at Kaiser Permanente in San Diego.



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"Some people were saying I got drunk. But I didn't. I just had wine," the student said. "I was telling (the therapist) that I couldn't believe it. I was crying. I was confused. As I started telling her my story she said, 'Hold on. I know what this is. ' "

The student learned from the therapist that her situation resembled a drugging, and that an epidemic of similar cases had arisen in the past six months.

"She said they all were feeling sluggish and drunk on dates that ended in rape," the student said.

That's when the student first heard about roofies.

"We have seen many date-rape cases," Kaiser Permanente spokesman Jim McBride said. "Many of those patients report being drugged. Our therapists believe these stories are credible. It's real. It's happening. ' "

The woman then notified the San Diego Police Department.

Investigators are looking into the matter.

Police Sgt. Joanne Archambault of the sex-crimes unit said she cannot comment on rape cases because of privacy reasons, but confirmed that the student's report had been taken.

"Recently, lots of girls have been coming in saying they were drugged or passed out after having one or two drinks," Archambault said. "We even talked to the Poison Control Center about it. ' "

Orange County drug counselors and law-enforcement officers are bracing for the arrival of roofies, which typically cost \$ 1 to \$ 5 for a single, 2-milligram pill. The pill is also taken by cocaine users who want to parachute down less harshly from a cocaine high.

"I would assume that because of the movement of things in the San Diego-Los Angeles-Orange County corridor, that yes, it may be here," said Bill Edelman, division manager in charge of alcohol and drug programs at the Orange County Health Care Agency. Reports of Rohypnol abuse have surfaced in Florida, Texas and other parts of the Southwest, he said.

Jennifer Trenshaw, health educator at the University of Southern California Health Center, had a word of advice for people, especially women: Don't leave your drink unattended, and don't accept a drink from a stranger.



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LANGUAGE: ENGLISH

LOAD-DATE: January 3, 1996



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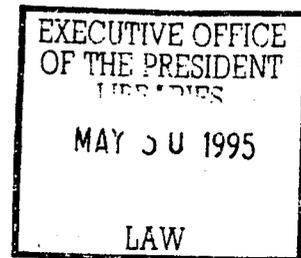
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CFR Index and Finding Aids

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Revised as of January 1, 1995



CFR	21 U.S.C.—Continued	CFR
ts 241.	53, 56, 72, 73, 75-79, 85, 91, 160-162	
'87, 788	120.....7 Part 1	
ts 200.	9 Parts 49, 70, 82, 93, 99	
201	122-123.....9 Parts 49, 70	
art 760	122.....7 Part 1	
art 750	9 Part 93, 99	
ts 34	123-126.....9 Parts 56,	
'art 31	72, 73, 75, 76, 78, 79, 82, 85	
art 750	125-127.....9 Parts 49, 70	
art 750	125.....9 Parts 50, 51, 160-162	
art 757	127.....7 Part 1	
art 230	134-134h.....9 Part 75	
rt 2400	134a.....9 Parts 82, 93	
rt 236	134a-134h.....9 Parts 54, 56	
ts 765	134a-134d.....9 Parts 92, 98	
art 757	134a-134c.....9 Part 94	
art 758	134b-134c.....9 Parts 49, 70, 93, 99	
art 757	134b.....9 Parts 50, 51, 161, 162	
57, 758	53, 71-73, 76-80, 82, 85, 91, 99, 160,	
57, 758	161, 162	
rt 722	134d.....9 Part 93	
rt 445	134e-134f.....7 Part 1	
rt 652	9 Parts 49, 70, 93, 99	
rt 652	134f.....9 Parts 71-73,	
art 47	76-80, 82, 85, 91, 92, 94, 98, 99, 160-	
Part 2	162	
	135-135a.....9 Parts 93, 99	
	135.....9 Part 92	
s 5, 14	135a.....7 Parts 1, 319	
5, 10,	136-136a.....7 Parts 320,	
1, 1220	330, 352, 354	
'art 5	9 Parts 91, 92, 95, 96, 130	
rt 307	136a.....7 Part 319	
93, 99	9 Part 156	
art 98	141-149.....21 Parts 5, 10, 12-16	
'art 1	151-159.....9 Parts 101-109, 116-118	
0-162	21 Part 112	
art 78	151-158.....9 Parts 113, 114, 122, 123	
6, 162	32 Part 627	
rt 50,	154.....7 Part 1	
1, 85,	159.....9 Part 113	
	262.....21 Part 56	
93, 99	271.....21 Parts 500, 505	
1, 330	301 note.....21 Part 101	
ts 54,	321 et seq.....21 Parts 10, 13, 514	
	321-394.....21 Part 5	
rt 627	321-393.....21 Parts 7,	
rt 91	10, 12-16, 20, 25	
1, 161	321-371.....21 Part 14	
9, 51,	321.....21 Parts 1-3,	
7, 160	50, 56, 70, 71, 73, 74, 100-107, 109, 130,	
t 130	131, 133, 135, 137, 145, 156, 160, 161,	
t 330	163, 164, 166, 168-179, 181, 182, 184,	
3, 130	186, 189, 200-202, 206, 207, 211, 250,	
2, 162	310, 312, 314, 330-333, 336, 338, 340,	
76, 78	341, 344, 347-349, 357, 361, 369, 430-	
7, 80	432, 500-502, 505, 510, 511, 570, 573,	
1, 162	579, 582, 584, 589, 600, 606, 607, 610,	
3, 56,	640, 700, 710, 730, 740, 800, 801, 1020	
1, 161	331.....21 Parts 2,	
t 161	20, 100, 201, 206, 299, 300, 500, 501,	
art 1	505, 510, 730, 807, 809, 812, 813, 821	
3, 53,	40 Part 177	
85,	331j.....40 Part 9	
	332-334.....21 Part 110	
1, 80	333.....21 Part 7	
1, 51,		

21 U.S.C.—Continued	CFR	21 U.S.C.—Continued	CFR
334.....	21 Part 800	206, 207, 211, 225, 226, 299, 329, 429,	
336.....	21 Parts 58,	432, 433, 607, 640, 803, 804, 895, 1040,	
	109, 130, 250, 509	1050	
337.....	21 Part 100	353.....	21 Parts 310, 312, 329, 500
341-343.....	21 Parts 70,	355-360a.....	21 Part 514
	73, 74, 156	355-358.....	21 Part 201
341.....	21 Parts 71,	355-357.....	21 Part 3,
103-105, 130, 131, 133, 135-137, 139,		50, 56, 58, 71, 170, 171, 202, 207, 211,	
145, 146, 150, 152, 155, 166, 158, 160,		312, 314, 320, 361, 430, 505, 510, 570,	
161, 163-166, 168-176, 178, 300, 556,		571, 700, 800, 812, 813, 1003	
564, 571, 573, 584		355-356.....	21 Part 200
342-343.....	21 Parts 100,	355.....	21 Parts 1, 2,
179, 501, 505, 514, 801		12, 60, 73, 74, 206, 250, 290, 291, 299,	
342.....	21 Parts 58,	300, 310, 330-333, 336, 338, 340, 341,	
108-110, 113, 114, 122, 129, 170, 172,		344, 347-349, 357, 433, 500, 501, 600,	
181, 182, 184, 186, 189, 250, 500, 507-		601, 606, 607, 610, 620, 630, 640, 801,	
609, 570, 589		809	
343.....	21 Parts 1,	356-357.....	21 Parts 369, 429
101-105, 107, 130, 131, 133, 135, 136,		356.....	21 Part 310
139, 145, 160, 161, 163, 164, 166, 168,		357-358.....	21 Part 200
169, 502, 564		357.....	21 Parts 2,
344.....	21 Parts 108, 508	60, 206, 300, 320, 430-433, 436, 440-	
345.....	21 Part 561	444, 446, 448-450, 452, 453, 455, 460,	
346-346a.....	21 Parts 60,	500, 501, 544, 801, 809	
56, 58, 71, 109, 170, 171, 193, 320, 361,		358.....	21 Part 299
430, 431, 514, 570, 571, 812, 813, 1003,		360-360 note.....	21 Parts 606, 610
1010		360.....	21 Parts 3,
	40 Parts 2, 180	20, 50, 56, 58, 71, 170, 171, 180, 201,	
346.....	21 Parts 176,	207, 225, 310, 320, 330, 332, 333, 336,	
176, 178, 250, 509, 561		338, 340, 341, 344, 347, 348, 349, 357,	
346a.....	21 Part 2	361, 430, 510, 511, 520, 571, 600, 607,	
	40 Parts 9, 23,	640, 803, 804, 809, 812-814, 821, 862,	
	160, 163, 178, 179, 185	864, 866, 868, 870, 872, 874, 876, 878,	
346c.....	21 Part 561	880, 882, 884, 886, 888, 890, 892, 1010,	
347.....	21 Parts 1, 166	1030, 1040, 1050	
	40 Part 180	360b-360f.....	21 Parts 58,
348.....	21 Parts 50,	71, 170, 171, 180, 314, 430, 431, 511,	
56, 58, 60, 70, 71, 73, 100, 101, 103,		570, 571, 812, 1003, 1010	
105, 109, 129, 131, 133, 135-137, 139,		360b-360c.....	21 Part 12
145, 146, 150, 156, 161, 163, 164, 166,		360b.....	21 Parts 1, 2,
168-173, 175-182, 184, 186, 189, 320,		70, 201, 207, 225, 226, 250, 299, 300,	
361, 430, 500, 501, 509, 570, 571, 573,		453, 505, 514, 520, 522, 524, 526, 529,	
579, 582, 584, 589, 700, 801, 813, 1003		556, 558, 801, 809	
	40 Parts 9, 23,	360c-360j.....	21 Part 814
	160, 177-180, 185, 186	360c-360f.....	21 Parts 3,
348a.....	21 Part 156	50, 56, 310, 320, 361, 510, 813	
350.....	21 Part 105	360c-360e.....	21 Parts 20, 860
350a.....	21 Parts 7, 106, 107	360c-360d.....	21 Parts 809, 861
351-353.....	21 Parts 3,	360c.....	21 Part 807,
56, 71, 170, 171, 180, 200, 201, 205, 312,		862, 864, 866, 868, 870, 872, 874, 876,	
314, 320, 330-333, 336, 338, 340, 341,		878, 880, 882, 884, 886, 888, 890, 892	
344, 347, 348, 349, 357, 430, 431, 505,		360e-360j.....	21 Parts 1010,
510, 511, 514, 570, 571, 600, 616, 620,		1020, 1030, 1040, 1050	
630, 640, 812-814, 1003, 1010		360e.....	21 Parts 60, 200,
351-352.....	21 Parts 2,	800, 820, 821, 862, 864, 866, 868, 870,	
20, 299, 300, 500, 501, 600, 606, 700,		872, 874, 876, 878, 880, 882, 884, 886,	
800, 801, 807, 809, 820, 821, 861		888, 890, 892	
351.....	21 Parts 70, 73,	360f.....	21 Part 895
210, 211, 225, 226, 310, 351, 505, 607,		360h-360j.....	21 Parts 3,
862, 864, 866, 868, 870, 872, 874, 876,		50, 56, 58, 71, 171, 180, 320, 361, 430,	
878, 880, 882, 884, 886, 888, 890, 892,		431, 809, 812, 813, 820, 1003, 1010	
1010, 1020, 1030, 1040, 1050		360h-360i.....	21 Parts 170, 571, 821, 895
352-353.....	21 Parts 50,	360i-360j.....	21 Parts 20, 801, 860
58, 202, 250, 290, 310, 361, 369		360i.....	21 Parts 800,
352.....	21 Parts 1, 73,	803, 804, 862, 874, 900	
		360j.....	21 Parts 60, 606,

30, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete text of this title and Tables volume, see Short Title note set out in this title and Tables volume, chapter 9, referred to in text, was in enacting Title III of Pub.L. 91-513, § 5. Part A of Title III comprises section 801. For classification of Part B, see Tables 1105 of Title III, see Tables

and Cosmetic Act, referred to in section 25, 1938, c. 675, 52 Stat. 1040, and generally to chapter 9 (§ 301 et seq.) of this title and Tables volume. The Internal Revenue Code of 1986, referred to in section 5001 et seq. of Title 26, U.S.C., Code.

and in par. (32)(A), are set out in

amendment by section 83 of Pub.L. 99-570 making identical

of 1954 in any law, etc., to include the Internal Revenue Code of 1986, except when section 99-514, § 2, Oct. 22, 1986, 100

301(a) of Pub.L. 98-509, Oct. 19, 1984, par. (28) which substituted "one hundred and twenty-one" was executed to par. (28) prior to its redesignation by section 507(a), Oct. 12, 1984, 98 Stat. 2617, et seq.

Amendments. Section 330024(d) of Pub.L. 102-190, Oct. 11, 1988, provided that: "The amendments made by sections 824, 960, and 961, shall take effect as of the date that is 120 days after the date of enactment of the Domestic Violence Act of 1993 [Dec. 17, 1993]."

Amendments. Section 11 of Pub.L. 102-190, Oct. 11, 1988, provided that: "This Act and the amendments made by sections 821, 822, 823, 824, 830, and 971 of this title and enacting section 102(28) of this title and section 102(29) of this title shall take effect on the date that is 120 days after the date of enactment of this Act [Dec. 17, 1993]."

Amendment. Section 1902(d) of Pub.L. 102-190, Oct. 11, 1988, provided that: "This section and the amendments made by sections 829 of this title, and enacting a provision of section 829 of this title shall take effect on the date of enactment of this Act [Nov. 29, 1990]."

Amendment. Section 6061 of Pub.L. 102-190, Oct. 11, 1988, provided that: "Except as otherwise provided in this title [enacting section 972 of this title, and sections 830, 841, 842, 843, 872, 876, 881,

960 and 961 of this title] shall take effect 120 days after the date of enactment of this Act [Nov. 18, 1988]."

Change of Name. "Secretary of Health and Human Services" was substituted for "Secretary of Health, Education, and Welfare" on authority of Pub.L. 96-88, Title V, § 509, Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508 of Title 20, U.S.C.A., Education.

Regulations by Attorney General. Section 1903 of Pub.L. 101-647 provided that:

"(a) **Abuse potential.**—The Attorney General, upon the recommendation of the Secretary of Health and Human Services, may, by regulation, exempt any compound, mixture, or preparation containing a substance in paragraph (41) of section 102 of the Controlled Substances Act [par. (41) of this section] (as added by section 2 of this Act [sic]) from the application of all or any part of the Controlled Substances Act [21 U.S.C.A. § 801 et seq.] if, because of its concentration, preparation, mixture or delivery system, it has no significant potential for abuse.

"(b) **Drugs for treatment of rare diseases.**—If the Attorney General finds that a drug listed in paragraph (41) of section 102 of the Controlled Substances Act (as added by section 2 of this Act [sic]) is—

"(1) approved by the Food and Drug Administration as an accepted treatment for a rare disease or condition, as defined in section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) [21 U.S.C.A. § 360bb]; and

"(2) does not have a significant potential for abuse, the Attorney General may exempt such drug from any production regulations otherwise issued under the Controlled Substances Act [21 U.S.C.A. § 801 et seq.] as may be necessary to ensure adequate supplies of such drug for medical purposes.

"(c) **Date of issuance of regulations.**—The Attorney General shall issue regulations implementing this section not later than 45 days after the date of enactment of this Act [Nov. 29, 1990], except that the regulations required under section 3(a) [sic] shall be issued not later than 180 days after the date of enactment of this Act [Nov. 29, 1990]."

Promulgation of Regulations for Administration of Amendment by Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984; Inclusion of Findings in Report. Section 301(b) of Pub.L. 98-509, Oct. 19, 1984, 98 Stat. 2364, provided that: "The Secretary of Health and Human Services shall, within ninety days of the date of the enactment of this Act [Oct. 19, 1984], promulgate regulations for the administration of section 102(28) of the Controlled Substances Act as amended by subsection (a) [probably par. 29 of this section] and shall include in the first report submitted under section 505(b) of the Public Health Service Act [section 290aa-4 of Title 42, The Public Health and Welfare] after the expiration of such ninety days the findings of the Secretary with respect to the effect of the amendment made by subsection (a) [amending par. (29) of this section]."

Code of Federal Regulations

Controlled drugs, warnings, see 21 CFR 290.5 et seq.

Treatment of narcotic addicts, see 21 CFR 291.501 et seq.

§ 803. Repealed. Pub.L. 95-137, § 1(b), Oct. 18, 1977, 91 Stat. 1169.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

§ 811. Authority and criteria for classification of substances

Rules and regulations of Attorney General; hearing

(a) The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

Evaluation of drugs and other substances

(b) The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be

listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

**Factors determinative of control
or removal from schedules**

(c) In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances

(d)(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this subchapter to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services, after consultation with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the

drug or substance and the Federal Food, Drug, and requirements of the schedule or schedule notice action:

(A) If such requirements existing controls but the Secretary of Health and Human Services nonetheless substance, the Secretary of Health and Human Services shall initiate proceedings for scheduling the drug or substance under subsections (a) and (b) of this section.

(B) If such requirements existing controls and the Secretary of Health and Human Services does not decide to schedule notification, the Secretary of Health and Human Services shall initiate proceedings for scheduling the drug or substance under subsection (a) of this section.

(C) If such requirements existing controls and the Secretary of Health and Human Services does not decide to schedule notification, the Secretary of Health and Human Services shall initiate proceedings for scheduling the drug or substance under subsection (a) of this section.

(i) if he deems it necessary to protect the public health, he shall recommend to the Secretary of Health and Human Services that he initiate proceedings for scheduling the drug or substance pursuant to this section, to apply

(ii) request the Secretary of Health and Human Services to issue a notice of qualified opinion under paragraph 7 of article 2 of the Convention on Psychotropic Substances.

(iii) request the Secretary of Health and Human Services to issue a notice of qualified opinion under clause (ii) and request the Secretary of Health and Human Services to ask for a review of the scheduling decision by the Council of the United States with paragraph 8 of the scheduling decision.

(iv) in the case of a schedule notice, the Secretary of Health and Human Services shall remove the drug or substance from the schedule under the Convention on Psychotropic Substances if the Secretary of Health and Human Services determines that the drug or substance does not meet the requirements of the schedule notice.

(4)(A) If the Attorney General determines that consultation with the Secretary of Health and Human Services is necessary to protect the public health, he shall recommend to the Secretary of Health and Human Services that he initiate proceedings for scheduling the drug or substance pursuant to this section, to apply

drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall—

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)(A) If the Attorney General determines, after consultation with the Secretary of Health and Human

Services, that proceedings initiated under recommendations made under paragraph (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If,

as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)—

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

Immediate precursors

(e) The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

Abuse potential

(f) If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

Non-narcotic substances sold over the counter without prescription; dextromethorphan

(g)(1) The Attorney General shall by regulation exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a non-narcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

Temporary scheduling to avoid imminent hazards to public safety

(h)(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 355 of this title. Such an order may not be issued before the expiration of thirty days from—

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drug application is submitted by a drug having a stimulant, central nervous system effect on the central nervous system that such drug has an immediate effect shall be forwarded to the Attorney General.

Drugs sold over the counter; dextromethorphan. A substance shall be by regulation scheduled under a schedule if the Attorney General, Drug, Food, and Cosmetic Administration fully sold over the counter.

shall not be deemed to be controlled by reason of enactment of this section after October 27, 1970, regarding provisions of this section.

may, by regulation, exclude a substance from the application of all provisions of this chapter if he finds such exclusion meets the requirements of the following categories:

1. A preparation containing a non-controlled substance, which mixture or preparation is intended for prescription use, and which contains no more other active ingredients than are listed in any schedule and which does not contain such combinations, quantity, or concentration as to vitiate the potential.

2. A mixture, or preparation which contains a controlled substance, which is not for the use of a human being or animal, and which is in such form or concentration, or such quantity, or such combination of ingredients, so that as packaged or presented it has no significant potential.

relating to avoid imminent hazard to public safety

The Attorney General finds that the scheduling of a substance in schedule I on a temporary basis would avoid an imminent hazard to the public health and safety of the United States, and without regard to the provisions of subsection (b) of this section, the Attorney General of Health and Human Services may schedule a substance in schedule I if the Attorney General finds that there is no exemption or approval of such substance under section 355 of this title, and that such order may not be issued before the date of the order.

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling for up to six months.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) of this section with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

(Pub.L. 91-513, Title II, § 201, Oct. 27, 1970, 84 Stat. 1245; Pub.L. 95-633, Title I, § 102(a), Nov. 10, 1978, 92 Stat. 3769; Pub.L. 96-88, Title V, § 509, Oct. 17, 1979, 93 Stat. 695; Pub.L. 98-473, Title II, §§ 508, 509(a), Oct. 12, 1984, 98 Stat. 2071, 2072.)

EDITORIAL NOTES

References in Text. The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (d)(3) and (g)(1), is Act June 25, 1938, c. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (section 301 et seq.) of Title 21, U.S.C.A., Food and Drugs.

Schedules IV and V, referred to in subsec. (d)(4)(A), (B), are set out in section 812(c) of this title.

The Psychotropic Substances Act of 1978, referred to in subsec. (d)(5), is Pub.L. 95-633, Nov. 11, 1978, 92 Stat. 3768, which enacted sections 801a, 830, and 852 of Title 21, U.S.C.A., Food and Drugs, amended this section and sections 352, 802, 812, 823, 827, 841 to 843, 872, 881, 952, 953, and 965 of Title 21 and section 242a of Title 42, U.S.C.A., and The Public Health and Welfare, and enacted provisions set

out as notes under sections 801, 801a, 812, and 830 of Title 21.

Change of Name. "Secretary of Health and Human Services" was substituted for "Secretary of Health, Education, and Welfare" on authority of Pub.L. 96-88, Title V, § 509, Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508 of Title 20, U.S.C.A., Education.

Code of Federal Regulations

Administrative functions, practices, and procedures, see 21 CFR 1316.01 et seq.

Debarment and suspension, drug-free workplace, grants, see 21 CFR 1404.100 et seq.

Drug abuse prevention, audiovisual education, see 34 CFR 763.1 et seq.

Drug-free schools and campuses, see 34 CFR 86.1 et seq.

Mandatory declassification review program, see 21 CFR 1402.1 et seq.

Schedules, see 21 CFR 1308.01 et seq. and Table.

Uniform administrative requirements, grants and cooperative agreements, see 21 CFR 1403.1 et seq.

§ 812. Schedules of controlled substances**Establishment**

(a) There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970 and shall be updated and republished on an annual basis thereafter.

Placement on schedules; findings required

(b) Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II.—

(A) The drug or other substance has a high potential for abuse.

UNITED STATES CODE ANNOTATED

Title 21
Food and Drugs
§§ 1 to 800

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ality for harmful effects through excessive use to the merely average man and even to those below the average. *National Nutritional Foods Ass'n v. Weinberger*, D.C.N.Y.1973, 366 F.Supp. 1841, affirmed 491 F.2d 845.

Commissioner is not required to set over-the-counter limit beyond which drug may be obtained only by prescription, at maximum which consumer might withstand; substantial margin of safety may be used. *National Nutritional Foods Ass'n v. Weinberger*, D.C.N.Y.1973, 366 F.Supp. 1841, affirmed 491 F.2d 845.

11. Elements of offense

Where federal law prohibits dispensing of a drug without a prescription, propriety of securing and adjusting that drug without a prescription does not depend upon user's knowledge of the particular dangers involved. *Lindsay v. Ortho Pharmaceutical Corp.*, C.A.N.Y.1980, 637 F.2d 87.

12. Jurisdiction

Reason Food and Drug Administration has primary jurisdiction to determine whether drug sought to be marketed constitutes "new drug" subject to this chapter is expertise of Federal Drug Administration in resolving technical and scientific questions. *Biotics Research Corp. v. Heckler*, C.A.Nev.1983, 710 F.2d 1375.

13. Persons liable

Under "bulk supplier doctrine," bulk supplier of polytetrafluoroethylene (PTFE) to manufacturer of jaw joint implant, which was regulated by the Food and Drug Administration (FDA), did not have any duty to warn of possible dangers of PTFE in implant, and thus, patients could not recover from supplier for injuries allegedly received as result of implant, on breach of duty to warn theory; FDA approved PTFE as appropriate medical device for use in a medical implant, and before filling the order, supplier informed manufacturer of its lack of knowledge of whether use of device in implants was appropriate. *Veil v. Vitek, Inc.*, D.N.D.1992, 803 F.Supp. 229.

R.C. Ohio §§ 3715.01(A) (5) (a), (A) (6) (a), (B) (2) do not apply to the administration of a drug or device by a licensed member of the medical profession. *Morse v. Riverside Hospital*, 1974, 339 N.E.2d 846, 44 Ohio App.2d 422.

Complaint brought by patient who contracted hepatitis during a blood transfusion did not state a valid claim for relief against hospital and blood bank based upon negligence by reason of a violation of R.C. Ohio § 3715.01(A) (5) (a), (A) (6) (a), (B) (2), inasmuch as provisions thereof did not apply to administration of a drug or device by a licensed member of medical profession.

§ 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to

Morse v. Riverside Hospital, 1974, 339 N.E.2d 846, 44 Ohio App.2d 422.

18. — Weight and sufficiency

Public promotion of high dosage quantities of vitamins A and D for the cure, mitigation, treatment, and prevention of a variety of ailments, when coupled with the fact that there exists little, if any, evidence of known nutritional requirements above the levels of 10,000 IU per dosage unit of vitamin A and 400 IU per dosage unit of vitamin D was sufficient to demonstrate that Food and Drug Administration requirements that preparations of vitamins A and D above those levels be restricted to prescription sale and be labeled accordingly was not arbitrary or capricious. *National Nutritional Foods Ass'n v. Mathews*, D.C.N.Y.1976, 418 F.Supp. 394.

Although evidence sufficient to support finding that high potency preparations of certain vitamins had no demonstrated usage as a food, at least for all but an extremely small percentage of the population, above levels established in Food and Drug Administration regulations requiring that high potency preparations be available for sale only by prescription and be labeled accordingly, might not, standing alone, be sufficient to sustain the regulations, it was a relevant and important data in favor of the regulations. *National Nutritional Foods Ass'n v. Mathews*, D.C.N.Y.1976, 418 F.Supp. 394.

19a. Witnesses

Commissioner of food and drugs would not be called at "Overton-type" hearing, which was being held to determine whether the Food and Drug Administration acted rationally in requiring that preparations of vitamins A and D in excess of specified dosages be restricted to prescription sale and be labeled accordingly, for cross-examination by those opposing the actions taken by the Food and Drug Administration. *National Nutritional Foods Ass'n v. Mathews*, D.C.N.Y.1976, 418 F.Supp. 394.

21. State regulation or control

Lethal injection statute was not preempted by Federal Drug Abuse Prevention and Control Act (DAPCA) or Federal Food, Drug and Cosmetic Act (FDCA); Statute's single goal was merely to effect execution of lawfully condemned inmates, in contrast to the federal Acts' concerns over deleterious effects of unregulated usage of controlled substances by individual citizens, and statute could not violate federal law, inasmuch as federal government utilized lethal injection method of execution. *State v. Deputy*, Del.Super.1994, 644 A.2d 111.

the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—

- (i) that such patent information has not been filed,
- (ii) that such patent has expired,
- (iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) Approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(B) Give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A) of this section, the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,

(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of Title

28 for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) of this section before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under subsection (b) of this section after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A) of this section. The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(d) **Grounds for refusing application; approval of application; "substantial evidence" defined**

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) **Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health**

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such informa-

tion; or (5) that the application contains any untrue statement of a material fact. *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

[See main volume for text of (f) to (i)]

(j) **Abbreviated new drug applications**

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic

class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn

or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35 or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the

Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(6)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (5), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(7) For purposes of this subsection:

(A) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(8) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Public disclosure of safety and effectiveness data

Safety and effectiveness data and information which has been submitted in an application under subsection (b) of this section for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) of this section is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) of this section which refers to such drug or upon the date upon which the approval of an application under subsection (j) of this section which refers to such drug could be made effective if such an application had been submitted.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the Patent and Trademark Office of the Department of Commerce.

(As amended Aug. 16, 1972, Pub.L. 92-387, § 4(d), 86 Stat. 562; Sept. 24, 1984, Pub.L. 98-417, Title I, §§ 101, 102(a)-(b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub.L. 102-282, § 5, 106 Stat. 161; Aug. 13, 1993, Pub.L. 103-80, § 3(n), 107 Stat. 777.)

HISTORICAL AND STATUTORY NOTES

1993 Amendments

Subsec. (j)(6)(A)(ii). Pub.L. 103-80, § 3(n)(1)(A), corrected a typographical error in the original by substituting "Secretary" for "Secretary".

Subsec. (j)(6)(A)(iii). Pub.L. 103-80, § 3(n)(1)(B), inserted a comma after "published by the Secretary".

Subsec. (k)(1). Pub.L. 103-80, § 3(n)(2), struck out " Provided, however, That regulations" and inserted in lieu thereof a period and "Regulations".

1992 Amendments

Subsec. (j)(8). Pub.L. 102-282, § 5, added par. (8).

1984 Amendment

Subsec. (a). Pub.L. 98-417, § 102(b)(1), added "or (j)" following "pursuant to subsection (b)".

Subsec. (6)(1). Pub.L. 98-417, § 103(a), designated the existing provisions of subsec. (b) as par. (1) thereof and redesignated existing cls. (1) through (6) of par. (1) as so redesignated as cls. (A) through (F) thereof, respectively.

Pub.L. 98-417, § 102(a)(1), added requirement that the applicant file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, that the applicant amend the application to include such information if an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, and that, upon approval of the application, the Secretary publish the information submitted.

Subsec. (b)(2), (3). Pub.L. 98-417, § 103(a), added pars. (2) and (3).

Subsec. (c)(1). Pub.L. 98-417, § 102(a)(2), designated the existing provisions of subsec. (c) as par. (1) thereof and in par. (1) as so designated redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively.

Pub.L. 98-417, § 102(b)(2), substituted "subsection (b) of this section" for "this subsection".

Subsec. (c)(2). Pub.L. 98-417, § 102(a)(2), added par. (2).

Subsec. (c)(3). Pub.L. 98-417, § 103(b), added par. (3).

Subsec. (d)(6). Pub.L. 98-417, § 102(a)(3)(A), added cl. (6) relating to the failure of the application to contain the patent information prescribed by subsec. (b) of this section. Former cl. (6) was redesignated (7).

Subsec. (d)(7). Pub.L. 98-417, § 102(a)(3)(A), redesignated former cl. (6) as (7).

Subsec. (e). Pub.L. 98-417, § 102(a)(3)(B), added, in the first sentence covering the grounds for withdrawal of approval by the Secretary, a new cl. (4) relating to the failure to file the patent information prescribed by subsec. (c) of this section within 90 days after the receipt of written notice from the Secretary specifying the failure to file such information, and redesignated the former cl. (4) as (5).

Pub.L. 98-417, § 102(b)(3), inserted, in the provisions of the second sentence preceding cl. (1) of the enumeration of clauses covering the grounds for withdrawal of approval by the Secretary, the phrase "submitted under subsection (b) or (j) of this section" after "withdraw the approval of an application".

Pub.L. 98-417, § 102(b)(4), substituted, in cl. (1) of the second sentence covering the grounds for withdrawal of approval by the Secretary, the phrase "under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title" for "under subsection (j)

of this section or to comply with the notice requirements of section 360(j)(2) of this title".

Subsec. (j). Pub.L. 98-417, § 101, added subsec. (j). Former subsec. (j) was redesignated (k).

Subsec. (k). Pub.L. 98-417, § 101, redesignated former subsec. (j) as (k).

Subsec. (k)(1). Pub.L. 98-417, § 102(b)(5), substituted "under subsection (b) or (j) of this section" for "pursuant to this section".

Subsecs. (l), (m). Pub.L. 98-417, § 104, added subsecs. (l) and (m).

1972 Amendment

Subsec. (e). Pub.L. 92-387 inserted "or to comply with the notice requirements of section 360(j)(2)" in clause (1) of the second sentence relating to the maintenance of records.

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L. 96-88, Title VI, Oct. 17, 1979, 93 Stat. 696, set out as a note under section 3401 of Title 20, Education, deemed to refer and apply to the Department of Health and Human Services or the Secretary of Health and Human Services, respectively, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under Pub.L. 96-88, Title III, §§ 301 to 307, Oct. 17, 1979, 93 Stat. 677 to 681. See section 3441 to 3447 and 3508 of Title 20.

Effective Date of 1984 Amendment

Section 105 of Pub.L. 98-417 provided that: "(a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code [section 553 of Title 5, Government Organization and Employees], such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act [this section], as amended by sections 101, 102, and 103 of this Act [enacting subsec. (j) of this section and amending subsecs. (a) to (e) and (k)(1) of this section and section 360c(a) and (b) of this title], within one year of the date of enactment of this Act [Sept. 24, 1984].

"(b) During the period beginning sixty days after the date of the enactment of this Act [Sept. 24, 1984], and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable

for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act [subsec. (c) of this section] before the date of the enactment of this Act [Sept. 24, 1984]. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act [subsec. (j) of this section], the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act [subsecs. (c)(3)(D) and (j)(4)(D) of this section], except in accordance with such section."

Effective Date of 1972 Amendment

Amendment by Pub.L. 92-387 effective on the first day of the sixth month beginning after Aug.

CROSS REFERENCES

Patents, extension of patent term, see 35 USCA § 156.

FEDERAL PRACTICE AND PROCEDURE

Review of administrative decisions in courts of appeals, see Wright, Miller, Cooper, & Gressman: Jurisdiction § 3941.

WEST'S FEDERAL PRACTICE MANUAL

Application for use of new drug, see § 3638.

CODE OF FEDERAL REGULATIONS

Formal evidentiary public hearing, see 21 CFR 12.1 et seq.
New animal drugs, see 21 CFR 510.3.

New animal feed drugs, see 21 CFR 558.3.
New drugs for human use, see 21 CFR 310.100 et seq.

LAW REVIEW COMMENTARIES

A survey of law regarding the liability of manufacturers and sellers of drug products and medical devices. Bryan J. Maedgen and Sheree Lynn McCall, 18 St. Mary's L.J. 395 (1986).

Brother can you spare a drug: Should the experimental drug distribution standards be modified in response to the needs of persons with Aids? 19 Hofstra L.Rev. 191 (1990).

Developing, testing, and marketing an AIDS vaccine: Legal concerns for manufacturers. Alison Joy Arnold, 139 U.Pa.L.Rev. 1077 (1991).

Drug Price Competition and Patent Term Restoration Act of 1984: Is it a healthy long term solution? Note, 21 Rutgers L.J. 147 (1989).

From dog food to prescription drug advertising: Litigating false scientific establishment claims under the Lanham Act. Charles J. Walsh and Marc S. Klein, 22 Seton Hall L.Rev. 389 (1992).

LIBRARY REFERENCES

Regulation of drugs and pharmacists generally, see Drugs and Narcotics § 1, 11, et seq.

Regulation of drugs and pharmacists generally, see C.J.S. Drugs and Narcotics § 27 et seq.

16, 1972, see section 5 of Pub.L. 92-387, set out as a note under section 360 of this title.

Federal Policy Regarding the Export of Banned or Significantly Restricted Substances

For provisions relating to the applicability of the term "banned or significantly restricted substance", as defined, and the Federal policy regarding the export of banned or significantly restricted substances, see section 1-101 of Ex. Ord. No. 12284, Jan. 15, 1981, 46 F.R. 4659, set out as a note under section 2403 of Title 50, Appendix, War and National Defense.

Legislative History

For legislative history and purpose of Pub.L. 92-387, see 1972 U.S. Code Cong. and Adm. News, p. 2963. See, also, Pub.L. 98-417, 1984 U.S. Code Cong. and Adm. News, p. 2647; Pub.L. 102-282, 1992 U.S. Code Cong. and Adm. News, p. 103.

NOTES OF DECISIONS

Generally 5a
 Active ingredient 9c
 Admissibility of evidence 22a
 Application, cancellation of 6a
 Approval of drug
 Timeliness 15a
 Authority of Secretary 5c
 Breast implants 13b
 Clinical studies 13a
 Components 9a
 Declaratory judgment 29
 Defenses 7b
 Discretion of court 18a
 Drugs administered by physicians 31
 Exclusive marketing period 9b
 Exemptions 7a
 Exhaustion of remedies 6b
 Insurance 16a
 Investigatory drugs 85
 Jurisdiction 17a
 Labeling information 86
 Notes of approval 32
 Offenses within section 5b
 Opinion letters 32a
 Prescription drugs 30
 Reapplication 6c
 Remand 34
 Remedy 33
 Retroactive effect 4a
 Review 23
 Standards of review 28a
 Summary judgment 27
 Timeliness, approval of drug 15a

1. Constitutionality

A single administrative proceeding in which each manufacturer of drug challenged on ground of efficacy may be heard is constitutionally permissible measured by requirements of procedural due process. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Defendant could be indicted for violations of recordkeeping regulations promulgated by Food and Drug Administration (FDA) for new drug investigations, as FDA had authority to create regulations and delegation of that authority to FDA satisfied constitutional concerns of non-delegation doctrine. *U.S. v. Garinkel, C.A.8 (Minn.) 1994*, 29 F.3d 451.

This section requiring new drug approval does not deny equal protection to person suffering from Down's Syndrome or their parents and custodians. *Duncan v. U.S.*, D.C.Ok.1984, 590 F.Supp. 89.

This chapter's statutory scheme for gaining approval for new drug applications in order to permit introduction into interstate commerce of such new drug does not require Food and Drug Administration to approve or disapprove any new drug in absence of application and is constitutional as exercise of Congress's power to set standards in order to protect public from unsafe drugs, even though drug application may involve costs which are so substantial as to cause persons appropriately situated to forego compliance with this chapter. *Gadler v. U.S.*, D.C.Minn. 1977, 425 F.Supp. 244.

2. Construction

Even if a substance is also a food, it may be subjected to requirements of this chapter if it is used in the diagnosis, cure, mitigation, treatment or prevention of diseases in man or other animals; intended use is an important aspect in determining whether the substance is a drug. *Rutherford v. U.S.*, C.A.Ok.1976, 542 F.2d 1137, on remand 424 F.Supp. 105.

A consistent construction of this chapter by the Food and Drug Administration for 30 years and a construction which accords with the literal language of this chapter may only be changed by Congress itself. *USV Pharmaceutical Corp. v. Richardson, C.A.Va.1972*, 461 F.2d 223, affirmed 93 S.Ct. 2498, 412 U.S. 655, 37 L.Ed.2d 244.

New drug provisions must be construed broadly to meet congressional purpose to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce. *U.S. v. General Nutrition, Inc.*, W.D.N.Y.1986, 638 F.Supp. 556.

Definition of "new drug," within meaning of this section, which provided that such drugs could not be marketed prior to approval by Food and Drug Administration of either new drug application or abbreviated new drug application, must be liberally construed in order to effectuate policy of this chapter, which is protection of public health and safety. *U.S. v. Articles of Drug HORMONIN, D.C.N.J.1980*, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.

3. With other laws

Reach of scientific inquiry under subsec. (d) of this section defining general contours of "substantial evidence" respecting efficacy of drug for purposes of refusal or approval of a new drug application, and under section 321 of this title defining a "new drug," subject to provisions of this chapter, as a drug not generally recognized among experts as effective as well as safe for its intended uses, is precisely the same. *Weinberger v. Bantex Pharmaceuticals, Inc.*, S.C. 1973, 93 S.Ct. 2488, 412 U.S. 645, 37 L.Ed.2d 235.

Court would presume that Congress was aware that this chapter would effect the earning potentiality of a drug patentee and chose to permit that effect when it tightened requirements for obtaining approval for new drugs. *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, C.A.Fed.1984, 733 F.2d 853, certiorari denied 105 S.Ct. 183, 469 U.S. 856, 83 L.Ed.2d 117.

Orders which do not deny or withdraw a new-drug application are reviewable under Administrative Procedure Act, sections 551 et seq. and 701 et seq. of Title 5, if they declare a "new drug" status. *North American Pharmaceutical, Inc. v. Department of Health, Ed. and Welfare*, C.A.8, 1973, 491 F.2d 546.

Provision of section 321 of this title defining a "new drug" as any drug not generally recognized among qualified experts as safe and effective for use under conditions prescribed, recommended, or suggested in labeling thereof should

be read with provision of this section requiring a new drug application to contain a full description of methods used in, and facilities and controls used for, manufacture, processing, and packing of drug and, as so read, should be construed as requiring premarketing approval for a new drug product of any manufacturer even if product purports to be a generic or "me-too" copy of a recognized drug. *Pharmadyne Laboratories, Inc. v. Kennedy, D.C.N.J.1979*, 466 F.Supp. 100, affirmed 596 F.2d 568.

Issues which were presented in complaint challenging Food and Drug Administration's administering of this section and section 357 of this title, governing withdrawal of approval of antibiotic and nonantibiotic drugs upon finding of lack of substantial evidence that the drugs have effect they are represented to have under conditions of use prescribed, recommended or suggested in labeling, and which did not deal with agency discretion were subject to review under the Administrative Procedure Act, sections 551 et seq. and 701 et seq. of Title 5. *American Public Health Ass'n v. Veneman, D.C.D.C.1972*, 349 F.Supp. 1811.

4. Purpose

In enacting 1962 amendments to this chapter which direct Food and Drug Administration to refuse approval for a new drug application and to withdraw any prior approval if substantial evidence that drug is effective for its intended use is lacking, Congress intended test for establishing efficacy to be a rigorous one; Congress intended that clinical impressions of practicing physicians and poorly controlled experiments would not constitute an adequate basis for establishing efficacy. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Drug Price Competition and Patent Term Restoration Act has the general purposes of increasing the availability of low-cost drugs by expanding the generic drug approval procedure and of encouraging new drug research by restoring some of the patent term lost while drug products undergo testing and await FDA premarket approval. *Glaxo Operations UK Ltd. v. Quigg, C.A.Fed. (Va.) 1990*, 894 F.2d 392.

This chapter and underlying regulations governing approval of marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer new drug application. *Upjohn Mfg. Co. v. Schweiker, C.A.Mich.1982*, 681 F.2d 480.

Purpose of this section relating to new drugs is to protect public against danger to human life arising from use of unsafe and ineffective drugs by assuring that, before any drug is marketed, it will have been carefully reviewed by Food and Drug Administration experts, and Congress' exclusion of generally recognized drug products from definition of "new drug" is very narrow one, which is not intended to permit pharmaceutical manufacturer to substitute its opinion regarding safety or effectiveness of a drug for that of the Food and Drug Administration or to require court to develop its own body of scientific knowledge in substitution for that of the FDA. *Premo Pharmaceutical Laboratories, Inc. v. U.S.*, C.A.N.Y.1980, 629 F.2d 795.

4a. Retroactive effect

Drug, with respect to which a new drug application had been filed under this chapter as originally enacted which permitted evaluation of a new drug solely on grounds of unsafety, was not exempt from 1962 amendments to this chapter, which directs the Food and Drug Administration to withdraw any prior approval if substantial evidence that the drug is effective for its intended use is lacking, by virtue of "grandfather clause" of 1962 amendments to this chapter, notwithstanding contention that when drug became generally recognized as safe and was no longer a "new drug," its new drug application ceased to be effective. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

This section contemplates that drugs whose new drug applications became effective prior to adoption thereof will be on basis of adequate and well-controlled investigations; withdrawal proceedings cannot be thwarted by a showing of general recognition of effectiveness based merely on expert testimony and reports with respect to investigations and clinical observations regardless of the controls used. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Efficacy requirements of this section were not designed to be prospective only. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

If, on October 9, 1962, laetrile was marketed for exactly the same uses for which it is presently being sold and was generally recognized by qualified experts as safe for those uses, it is exempt, under grandfather clause contained in 1962 amendment to this chapter [set out as a note under section 321 of this title], from the test of general recognition by experts as being safe and effective for its claimed uses. *Rutherford v. U.S.*, C.A.Ok.1976, 542 F.2d 1137, on remand 424 F.Supp. 105.

Where new drug application had been approved and no proceedings had been commenced by the Secretary to withdraw approval, drug manufacturer's purported withdrawal prior to day immediately preceding effective date of 1962 effectiveness amendment [set out as a note under section 321 of this title] to this chapter was ineffective for purpose of determining whether drugs qualified for permanent "grandfather clause" exemption from enlarged definition of a "new drug" included in amendments. *USV Pharmaceutical Corp. v. Richardson, C.A.Va. 1972*, 461 F.2d 223, affirmed 93 S.Ct. 2498, 412 U.S. 655, 37 L.Ed.2d 244.

Manufacturer, whose marketing approval for its drug was outstanding and had not been legally withdrawn on date of 1962 amendment to this chapter was not entitled to claimed benefit of section 107 of Pub.L. 87-781, set out as a note under section 321 of this title, applicable to drugs not covered by an effective marketing order on day immediately before enacting date of amendments. *Hynson, Westcott & Dunning, Inc. v. Richardson, C.A.4, 1972*, 461 F.2d 215, modified on other grounds 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

5a. Generally

While this chapter provides the Food and Drug Administration with sanctions, such as civil injunction proceedings, criminal penalties, and in rem seizure and condemnation, to enforce prohibition against sale in commerce of any article without an effective new drug application, this chapter does not create a dual system, one administrative and the other judicial. *CIBA Corp. v. Weinberger*, N.J.1973, 93 S.Ct. 2495, 412 U.S. 640, 87 L.Ed.2d 230.

Food and Drug Administration was not compelled to pursue new drug procedure in the laetrile situation in the absence of an application. *Rutherford v. U.S.*, C.A.Ok1.1976, 542 F.2d 1137, on remand 424 F.Supp. 105.

Where it was well-known that liver damage was among adverse effects on humans from prolonged use of drug, drug manufacturer, which was neither sponsor nor promoter of drug, was not liable for death of user from liver damage on theory that drug had not been properly tested for dangerous and harmful side effects it would produce. *Brick v. Barnes-Hines Pharmaceutical Co., Inc.*, D.C.D.C.1977, 428 F.Supp. 496.

5b. Offenses within section

Cancer patient's purchase of Laetrile in Mexico and subsequent transportation of that drug to Minnesota for his personal use constituted introduction of Laetrile into interstate commerce and was prohibited by this section prohibiting introduction or delivery for introduction into interstate commerce any new drug, unless approval of application by Food and Drug Administration is effective with respect to such drug; this section does not purport to apply only to manufacturers or distributors, but plainly states that "no person shall introduce or deliver for introduction into interstate commerce any new drug." *Gadler v. U.S.*, D.C.Minn.1977, 425 F.Supp. 244.

5c. Authority of Secretary

Although this section requiring Secretary of Health, Education and Welfare (now Secretary of Health and Human Services) to disapprove a new drug application if he or she finds that proposed labeling is false or misleading reflects Congress' continuing concern that drug labeling should be both truthful and complete, it cannot fairly be read to encompass authority for requiring the delivery of written material to patient at time of dispensing and these provisions, as contrasted with mislabeling provisions of this chapter, apply only at moment of shipment in interstate commerce and not to action subsequent to shipment in interstate commerce. *Pharmaceutical Mfrs. Ass'n v. Food and Drug Administration*, D.C.Del.1980, 484 F.Supp. 1179.

In deciding that phenformin hydrochloride posed an imminent hazard, Secretary was authorized to create within suspension order voluntary system of limited distribution to those small number of patients for whom it might be determined that drug's benefits outweighed its risks and was also authorized to delay implementation of order for 90 days. *Forsham v. Califano*, D.C.D.C.1977, 442 F.Supp. 203.

6. Rules and regulations

Strict and demanding standards in regulations issued under this subchapter, which standards bar anecdotal evidence indicating that doctors "believe" in efficacy of a drug, are amply justified by legislative history of its provisions. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Food and Drug Administration (FDA) may impose regulations on development of drugs but authorized regulations must be for purpose of conditioning investigational drug exemptions which will apply only to drugs intended for use by qualified experts investigating the safety and effectiveness of the drug, but regulations may not require clinical investigators to submit investigational reports directly to FDA. *U.S. v. Garfinkel*, C.A.8 (Minn.) 1994, 29 F.3d 451.

Amendment to Food and Drug Administration's over-the-counter drug review regulations, creating 12-month period for comment on temporary final monographs, which consumers alleged served only to delay implementation of Food, Drug, and Cosmetic Act's safety and efficacy requirements by further postponing publication of final monographs, was consistent with Act, and was designed to facilitate gathering of supplemental information to promote efficiency, and thus was not arbitrary, capricious or otherwise improper. *Cutler v. Hayes*, 1987, 818 F.2d 879, 260 U.S.App.D.C. 230.

Authority granted by subsec. (f) of this section allowing the Secretary of Health and Human Services to establish "other conditions relating to the protection of public health" with respect to maintaining accurate drug records is insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability. *U.S. v. Smith*, C.A.Cal.1984, 740 F.2d 734.

The fact-finding procedures employed by Food and Drug Administration in approving British drug manufacturer's new drug application and rejecting American drug manufacturer's petition urging denial of the application was adequate, since Administration followed applicable statutory and regulatory criteria for approving the application, and engaged in informal fact-finding procedures to gather evidence concerning the safety and effectiveness of the drug. *Upjohn Mfg. Co. v. Schweiker*, C.A.Mich.1982, 681 F.2d 480.

Where drug manufacturer failed to comply with this chapter and regulations governing the manufacturing, sampling and labeling of proposed new drug, new drug application could not be approved. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App. D.C. 17.

Only those studies of effectiveness of drug that meet the standards particularized in 21 C.F.R. 130.14 pertaining to adequate and well-controlled studies are acceptable in determining whether there is substantial evidence to support the claims of effectiveness for any drug. *Sterling Drug Inc. v. Weinberger*, C.A.2, 1974, 503 F.2d 675.

In rejecting evidence submitted in support of new drug application, Food and Drug Administration should make its criticisms express and detailed and cite pertinent regulations and evidentiary flaws. *Cooper Laboratories, Inc. v. Commissioners, Federal Food and Drug Administration*, 1974, 501 F.2d 772, 163 U.S.App.D.C. 212.

Under regulation pursuant to this section, as it existed prior to 1960 a drug company had the option of filing a supplemental application for a proposed change in the conditions under which such drug is to be used instead of a new drug application when a new drug application has already been approved, thereby eliminating the need to duplicate parts of the application previously approved, rather than mere option of filing a supplemental application or not. *Hoffman v. Sterling Drug, Inc.*, C.A.Pa.1973, 485 F.2d 132, on remand 374 F.Supp. 850.

Regulations whereby new drug application would not be accepted for filing if incomplete on its face by omission of required material and which called for notice to the applicant and, in later regulation, provided for requested filing over protest were reasonable and valid. *Durovic v. Richardson*, C.A.Ill.1973, 479 F.2d 242, certiorari denied 94 S.Ct. 232, 414 U.S. 944, 38 L.Ed.2d 168, rehearing denied 94 S.Ct. 611, 414 U.S. 1088, 38 L.Ed.2d 494.

Food and Drug Administration's (FDA) regulation concerning waiver of in vivo bioequivalence testing for approval of generic drugs in certain circumstances did not exceed FDA's authority under Hatch-Waxman Amendments which govern FDA's approval of applications for generic versions of pioneer drugs, where FDA regulation did not attempt to waive bioequivalence determinations but, rather, regulation permitted waiver of discrete, specific form of in vivo testing for those categories of drugs where in vivo bioavailability or bioequivalence of drug product could be considered self-evident based on other data. *Federal Food, Drug, and Cosmetic Act*, § 505(j)(7)(B), as amended, 21 U.S.C.A. § 355(j)(7)(B). *Fisons Corp. v. Shalala*, D.D.C. 1994, 860 F.Supp. 859.

It is not a crime for protocol investigators to fail to maintain adequate and accurate records; although statute expressly authorizes promulgation of regulations requiring drug manufacturers or sponsors of clinical investigations to maintain and submit reports setting forth the results of clinical tests involving experimental drugs to Food and Drug Administration (FDA), statute's general regulatory authority is insufficient legislative guidance for issuance of regulations which, if violated, would furnish basis for criminal liability. *U.S. v. Garfinkel*, D.Minn.1993, 822 F.Supp. 1457.

Regulation promulgated by the Food and Drug Administration (FDA), which interpreted "feasibility" exception to statutory prohibition against administration of unapproved drugs to permit administration of such drugs in specific combat circumstances, was not arbitrary, capricious, or manifestly contrary to statute. *Doe v. Sullivan*, D.D.C.1991, 756 F.Supp. 12; affirmed 938 F.2d 1370, 291 U.S.App.D.C. 111.

Regulations adopted by the Food and Drug Administration for policing the nation's over-the-

counter drug market were unlawful to the extent that they affirmatively sanctioned continued marketing of Category III drugs in the absence of an administrative determination that the products were generally recognized by experts as safe and effective. *Cutler v. Kennedy*, D.C.D.C.1979, 475 F.Supp. 888.

While Food and Drug Administration is to be given administrative flexibility to make regulations and determine new drug status of individual drugs or classes of drugs, argument that Food and Drug Administration lacks administrative resources to insure compliance with this section, cannot be permitted to postpone to some indefinite future date implementation of required preclearance approval of new drug applications. *Hoffmann-LaRoche, Inc. v. Weinberger*, D.C.D.C.1975, 425 F.Supp. 890.

The Food and Drug Administration does not have unbridled discretion to do what it pleases in determining whether product is a "new drug" since its procedures must satisfy the rudiments of fair play. *National Ethical Pharmaceutical Ass'n v. Weinberger*, D.C.S.C.1973, 365 F.Supp. 735, affirmed 503 F.2d 1051.

6a. Application; cancellation of

Where new drug application applicant fails to produce adequate and well-controlled studies showing efficacy, summary disposition of application is authorized. *Cooper Laboratories, Inc. v. Commissioner, Federal Food and Drug Administration*, 1974, 501 F.2d 772, 163 U.S.App. D.C. 212.

While an applicant for approval to market a new drug may withdraw his application during pendency thereof, he has no such right after approval of the application by the Secretary; at that point only the Secretary can withdraw the approval. *USV Pharmaceutical Corp. v. Richardson*, C.A.Va.1972, 461 F.2d 223, affirmed 93 S.Ct. 2498, 412 U.S. 655, 37 L.Ed.2d 244.

Criteria which were used by Secretary of Health, Education, and Welfare in deciding to suspend new drug applications for phenformin hydrochloride on ground that drug posed an "imminent hazard" did not improperly reflect intent of Congress nor were they at substantial variance with Food and Drug Administration regulation. *Forsham v. Califano*, D.C.D.C.1977, 442 F.Supp. 203.

Under this section authorizing Secretary of Health, Education, and Welfare to suspend new drug application for a drug which poses an "imminent hazard," meaning of "imminent hazard" is not to be restricted to a concept of crisis. *Forsham v. Califano*, D.C.D.C.1977, 442 F.Supp. 203.

6b. Exhaustion of remedies

Failure of consumers of over-the-counter drugs to exhaust their administrative remedies before challenging Food and Drug Administration's regulations implementing Food, Drug and Cosmetic Act program concerning new over-the-counter drugs did not require dismissal of action in view of Food and Drug Administration's waiver of issue by failing to raise objection and futility of pursuing administrative remedies. *Cutler v. Hayes*, 1987, 818 F.2d 879, 260 U.S.App.D.C. 230.

When Food and Drug Administration has primary jurisdiction to determine status of product, one seeking to contest agency's determination must exhaust all administrative remedies before seeking judicial review. *Biotech Research Corp. v. Heckler*, C.A.Nev.1983, 710 F.2d 1375.

Food and Drug Administration and California State Department of Health Services had primary jurisdiction to determine whether persons could traffic in new drug; thus, if plaintiff wished to obtain Laetrile to use in the nutritional program for prevention of cancer, he had to exhaust his administrative remedies prior to seeking judicial relief. *Carnohan v. U.S.*, C.A.Cal.1980, 616 F.2d 1120.

Alleged statements by Food and Drug Administration (FDA) employees that they intended to waive bioequivalence testing for certain abbreviated new drug applications and that they intended to treat impurity analysis for generic drugs differently were not final agency actions and, therefore, could not be challenged under Administrative Procedure Act. *Fisons Corp. v. Shalala*, D.D.C.1994, 860 F.Supp. 859.

Soap manufacturer was required to exhaust his administrative remedies with Food and Drug Administration regarding to determination of whether soap was "safe and effective" for particular purpose for which it had already been marketed, and whether it was therefore not subject to new drug hearings. *Farquhar v. Food and Drug Admin.*, D.C.D.C.1985, 616 F.Supp. 190.

Drug manufacturer which marketed drug under trademark and which filed pioneer new drug application for that drug could maintain action challenging Food and Drug Administration's approval of new drug application to British manufacturer and distributor of drug called "ibuprofen," even though manufacturer had not exhausted its administrative remedies where, to obtain withdrawal of British manufacturer's application, manufacturer would have to show that drug was not safe or not effective and that avenue would have been fruitless. *Upjohn Mfg. Co. v. Schweiker*, D.C.Mich.1981, 620 F.Supp. 58, affirmed 681 F.2d 480.

Where substantive questions as refined in proceedings required decision as to whether Finkel memorandum to effect that Food and Drug Administration would approve post-1962 duplicate new drug applications in reliance on published reports without fresh clinical investigations or available raw data should be issued as a rule or as a general statement of policy, exempt from notice and comment requirement, questions should have been confronted squarely and decided by the Food and Drug Administration before judicial review was sought and, thus, case would be dismissed for failure to exhaust administrative remedies. *Hoffmann-La Roche, Inc. v. Harris*, D.C.D.C.1979, 484 F.Supp. 58.

District court's assertion of jurisdiction over action for determination as to whether drug was a "new drug" would be premature prior to refusal of Food and Drug Administration to issue declaratory order *Carolina Brown, Inc. v. Weinberger*, D.C.S.C.1973, 365 F.Supp. 310.

6c. Reapplication

Unless pharmaceutical manufacturer can show that its drug product is generally recognized, among experts qualified by scientific training and experience to evaluate safety and effectiveness of drugs, as safe and effective for use under conditions prescribed and that, being so recognized, it has been used to material extent or for material time under such conditions, manufacturer must file with Food and Drug Administration a new drug application and establish by substantial evidence to satisfaction of Food and Drug Administration that drug is safe and effective for its intended uses. *Premo Pharmaceutical Laboratories, Inc. v. U.S.*, C.A.N.Y.1980, 629 F.2d 795.

Food and Drug Administration acted reasonably in interpreting term "drug" as used in provisions of Federal Food, Drug and Cosmetic Act requiring information to be filed on "any patent which claims the drug for which the applicant submitted the application," to mean "drug product" for which new drug application was filed. *Pfizer, Inc. v. Food and Drug Admin.*, D.Md.1990, 753 F.Supp. 171.

7. Necessity of approval

Durovic v. Richardson, 327 F.Supp. 386, [main volume] affirmed 479 F.2d 242, certiorari denied 94 S.Ct. 232, 414 U.S. 944, 38 L.Ed.2d 168, rehearing denied 94 S.Ct. 611, 414 U.S. 1088, 38 L.Ed.2d 494.

Drug that had same active ingredient as Food and Drug Administration-approved drug product, which had been marketed for many years, but which had different inactive ingredients, could not be marketed without obtaining approval of new drug application from Food and Drug Administration, where it was not generally recognized among qualified experts as safe and effective for use under conditions stated in labeling, there was no published scientific literature as to drug to enable qualified experts to make necessary determination, experts had sharp differences of opinion, both as to methods used and results claimed, and, although manufacturer had sold 16,500,000 tablets there was no evidence that drug had been used to material extent or for any substantial period of time. *Premo Pharmaceutical Laboratories, Inc. v. U.S.*, C.A.N.Y. 1980, 629 F.2d 795.

Constitutional rights of privacy and personal liberty do not give individuals the right to obtain Laetrile free of lawful exercise of government police power. *Carnohan v. U.S.*, C.A.Cal.1980, 616 F.2d 1120.

Regional compounding centers which performed same function that doctors would otherwise have performed by taking chemotherapeutic drugs approved by the FDA and diluting and repackaging them into single-dosage units ready to be used by patients did not fall within the "repackaging" or "bioequivalent product" exceptions to federal premarketing approval requirements. *U.S. v. Baxter Healthcare Corp.*, N.D.Ill.1989, 712 F.Supp. 1352.

New drug approval requirement applies to patients or users of a new drug as well as to manufacturers of it. *Duncan v. U.S.*, D.C.Okl. 1984, 590 F.Supp. 39.

Options available to Food and Drug Administration such as good manufacturing practice regulations and section 351 of this title did not adequately protect the public so as to obviate need for preclearance, as "new drugs", generic drugs having the same active ingredients and in some cases the same inactive ingredients as in their FDA-approved pioneer counterparts. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, D.C.N.J.1981, 511 F.Supp. 958.

Food and Drug Administration's policy of permitting new drugs that were chemically equivalent to pioneer drug for which full new drug application was in effect to be marketed without approved new drug application contravened clear statutory requirement of preclearance, was not within intentment of 1962 amendments to this section and legislative scheme they embody, and, by permitting marketing of large classes of such drugs, violated its own regulations. *Hoffmann-La Roche, Inc. v. Weinberger*, D.C.D.C. 1975, 425 F.Supp. 890.

Manufacturer of drug called "PAX," which was a "new drug" within the meaning of this section, would be preliminarily enjoined from introducing and delivering such drug into interstate commerce from foreign trade zone unless and until approval of an application filed pursuant to this section was effective with respect to such drug. *U.S. v. Yaron Laboratories, Inc.*, D.C.Cal.1972, 365 F.Supp. 917.

7a. Exemptions

Phrase "any drug," in "grandfather clause" of Drug Amendments of 1962, set out as a note under section 321 of this title, which exempts from effectiveness requirements any drug which on date preceding enactment was commercially used or sold in the United States, was not a "new drug" as defined in this chapter as originally enacted, and was not covered by an effective application for a new drug under this chapter as originally enacted, is used in the generic sense, so that "me-toos," those drugs similar or identical to drugs with effective new drug applications, whether products of same or different manufacturers "covered" by an effective new drug application, are not exempt from efficacy requirements. *USV Pharmaceutical Corp. v. Weinberger*, Va.1973, 93 S.Ct. 2498, 412 U.S. 640, 37 L.Ed.2d 230.

Exemption under the "grandfather clause" of the Drug Amendments of 1962, set out as a note under section 321 of this title, is afforded only for drugs that never had been subject to new drug regulation. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Food and Drug Administration (FDA) is required to promulgate regulations allowing for exemptions from operation of new drug application process which will apply only to drugs intended solely for investigational use, by experts to investigate safety and effectiveness of

drugs, and those exemptions must be conditioned on imposition of informed-consent provisions on manufacturers or sponsors. *U.S. v. Garfinkel*, C.A.8 (Minn.) 1994, 29 F.3d 451.

As an exemption to a comprehensive regulatory statute concerned with public safety, grandfather clause of 1962 amendments to this subchapter is to be strictly construed, and party seeking to grandfather in pre-1962 drug bears burden of proof as to each condition. *U.S. v. Articles of Drug Consisting of following: 5,906 Boxes, C.A.Puerto Rico 1984, 745 F.2d 105, certiorari denied 105 S.Ct. 1358, 470 U.S. 1004, 84 L.Ed.2d 379.*

Grandfather clause exempting certain drugs from requirement under this chapter of providing effectiveness makes no distinction between pioneer and "me-too" drugs but exempts only that generic class of drugs which on October 9, 1962, were not covered by an effective new drug application. *Smithkline Corp. v. Food and Drug Administration*, 1978, 587 F.2d 1107, 190 U.S.App.D.C. 210.

Where there was similarity in formula between drug marketer's citrus bioflavonoid drugs subject to new drug applications and its "me-too" drugs, both the NDA'd and the "me-too" drugs would be treated alike and neither could qualify for exemption under the "grandfather clause" from 1962 effectiveness amendment [set out as a note under section 321 of this title] to this chapter. *USV Pharmaceutical Corp. v. Richardson*, C.A.Va.1972, 461 F.2d 223, affirmed 93 S.Ct. 2498, 412 U.S. 655, 37 L.Ed.2d 244.

In light of health risks associated with estrogenic drug products, drug product which was fixed combination of three unconjugated estrogens was not apt subject for exemption from requirement that expert consensus as to general recognition of the product's safety and effectiveness be founded upon substantial evidence in order for the product to transcend "new drug" status. *U.S. v. Articles of Drug . . . HORMONIN*, D.C.N.J.1980, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.

Practice of pharmacy exemption from sanctions of this chapter was not applicable where corporation disseminated information to solicit applications for membership in its organization and, as a result of such memberships, prescriptions for its products were referred to single pharmacy that specialized in compounding the drug. *U.S. v. Sene X Eleemosynary Corp., Inc.*, D.C.Fla.1979, 479 F.Supp. 970.

Where there had been no completed tests or investigations to determine either the efficacy or safety of animal drugs, they were never generally recognized as safe and effective for the uses intended, and thus "grandfather clause" exemption from the effectiveness requirement of this section was not applicable. *U.S. v. 14 Cases More or Less, "Naremc Medi-Matic Free Choice Poultry Formula"*, D.C.Mo.1974, 374 F.Supp. 922.

7b. Defenses

Producer and distributor of nutritional, personal care and related products, and its officers and employees, all of whom were prosecuted for

allegedly "misbranding" drug could not complain that drug was improperly classified as prescription drug where they did not avail themselves of procedures to make its arguments before appropriate agency and waited until they had been prosecuted to make arguments in district court. *U.S. v. General Nutrition, Inc.*, W.D.N.Y.1986, 638 F.Supp. 566.

Cancer patient's right to privacy would not protect his importation for personal use of new drug Laetrile in violation of this section prohibiting introduction into interstate commerce of any new drug unless approval of application by Food and Drug Administration is effective with respect to such drug. *Gadler v. U.S.*, D.C.Minn. 1977, 425 F.Supp. 244.

8. Interstate commerce

In order for a court properly to condemn a drug item, a nexus must be shown between drug item and commerce so as to invoke federal jurisdiction; on the one hand, in a case in which a drug is found to be misbranded, it may be condemned when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce; on the other hand, if a drug is confiscated because it is an unapproved "new drug," it must be shown to have been introduced or delivered for introduction in interstate commerce before it may be condemned. *U.S. v. Articles of Drug, C.A.Pa.* 1978, 585 F.2d 575.

A drug is "in interstate commerce" for purposes of this section, if one of its components previously traveled in interstate commerce, and if finished drug itself is destined in ordinary course of business for interstate distribution; therefore, since ingredients of drugs seized from pharmaceutical laboratory traveled in interstate commerce, were manufactured in usual course of laboratory's business, and were intended for interstate distribution, there was sufficient nexus with interstate commerce to justify their seizure. *U.S. v. Articles of Drug . . . WANS, D.C. Puerto Rico* 1981, 526 F.Supp. 703.

Within subsec. (a) of this section, "into interstate commerce" necessarily encompasses introduction of items into flow of shipments and transportation within United States, even if the final destination of the drug is not within the United States. *U.S. v. An Article of Drug Consisting of 197 Boxes, More or Less, each Containing 150 Capsules, D.C.Tex.*1981, 520 F.Supp. 467.

9. New drug, determination of status as

Although drug marketer in 1961 had stated in a letter to director of new drug branch of bureau of medicine in the Food and Drug Administration that a certain class of products were no longer considered to be new drugs, and marketer in 1961 had stopped filing supplemental information as required by regulation with regard to products for which new drug applications had become effective, marketer's new drug applications had not been withdrawn prior to 1962 so that its products were no longer covered by an effective application for purposes of "grandfather clause" in Drug Amendments of 1962, set out as a note under section 321 of this title. *USV Pharmaceutical Corp. v. Weinberger,*

*Va.*1973, 93 S.Ct. 2498, 412 U.S. 640, 37 L.Ed.2d 230.

Parties cannot confer jurisdiction to determine "new drug" status of a drug; only Congress can do so. *Weinberger v. Bentex Pharmaceuticals, Inc.*, S.C.1973, 93 S.Ct. 2488, 412 U.S. 645, 37 L.Ed.2d 235.

Whether a particular drug is a "new drug," so as to require an effective new drug application before it may be introduced into commerce, depends in part on expert knowledge and experience of scientists based on controlled clinical experimentation and backed by substantial support in scientific literature. *Weinberger v. Bentex Pharmaceuticals, Inc.*, S.C.1973, 93 S.Ct. 2488, 412 U.S. 645, 37 L.Ed.2d 235.

Issue whether drugs were generally recognized as safe and effective and thus not "new drugs" within this chapter and whether the drugs were exempt from new effectiveness requirements by reason of grandfather clause in the Drug Amendments of 1962, set out as a note under section 321 of this title, were kinds of issues peculiarly suited to initial determination by the Food and Drug Administration with its specialized competence and expertise, and district court's referral of these issues to the Administration was appropriate. *Weinberger v. Bentex Pharmaceuticals, Inc.*, S.C.1973, 93 S.Ct. 2488, 412 U.S. 645, 37 L.Ed.2d 235.

Food and Drug Administration has jurisdiction to determine jurisdictional question whether a particular drug is a "new drug" so as to acquire an effective new drug application before drug may be introduced into commerce. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, *Va.*1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Toothpaste manufacturer failed to show by substantial evidence that potassium nitrate made contribution to claimed effect of treating dentin hypersensitivity and could not rely solely upon laboratory testing profiles for toothpastes with single active ingredient of sodium MFP to prove anticaries effectiveness; therefore, toothpaste combining sodium MFP and potassium nitrate was "new drug" for which application had to be filed and approved before marketing. *U.S. v. Articles of Drug, C.A.7 (Ill.)* 1987, 826 F.2d 564.

Food and Drug Administration memorandum, concerning approval of new drug applications for generic versions of drugs first marketed after 1962 that are based on reports in the scientific literature to establish the drug's safety and effectiveness, was consistent with published regulations of the Administration; the memo did not conflict with regulation requiring an applicant to submit reports of all clinical tests sponsored or received by the applicant, nor did it conflict with regulation stating that certain summaries of safety and effectiveness data do not constitute full reports of investigations. *Burroughs Wellcome Co. v. Schweiker*, C.A.N.C.1981, 649 F.2d 221.

Requirements of "new drug" section of this chapter, namely, general safety and effectiveness recognition, were met once the Government admitted that all of manufacturer's drugs were the same generically as a drug already approved as safe and effective and it was not necessary,

therefore, for the Government to perform bioavailability, bioequivalence, and other qualified controlled tests to establish safety and efficacy. *U.S. v. Articles of Drug, C.A.Pa.*1978, 585 F.2d 575.

Acceptance by the Federal Trade Commission of the Food and Drug Administration determination that drug used by weight reducing clinic was a new drug when used for the treatment of obesity, and thus that the fact should be disclosed to consumers, was supported by substantial evidence and was reasonable. *Simeon Management Corp. v. F.T.C., C.A.9, 1978, 579 F.2d 1137.*

Although substantial evidence of effectiveness for the labeled use is required for a drug to be generally recognized as effective, such substantial evidence may exist long before the drug is generally recognized as effective for that use; approval of a new drug application does not, alone, remove the approved drug from new drug status. *Simeon Management Corp. v. F.T.C., C.A.9, 1978, 579 F.2d 1137.*

In the absence of evidence as to how laetrile was marketed before passage of 1962 amendment to this chapter requiring drugs to be recognized as effective, court could not determine whether drug was subject to the new requirement or was grandfathered in. *Rutherford v. U.S., C.A.Okla.*1976, 542 F.2d 1137, on remand 424 F.Supp. 105.

"New drug" for purposes of this section is a substance which is generally recognized by scientific experts as safe and effective for use under the conditions prescribed or suggested in the labeling thereof unless, prior to 1962, it was subject to the requirements of the Food and Drugs Act of 1906, Act June 30, 1906, Ch. 3915, 34 Stat. 768. *Rutherford v. U.S., C.A.Okla.*1976, 542 F.2d 1137, on remand 424 F.Supp. 105.

Fact that label contained a contraindication of use in cases of "known or suspected malignancies" did not preclude consideration of danger of activation of latent cancer of prostate in determining whether drug marketed by claimant was a new drug within this subchapter especially in light of evidence that in four out of five cases a patient may have latent cancer of the prostate though not known or suspected. *U.S. v. 1,048,000 Capsules, More or Less, "Afronex," C.A.Tex.*1974, 494 F.2d 1158.

The newness of a drug within meaning of provision of this section relating to introduction into interstate commerce of any "new drug" may arise by reason of a new or different recommended use for the drug even though the same drug may not be a "new drug" when used for another disease. *Hoffman v. Sterling Drug, Inc., C.A.Pa.*1973, 485 F.2d 132, on remand 374 F.Supp. 850.

Affidavits in declaratory judgment action established that drug intended for use in management of malignant tumors had not, either before or after the Drug Amendments of 1962, set out as note under section 321 of this title, achieved general recognition among qualified experts as safe and effective for such use, so as to be exempt from requirement of new drug application. *Durovic v. Richardson, C.A.Ill.*1973, 479 F.2d 242, certiorari denied 94 S.Ct. 232, 414 U.S.

944, 38 L.Ed.2d 168, rehearing denied 94 S.Ct. 611, 414 U.S. 1088, 38 L.Ed.2d 494.

Where drug was offered for use in the management of malignant tumors, "grandfather clause" in the Drug Amendments of 1962, set out as note under section 321 of this title, had no effect on it, in determining whether a new drug application was required. *Durovic v. Richardson, C.A.Ill.*1973, 479 F.2d 242, certiorari denied 94 S.Ct. 232, 414 U.S. 944, 38 L.Ed.2d 168, rehearing denied 94 S.Ct. 611, 414 U.S. 1088, 38 L.Ed.2d 494.

Drug is a "new drug," and thus is subject to seizure if shipped in interstate commerce without prior approval of a new drug application, unless it is presently regarded by qualified experts as both safe and effective for its intended use or unless it was generally regarded by qualified experts on the October 9, 1962, effective date of the "grandfather clause" exemption as safe for intended use. *U.S. v. An Article of Drug * * * "Bentex Ulcerine," C.A.Tex.*1972, 469 F.2d 875, certiorari denied 93 S.Ct. 2772, 412 U.S. 938, 37 L.Ed.2d 397.

Fact that pre-1962 new drug application drugs became generally recognized as safe on or before effective date of 1962 effectiveness amendments [set out as a note under section 321 of this title] to this chapter did not establish that such drugs were no longer covered by an effective new drug application and, thus, exempt, under the permanent "grandfather clause", from the amendment. *USV Pharmaceutical Corp. v. Richardson, C.A.Va.*1972, 461 F.2d 223, affirmed 93 S.Ct. 2498, 412 U.S. 655, 37 L.Ed.2d 244.

Hair care products which were intended to prevent or cure baldness or thinning hair and which had not been generally recognized as safe and effective for their intended use were "new drugs" and, as such, were subject to regulation by Food and Drug Administration (FDA). *U.S. v. Kasz Enterprises, Inc., D.R.I.*1994, 855 F.Supp. 534.

Before a product can be exempted from statutory new drug preclearance procedures it must be generally recognized by qualified experts as safe and effective for its intended use, and "general recognition" requirement does not involve actual safety or effectiveness of product, rather it is product's reputation in scientific community that is relevant. *U.S. v. 225 Cartons, More or Less, of an Article of Drug, D.N.J.*1988, 687 F.Supp. 946.

Drug manufacturer's application for approval of oral dosage of injectable calcium product, even if properly termed "paper" new drug application or abbreviated new drug application, was not subject to competing manufacturer's exclusivity rights where former's application did not refer to latter's oral product or to any investigations which were conducted by or for the latter; hence, effective date of approval of former's application was not delayed by 1984 amendments to Federal Food, Drug, and Cosmetic Act. *Burroughs Wellcome Co. v. Bowen, E.D.N.C.* 1986, 630 F.Supp. 787.

Government can prove lack of "general recognition" of drug as safe and effective for recommended uses so as to require filing of new drug application by proving absence of material fact as to any of following issues: general recogni-

tion in fact among nation's experts that seized drugs are safe and effective for intended use, existence of adequate and well-controlled studies which constitute substantial evidence of safety and effectiveness required for approval of new drug application, and generally available scientific literature substantiating expert consensus of safety and effectiveness. *U.S. v. Articles of Drug*, N.D.Ill.1985, 624 F.Supp. 776, affirmed 828 F.2d 564.

Food and Drug Administration Compliance Policy Guide did not bar enforcement action against manufacturer of toothpaste grounded on its introduction into interstate commerce without approved new drug application where language of Guide at issue was not statement of policy or interpretation constituting advisory opinion and where Guide discussed action to be taken by Food and Drug Administration personnel only and did not purport to address behavior by anyone outside Administration. *U.S. v. Articles of Drug . . . Promise Toothpaste for Sensitive Teeth*, D.C.Ill.1984, 594 F.Supp. 211.

Generic drugs manufactured without submission to and approval by Food and Drug Administration of a new-drug application or abbreviated new-drug application were "new drugs" for purpose of application requirement where although active ingredients and in some cases inactive ingredients as well were the same as those in FDA-approved, pioneer counterparts there, was expert testimony that such drugs were not generally recognized among qualified experts as safe and effective and even assuming identity of ingredients quantitatively and qualitatively, there were potentially significant differences in manufacturing processes between the generic and pioneer products. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, D.C.N.J. 1981, 511 F.Supp. 958.

Pharmaceutical manufacturer is not permitted to substitute its judgment as to whether drug product is "new drug" for that of Food and Drug Administration, nor is the court required to develop its own body of scientific knowledge in substitution for the Administration. *U.S. v. Articles of Drug . . . HORMONIN*, D.C.N.J. 1980, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.

Decision as to whether drug X-Otag Plus shipped by defendants in interstate commerce was a "new drug" and subject to requisite approval before being held for sale in interstate market was to be made by Food and Drug Administration, as agency entrusted by Congress with necessary expertise to make well-informed decisions on issue, and was not a decision which was within jurisdiction of district court in enforcement and injunction proceedings brought against defendants by United States. *U.S. v. X-Otag Plus Tablets*, D.C.Colo.1977, 441 F.Supp. 106, affirmed in part, remanded in part on other grounds 602 F.2d 1387.

Plaintiff who was dying from cancer of the pancreas and who sought to enjoin the Food and Drug Administration from preventing importation or interstate transportation of Laetrile for purposes of his own consumption raised statutory questions as to classification of Laetrile as a "new drug" sufficiently serious to make them

fair grounds for litigation. *Rizzo v. U.S.*, D.C.N.Y.1977, 432 F.Supp. 356.

Food and Drug Administration does not have unbridled discretion to do what it pleases in determining whether a product is a new drug, and its procedures must satisfy rudiments of fair play. *Rutherford v. U.S.*, D.C.Ok.1977, 429 F.Supp. 506.

Where shelf life of drug had been exceeded and, beyond the Food and Drug Administration approved shelf life, it was a drug of unknown effectiveness, it was, in effect, a "new drug" without Administration approval and had to be presumed dangerous. *Blanton v. U.S.*, D.C.D.C. 1977, 428 F.Supp. 360.

Food and Drug Administration has complete authority to determine which drugs are "new" and require an approved new drug application in order to be sold to the public. *U.S. v. Marcen Laboratories, Inc.*, D.C.N.Y.1976, 416 F.Supp. 453, affirmed 556 F.2d 562.

Kit designed for use for performing in home, "preliminary screening test" by which human female may obtain indication of probability that she is or is not pregnant was not "drug" within meaning of this section requiring that "new drug" may be marketed in interstate commerce without first filing "new drug application." *U.S. v. Article of Drug—OVA II*, D.C.N.J.1975, 414 F.Supp. 660, affirmed, 535 F.2d 1248.

The actual safety or efficacy of a drug is irrelevant as to whether its safety and efficacy is generally recognized among qualified experts, and an announcement by the Food and Drug Administration or any other person as to the actual effectiveness of a drug is not determinative, and is irrelevant, to the ultimate issue of whether a drug is a "new drug." *National Ethical Pharmaceutical Ass'n v. Weinberger*, D.C.S.C.1973, 365 F.Supp. 735, affirmed 503 F.2d 1051.

In determining whether a drug is "new drug" there must be determination of whether drug has mastered the requisite scientifically reliable evidence of safety and effectiveness before they are in position to drop out of active regulation by ceasing to be "new drug." *National Ethical Pharmaceutical Ass'n v. Weinberger*, D.C.S.C. 1973, 365 F.Supp. 735, affirmed 503 F.2d 1051.

Where drug which consisted of 14 mgs. of chemical ingredient 9-aminoacridine hydrochloride and binder of 14 mgs. of polyvinylpyrrolidone and which was marketed as prescription drug for alleviation of various vaginal infections had much larger dosage than used in other aminoacridine medication for vaginal infections, was in tampon form rather than gel tablet and cream form, and had binder, drug was "new drug" and not exempt from seizure based on claim of misbranding. *U.S. v. Article of Drug "Mykoert"*, D.C.Ill.1972, 345 F.Supp. 571.

9a. Components

Federal Trade Commission order purporting to remedy wrongs which Commission has found not to have been committed should be set aside, but portion of its order applying to "unusual or special ingredient representations" for all of plaintiff's over-the-counter drugs was reasonably related to violation made by misrepresenting that plaintiff's analgesics did not contain aspirin.

Bristol-Myers Co. v. F.T.C., C.A.2, 1984, 738 F.2d 554, certiorari denied 105 S.Ct. 960, 469 U.S. 1189, 83 L.Ed.2d 966.

Before two or more drugs may be recombined in single product, manufacturer must demonstrate by adequate and well-controlled investigations that each additional component provides specific benefit to patient that warrants increased risk. *U.S. v. 225 Cartons, More or Less, of an Article of Drug*, D.N.J.1983, 687 F.Supp. 946.

With respect to combination drug, it must be demonstrated that the combination of ingredients is generally recognized as safe and effective in order for the drug to transcend "new drug" status. *U.S. v. Articles of Drug . . . HORMONIN*, D.C.N.J.1980, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.

Although each of the components of a drug may be generally recognized as safe and effective, a new drug is created when they are combined together in a new and different formulation. *U.S. v. An Article of Drug Labeled "Entrol-C Medicated"*, D.C.Cal.1973, 362 F.Supp. 424, affirmed 513 F.2d 1127.

9b. Exclusive marketing period

A new drug developer's interpretation of the phrase "active ingredient (including any ester or salt of the active ingredient)" as permitting a drug company to obtain an extended period of market exclusivity for the new drug by applying for an approval of the acid first, followed by the salt, but not under the reverse sequence, was not a reasonable interpretation of the statute giving developers of new drugs a specified period of market exclusivity. *Abbott Laboratories v. Young*, 1990, 920 F.2d 984, 287 U.S.App.D.C. 190, certiorari denied 112 S.Ct. 76, 116 L.Ed.2d 49.

Generic manufacturer of drug products containing controlled released propranolol HCl, which had filed abbreviated new drug application, was entitled to 180 days of exclusivity from date of first commercial marketing of manufacturer's product, even though relevant patent holder chose not to sue manufacturer for patent infringement. *Inwood Laboratories, Inc. v. Young*, D.D.C.1989, 723 F.Supp. 1523.

Federal Food, Drug, and Cosmetic Act, § 505(j)(4)(D)(ii), as amended, 21 U.S.C.A. § 355(j)(4)(D)(ii), establishing five-year exclusive marketing period following approval of new drug application for nonantibiotic drug in which no abbreviated new drug application may be filed to market generic version of such drug did not apply to provide manufacturer of new antibiotic drug with exclusive marketing period during which Food and Drug Administration could not approve competitor's generic version of pioneer antibiotic drug, particularly where Congress had refused to amend language of provision pertaining to approval of antibiotic drugs [Federal Food, Drug, and Cosmetic Act, § 507, as amended, 21 U.S.C.A. § 357] to create similar exclusivity period. *Glaxo, Inc. v. Heckler*, D.C.N.C. 1985, 623 F.Supp. 69.

9c. Active ingredient

In the context of a statute that gave developers of new drugs a specified period of market

exclusivity depending primarily on pharmaceutical novelty, the phrase "active ingredient (including any ester or salt of the active ingredient)" was ambiguous, as the phrase could refer to either the active ingredient of the original approved drug or to the active ingredient in the new drug. *Abbott Laboratories v. Young*, 1990, 920 F.2d 984, 287 U.S.App.D.C. 190, certiorari denied 112 S.Ct. 76, 116 L.Ed.2d 49.

12. Submission of investigative reports

Claimant failed to demonstrate that the Food and Drug Administration committed a clear error of judgment or acted arbitrarily and capriciously in denying claimant's request for relabeling of medical device known as "Diapulse" device, in light of the FDA's thorough examination of claimant's supporting documents and characterization of studies as either concerning basic biological phenomena which offered little more than encouragement for follow-up studies, studies with animals which were only indicative as to efficacy of device, studies in humans concerning medical conditions differing from those proposed by claimant, and studies conducted with devices substantially different from "Diapulse." *U.S. v. An Article of Device . . . Diapulse*, C.A.7 (Ill.) 1985, 768 F.2d 826.

For purpose of determining whether a new drug is effective, substantial evidence consisting of well-controlled scientific testing is required and isolated case reports, random experience and reports lacking details needed to permit scientific evaluation are not to be considered. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

Substantial evidence supported finding of the Commissioner, made in connection with refusal to approve new drug application, that studies submitted by drug manufacturer to prove the efficacy of new drug were replete with inaccuracies and ambiguities and lacked protocol and statistical analysis and that, therefore, the studies were not "adequate and well controlled" within the meaning of this section and did not establish the efficacy of the new drug. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

Studies conducted on manufacturer's old formulation of Fiorinal with Codeine were not well-controlled clinical investigations of products using manufacturer's new formulation in which phenacetin was replaced with increased dosages of aspirin, and thus extrapolation of data derived from studies of old formulation could not be used to obviate need for new drug application for new formulation; manufacturer did not submit any data to indicate bioequivalence of new formulation with old formulation. *U.S. v. 225 Cartons, More or Less, of an Article of Drug*, D.N.J.1983, 687 F.Supp. 946.

In determining validity of approval of duplicate new drug application, law does not require any single study, viewed in isolation, to provide total support for Food and Drug Administration's action, but rather, record must be viewed as whole, taking into account cumulative and reinforcing nature of evidence. *Upjohn Mfg.*

Co. v. Schweiker, D.C.Mich.1981, 520 F.Supp. 58, affirmed 681 F.2d 480.

In determining whether allegedly misbranded drug came under grandfather clause exemption from requirement of "effectiveness," court could properly consider reprints of professional medical studies of the drug published by doctors in medical journals, and "dear doctor" letters printed by claimant which were distributed to physicians in promoting the sale of the drug. U.S. v. 1,048,000 Capsules, More or Less, "Afroder," D.C.Tex.1972, 847 F.Supp. 768, affirmed 494 F.2d 1168.

13. Testing of drugs

Commissioner of Food and Drug Administration did not err in requiring drug manufacturers to show that their oral proteolytic enzymes were therapeutically effective in order to satisfy requirement for FDA approval that drugs be effective by showing of clinical, rather than merely statistical, significance. Warner-Lambert Co. v. Heckler, C.A.3, 1986, 787 F.2d 147.

Dismissal without prejudice of post-office proceeding against manufacturer of hair and scalp products did not collaterally estop Food and Drug Administration from denying efficacy of the treatment, since issue in post-office case concerned accuracy of advertising while issue before Food and Drug Administration was whether data submitted constituted adequate and well-controlled studies, and since dismissals without prejudice do not constitute a final determination. Brandenfels v. Heckler, C.A.9, 1983, 716 F.2d 558.

Under this chapter, before a new drug intended for human use can be marketed in interstate commerce, the drug must be clinically tested to establish that it is both safe and effective. Edison Pharmaceutical Co., Inc. v. Food and Drug Administration, Dept. of Health, Ed., and Welfare, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

In proceeding on new drug application, substantial evidence supported conclusion of the Commissioner that, though it might be unethical to conduct such a study comparing two groups of cardiac patients, double-blind controlled testings of the new drug and one of its components could ethically be performed on noncardiac patients and that such testing was necessary before the drug could be administered to cardiac patients. Edison Pharmaceutical Co., Inc. v. Food and Drug Administration, Dept. of Health, Ed., and Welfare, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

That multiinvestigator clinical trials testing effectiveness of combination drug which contained Dexedrine and amobarbital and which was labelled for use with obese patients involved subjects who were anxious, obese patients so that trials provided no assurance that Dexedrine, in amounts contained in drug, produced in nonanxious, obese patients side effects capable of being remedied by amobarbital did not render trials deficient under Food and Drug regulation requiring suitability of subjects so as to authorize summary, denial of new drug application in that present labeling of drug could be altered to recommend use with anxious, obese patients. Smithkline Corp. v. Food and Drug Administration, 1978, 587 F.2d 1107, 190 U.S.App.D.C. 210.

Regulation promulgated by Food and Drug Administration with respect to "new drugs" indicates that newness is a function of the novelty of a particular formulation, including the novel composition, combination, dosage, or administration and, though regulation extends so far as to encompass new uses for a drug or new methods of application, it does not encompass a scope so broad as to require bioavailability and bioequivalence tests once a drug is established as being the same generically as a drug already approved safe and effective. U.S. v. Articles of Drug, C.A.Pa.1978, 585 F.2d 576.

Even if reliance on a single well-known active ingredient like gentian violet lowered test for general recognition of efficacy and safety, animal drugs and food additive, which government sought to condemn, could not be properly deemed to be generally recognized as safe or effective, in absence of any adequate, well controlled, completed test of safety or efficacy of these combinations. U.S. v. Articles of Food and Drug Consisting of Coli-Trol 80, F4C-60 Feed Grade, Entrol-S Medicated, Entrol-P, C.A.Ga.1975, 518 F.2d 743.

That pain is difficult, or even impossible, to measure quantitatively does not entail infeasibility of controlled tests for determining drug's efficacy so as to establish grounds for waiver of regulations requiring efficacy of drug to be established by controlled investigation. Cooper Laboratories, Inc. v. Commissioner, Federal Food and Drug Administration, 1974, 501 F.2d 772, 163 U.S.App.D.C. 212.

Where drug manufacturer's submission did not set forth clearly and concisely the specific provision or provisions in regulations which were inapplicable to research dealing with drug's efficacy and did not specify or define alternative procedures which should be used to test drug's efficacy, neither Food and Drug Administration nor court could waive regulations requiring that efficacy of drug be established by controlled investigation. Cooper Laboratories, Inc. v. Commissioner, Federal Food and Drug Administration, 1974, 501 F.2d 772, 163 U.S.App.D.C. 212.

That causal connection between chloroquine phosphate and chloroquine retinopathy was not even suspected in the long term use by humans of the drug at the time manufacturers tested the drug would not relieve them of negligence in failing to conduct animal studies to show the connection between the drug and the disease. Hoffman v. Sterling Drug, Inc., C.A.Pa.1973, 485 F.2d 182, on remand 374 F.Supp. 850.

The safety and efficacy of combination drug involved in misbranding action cannot be equated with the safety of the components separately or in combination with different ingredients; the fact that one individual component of combination drug may be generally recognized as safe and effective is not relevant to the issue whether the combination itself is so recognized. U.S. v. 1,048,000 Capsules, More or Less, D.C.Tex.1972, 347 F.Supp. 768, affirmed 494 F.2d 1168.

Raw manufacturer of DES could not be vertically liable for distribution of DES tablets where tablet manufacturer bore responsibility of conducting separate test to determine adverse ef-

fects of drug. George v. Parke-Davis, 1987, 733 P.2d 507, 107 Wash.2d 584.

13a. Clinical studies

Food and Drug Administration bulletin, which provided that physician may, as part of practice of medicine, prescribe different dosage for patient without obtaining approval of the FDA, related to drugs which already had received FDA approval, and did not support contention of claimant, who sought relabeling of medical device known as "Diapulse" device, that differing conditions of use between studies and relabeling proposal were irrelevant, in light of statutory criteria contained in Federal Food, Drug, and Cosmetic Act, §§ 505(d), 513(a)(3)(B)(i, ii) as amended, 21 U.S.C.A. §§ 355(d), 360(a)(3)(B)(i, ii), which provides that scientific studies must be such that it could fairly and responsibly be concluded that drug or device will have effect it purports or is represented to have under conditions of use prescribed, recommended or suggested in labeling or proposed labeling thereof. U.S. v. An Article of Device . . . Diapulse, C.A.7 (Ill.) 1985, 768 F.2d 826.

Food and Drug Administration had established that published clinical studies on Fiorinal with Codeine Nos. 1 and 2 did not establish requisite recognition of product or contribution of its components so as to obviate need for new drug application with respect to drugs; manufacturer submitted no studies with respect to Fiorinal with Codeine No. 1, most studies submitted were conducted with old formulation of Fiorinal with Codeine Nos. 2 and 3, and studies failed to measure efficaciousness of certain components of drugs. U.S. v. 225 Cartons, More or Less, of an Article of Drug, D.N.J.1988, 687 F.Supp. 946.

13b. Breast implants

Food and Drug Administration (FDA) report on risks of silicone gel breast implants was sufficiently reliable to be admissible hearsay as product of factual investigation conducted by FDA pursuant to its statutory authority. Toole v. McClintock, M.D.Ala.1991, 778 F.Supp. 1543.

14. Approval of drug—Administrative agency

Food and Drug Administration has jurisdiction to decide with administrative finality, subject to types of judicial review provided, the "new drug" status of individual drugs or classes of drugs. Weinberger v. Bentex Pharmaceuticals, Inc., S.C.1973, 93 S.Ct. 2488, 412 U.S. 645, 37 L.Ed.2d 235.

Even though a drug manufacturer does not have any new drug application in effect and is not seeking approval of any drugs, the Food and Drug Administration may make a declaratory order that a drug is a "new drug" so as to acquire an effective new drug application before drug may be introduced into commerce; power of the Administration to decide threshold jurisdictional question whether the drug is a "new drug" is not only an incident to its power to approve or withdraw approval of a new drug application. Weinberger v. Hynson, Westcott and Dunning, Inc., Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Trial court's order that drug manufacturer provide drug free of charge to participants in double-blind study of drug for 12 months after study was completed as agreed to in contract did not violate doctrine of primary jurisdiction by taking decision away from Food and Drug Administration (FDA) with respect effectiveness of drug; FDA's determination of efficacy did not have to precede injunction requiring one year of drug be provided free of charge to participants who subjected themselves to double-blind study. Dahl v. HEM Pharmaceuticals Corp., C.A.9 (Nev.) 1993, 7 F.3d 1399.

Determination that new drug application was "approved" in December of 1981 when manufacturer was informed of approval, even though the approval was granted with the understanding that remaining issues concerning final printed labeling be resolved, was not arbitrary and capricious, so that drug was not entitled to period of nonpatent exclusivity under the Hatch-Waxman Amendments. Mead Johnson Pharmaceutical Group, Mead Johnson & Co. v. Bowen, 1988, 838 F.2d 1332, 267 U.S.App.D.C. 382.

Position of Food and Drug Administration that it could approve new drug application prior to submission of final labeling was reasonable interpretation of statute where statute only required submission of proposed labeling and FDA regulation stated that approval would ordinarily follow submission of final labeling. Norwich Eaton Pharmaceuticals, Inc. v. Bowen, C.A.6 (Ohio) 1987, 808 F.2d 486, certiorari denied 108 S.Ct. 68, 484 U.S. 816, 98 L.Ed.2d 32.

In determining effectiveness of drugs, Commissioner of Food and Drug Administration is not required to defer to conclusions of experts that studies submitted by drug companies are adequate and well-controlled and prove effectiveness of drugs under consideration; both validity of methodology used in particular studies and ultimate question of effectiveness are issues for Commissioner to determine. Warner-Lambert Co. v. Heckler, C.A.3, 1986, 787 F.2d 147.

With respect to application for clearance to market a new animal drug, when Food and Drug Administration proceeds by way of ad hoc articulation of safety standards, it is incumbent upon it to give applicant notice of those standards and of manner in which the data before it failed to meet them and that notice must be given in timely fashion to put manufacturer in position to dispute Administration's interpretation of the safety criteria, object to Administration's critique of submitted studies, and conduct and proffer new studies meeting newly articulated requirements, and, should applicant then identify a material issue of fact, Administration must hold hearing. American Cyanamid Co. v. Food and Drug Administration, 1979, 606 F.2d 1307, 196 U.S.App.D.C. 400.

Recommendations of the National Academy of Sciences-National Research Council as to effectiveness of a new drug are advisory in nature. Holland Rantos Co., Inc. v. U.S. Dept. of Health, Ed. and Welfare, 1978, 587 F.2d 1173, 190 U.S.App.D.C. 276.

Food and Drug Administration's disregard, without reasons, of recommendation of study group of the National Academy of Sciences-National Research Council that new drug be

considered effective for treatment of vaginitis did not constitute sufficient ground to set aside final order denying new drug application where refusal to accept panel's rating of effectiveness was essentially judgment that applicant had not yet offered substantial evidence of drug's effectiveness and should be put to its proof and where subsequent events vindicated such judgment in that application was unable to produce necessary adequate and well-controlled studies of drug's effectiveness. *Holland Rantos Co., Inc. v. U.S. Dept. of Health, Ed. and Welfare, 1978, 587 F.2d 1173, 190 U.S.App.D.C. 276.*

Action of Federal Trade Commission in ordering operations of weight loss clinics to state in their advertisements that one of the drugs being used was a new drug which had not been determined to be effective for obesity did not impermissibly encroach upon the confidential relationship between a physician and a patient; the FTC order did not affect the right of a physician to prescribe or administer the drug for his or her patients but merely prevented the weight loss clinics from advertising their clinics and weight reduction program in a way which failed to disclose that the Food and Drug Administration had not approved the drug for such use. *Simco Management Corp. v. F.T.C., C.A.9, 1978, 579 F.2d 1187.*

A new drug may not be introduced into interstate commerce unless an application has been filed with and approved by the Food and Drug Administration; the FDA may not approve a new drug application unless it finds that there is substantial evidence that the drug is effective for the labeled use. *Simco Management Corp. v. F.T.C., C.A.9, 1978, 579 F.2d 1187.*

Under this subchapter, ultimate determination of safety of a drug is not a matter given to the courts, but one to be determined by the Food and Drug Administration upon submission of a new drug application. *U.S. v. 1,048,000 Capsules, More or Less, "Afrodex", C.A.Tex.1974, 494 F.2d 1158.*

Order of Commissioner of Food and Drugs withdrawing approval of line of drugs for interstate marketing was not supported by adequate findings and conclusions, where order merely tracked language of this section, stating in conclusory terms that there was lack of substantial evidence that the drugs were effective, and did not disclose evidence upon which the Commissioner based his judgment. *USV Pharmaceutical Corp. v. Secretary of Health, Ed. and Welfare, 1972, 466 F.2d 455, 151 U.S.App.D.C. 284.*

Where Commissioner of Food and Drugs had failed to name hearing examiner in response to drug manufacturer's demand and delayed more than two months in responding to manufacturer's request, filed two years later, for a stay pending decision in manufacturer's action for declaratory judgment that its drugs were not new drugs, Commissioner's precipitous summary withdrawal of approval of previously granted new drug applications were arbitrary. *USV Pharmaceutical Corp. v. Secretary of Health, Ed. and Welfare, 1972, 466 F.2d 455, 151 U.S.App.D.C. 284.*

Issue of whether drug is actually safe and effective is for the Food and Drug Administration. *USV Pharmaceutical Corp. v. Secretary of*

Health, Ed. and Welfare, 1972, 466 F.2d 455, 151 U.S.App.D.C. 284.

Commissioner of Food and Drugs has jurisdiction, in proceeding to determine whether lack of effectiveness as claimed makes a drug unmarketable, to decide the threshold question whether the product in controversy is a "new drug," and if the administrative agency takes jurisdiction, the same jurisdictional issue is present for judicial review on direct appeal from the administrative decision. *Ciba Corp. v. Richardson, C.A.N.J.1972, 463 F.2d 225, affirmed 93 S.Ct. 2495, 412 U.S. 640, 37 L.Ed.2d 230.*

In light of Food and Drug Administration's function of protecting public health and safety, "paper new drug application policy" which allows approval of duplicate new drug application without examination of raw data when verification of prior studies has been accomplished through scrutiny of scientific community and which is supported by argument that likelihood of fraud or bias existing after years of published studies subject to verification through scrutiny of publishing journals and general scientific community, potential for testing and duplication, and experience of drug's performance once it has been on market, becomes vastly diminished, is valid. *Upjohn Mfg. Co. v. Schwelker, D.C.Mich.1981, 520 F.Supp. 58, affirmed 681 F.2d 480.*

Determination of actual safety and effectiveness of drug product is committed to Food and Drug Administration due to its superior access to technical expertise. *U.S. v. Articles of Drug . . . HORMONIN, D.C.N.J.1980, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.*

Determination of whether product constituted a "new drug" requiring filing and approval of a new drug application was within the primary jurisdiction of the Food and Drug Administration, precluding district court review until final agency action and exhaustion of administrative remedies. *IMS Ltd. v. Califano, D.C.Cal.1977, 453 F.Supp. 167.*

Since the Federal Drug Administration has failed to act in contemplation of what Congress intended in this section, the Administration and Department of Health, Education and Welfare would be found to have in fact disapproved the use of laetrile for treating cancer, and the district court, for want of action on the part of the agencies, had jurisdiction of class action brought by cancer victims and their spouses seeking an order directing the Administration to desist from precluding the administration of laetrile to patients in the United States suffering from cancer. *Rutherford v. U.S., D.C.Ok.1975, 399 F.Supp. 1208, affirmed and remanded on other grounds 542 F.2d 1187, on remand 424 F.Supp. 105.*

Whether drugs are "new" or "old" requires determination by the Food and Drug Administration as to whether they are generally recognized, among qualified experts, as safe and effective for their intended use. *National Ethical Pharmaceutical Ass'n v. Weinberger, D.C.S.C. 1973, 865 F.Supp. 785, affirmed 503 F.2d 1051.*

15. — Judicial

In cases where there has been no formal administrative determination of jurisdictional is-

sue whether drug product is a "new drug" subject to provisions of this chapter district court might well stay its hand, awaiting appropriate administrative determination of this threshold jurisdictional question; however, where there is an administrative determination, whether it be explicit or implicit in the withdrawal of a new drug application, the tactic of "reserving" the threshold jurisdictional question for later judicial determination is not tolerable. *CIBA Corp. v. Weinberger, N.J.1973, 93 S.Ct. 2495, 412 U.S. 640, 37 L.Ed.2d 230.*

Action by pharmaceutical trade association and one of its member companies seeking judicial review of Food and Drug Administration's regulation of certain drugs which were treated as "new drugs," and seeking a judgment declaring that those drugs were not "new drugs," was properly dismissed on the ground that the matter lay within the primary jurisdiction of the Food and Drug Administration, that judicial review was available only after a formal administrative ruling, and that, in respect to the prayer for declaratory relief, a sound exercise of discretion required the court to refuse to take jurisdiction. *National Ethical Pharmaceutical Ass'n v. Weinberger, C.A.S.C.1974, 503 F.2d 1051.*

Determination of Court of Appeals reviewing decision of Commissioner of Food and Drugs that a drug is a "new drug" within meaning of this section providing for exclusion of new drugs from market unless proven effective as claimed is reviewable by the Supreme Court, and it is not appropriate that a district court entertain a separate suit by the loser in the administrative proceeding for a redetermination of the same question. *Ciba Corp. v. Richardson, C.A.N.J. 1972, 463 F.2d 225, affirmed 93 S.Ct. 2495, 412 U.S. 640, 37 L.Ed.2d 230.*

The Food and Drug Administration had primary jurisdiction to determine whether each drug named in applicants' complaint was "new drug" and, following such administrative determination, applicants would then be entitled to seek judicial review. *National Ethical Pharmaceutical Ass'n v. Weinberger, D.C.S.C.1973, 365 F.Supp. 785, affirmed 503 F.2d 1051.*

Determination by Food and Drug Administration that a product is "new drug" or a "me-too" drug is reviewable. *National Ethical Pharmaceutical Ass'n v. Weinberger, D.C.S.C.1973, 365 F.Supp. 785, affirmed 503 F.2d 1051.*

15a. — Timeliness

Writ of mandamus would not issue to compel Food and Drug Administration to expedite processing of application for approval of generic drug, following expiration of statutory period during which decision was to be made; while judicial intervention might benefit applicant, there would be corresponding harm to other applicants whose processing would be further delayed. *In re Barr Laboratories, Inc., 1991, 930 F.2d 72, 289 U.S.App.D.C. 187, certiorari denied 112 S.Ct. 297, 298, 116 L.Ed.2d 241.*

16. Withdrawal of approval

Under this chapter as originally enacted, which empowers the Food and Drug Administration to withdraw approval of a new drug application whenever new evidence comes to

light suggesting that the drug has become unsafe, whether or not the drug was generally recognized as safe in the interim, a new drug application remains effective unless it is suspended. *Weinberger v. Hynson, Westcott and Dunning, Inc., Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.*

Substantial evidence supported determination of Commissioner of Food and Drug Administration that use of concomitant medication flawed clinical study of oral proteolytic enzymes and that other studies were in violation of regulatory criteria such that withdrawal of approval was appropriate. *Warner-Lambert Co. v. Heckler, C.A.3, 1986, 787 F.2d 147.*

Manufacturer was not prejudiced by nine-year delay between request for hearing before Food and Drug Administration on hair and scalp products and Food and Drug Administration's withdrawal of approval, where the delay enabled him to continue marketing the products and where the deaths of doctors who conducted studies did not prejudice defendant in that the truth of their views was not the issue but whether the studies on their face complied with Food and Drug Administration guidelines. *Brandenfels v. Heckler, C.A.9, 1983, 716 F.2d 553.*

Manufacturers of drug were entitled to notice of specific grounds on which the Food and Drug Administration proposed to withdraw approval of the drug's new drug application and to an opportunity to submit evidence which would entitle them to a hearing before an order of withdrawal could be validly issued. *Sterling Drug Inc. v. Weinberger, C.A.2, 1974, 503 F.2d 675.*

If court finds that Food and Drug Administration's order withdrawing drug from market identified defects which conclusively rendered each piece of evidence submitted in support of drug's efficacy as being inadequate or uncontrolled in light of permit regulations, court must affirm order. *Cooper Laboratories, Inc. v. Commissioner, Federal Food and Drug Administration, 1974, 501 F.2d 772, 163 U.S.App.D.C. 212.*

Standard of review to be applied to order of the Food and Drug Administration denying an evidentiary hearing on effectiveness of drug previously approved for marketing solely on demonstration that it was safe for its intended use is whether deficiencies found in the studies submitted by manufacturer of the drug conclusively render the studies inadequate. *E. R. Squibb & Sons, Inc. v. Weinberger, C.A.3, 1973, 483 F.2d 1382.*

Satisfactory adjudication of appeal from denial by the Food and Drug Administration of evidentiary hearing on effectiveness of drug which had been previously approved on the basis of safety only mandated that a meaningful comparison be made by the FDA between the study submitted in the instant case and study held sufficient by the Supreme Court, and also mandated amplification and clarification in light of highly esoteric and scientific terms employed in the information before the court. *E. R. Squibb & Sons, Inc. v. Weinberger, C.A.3, 1973, 483 F.2d 1382.*

Action of Food and Drug Administration (FDA) in rescinding its approval of manufacturer's application to make and sell new drug, on ground that approval had been issued through

inadvertent mistake, was not so clearly ultra vires as to justify disregard of exclusive jurisdiction of Court of Appeals and intervention by district court; even if right vested, manufacturer was not deprived of factual hearing to prove its qualifications to make and sell drug, and postdenial hearing met due process requirements. *American Therapeutics, Inc. v. Sullivan*, D.D.C.1990, 755 F.Supp. 1.

Proposed withdrawal of approval of new drug applications in effect for drug is not a final order and is not ordinarily reviewable in district court. *Sterling Drug, Inc. v. Weinberger*, D.C.N.Y. 1974, 384 F.Supp. 557, affirmed 509 F.2d 1236.

Secretary of Health, Education, and Welfare must, under this section and section 357 of this title governing withdrawal of antibiotic and non-antibiotic drugs, upon finding of lack of substantial evidence that the drugs have effect they are represented to have under conditions of use prescribed, recommended or suggested in labeling, begin procedures to withdraw a drug when he concludes that there is no substantial evidence of efficacy rather than thereafter granting manufacturers time to bolster record regarding the drug's effectiveness. *American Public Health Ass'n v. Veneman*, D.C.D.C.1972, 349 F.Supp. 1811.

Invocation of emergency procedure to immediately suspend drugs which present an imminent hazard to the public health is matter which is peculiarly one of judgment. *American Public Health Ass'n v. Veneman*, D.C.D.C.1972, 349 F.Supp. 1811.

16a. Insurance

Notwithstanding provisions in health insurance policy providing that policy was to be interpreted in accordance with laws of District of Columbia where laetrile was illegal, insured, who was terminally ill, who received laetrile treatments in Oklahoma under specific authority under an order of United States district court and who complied with policy's requirements with regard to establishing her claim, was entitled to have laetrile treatments paid for by insurer as covered medical expenses. *Wilson v. Travelers Ins. Co.*, Okl.1980, 606 P.2d 1327.

17. Hearing

Food and Drug Administration's so-called administrative summary judgment procedure, whereby it will not provide a formal hearing on proposed withdrawal of an effective new drug application because of lack of substantial evidence of efficacy of drug when it is apparent at threshold that applicant has not tendered any evidence which on its face meets statutory standards as particularized by regulations, is valid. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

This section and regulations issued thereunder, which express well-established principles of scientific investigation, in their reduction of "substantial evidence" standard to detailed guidelines for protection of public, make Food and Drug Administration's so-called administrative summary judgment procedure, whereby the FDA will not provide a formal hearing on proposed withdrawal of effective new drug applica-

tion because of lack of substantial evidence of efficacy of drug when it is apparent at threshold that applicant has not tendered any evidence which on its face meets statutory standards as particularized by regulations, appropriate. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Due process does not demand a hearing on proposed withdrawal of an effective new drug application because of lack of substantial evidence of efficacy of drug when it appears conclusively from applicant's pleadings that it cannot succeed. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Food and Drug Administration's denial of adjudicatory hearing on application for clearance to market a new animal drug will be upheld if Administration identifies at least one conclusive deficiency in each of tests proffered, but if studies adopting all reasonably applicable methods of showing drug's safety have not been conclusively demonstrated to be inadequate, Administration must hold a hearing. *American Cyanamid Co. v. Food and Drug Administration*, 1979, 606 F.2d 1307, 196 U.S.App.D.C. 400.

Food and Drug Administration would have valid ground for denying hearing on application for clearance to market a new animal drug if Administration's interpretation and application of statutory safety standards are unimpeachable. *American Cyanamid Co. v. Food and Drug Administration*, 1979, 606 F.2d 1307, 196 U.S.App.D.C. 400.

Only if drug manufacturer has had fair opportunity to dispute newly articulated safety standards of Food and Drug Administration and to resubmit compliant tests, or if original tests conclusively failed to meet general statutory prerequisites, may Food and Drug Administration deny hearing on basis of methodology of research relied upon by manufacturer. *American Cyanamid Co. v. Food and Drug Administration*, 1979, 606 F.2d 1307, 196 U.S.App.D.C. 400.

Under this chapter, it is contemplated that a new drug will be approved or disapproved on the basis of scientific tests contained in the new drug application; the hearing offers an opportunity to test the strength and credibility of this material. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

Though a new drug applicant may present testimony or evidence at the hearing to show that the studies and data submitted with the new drug application in fact constitute the adequate tests and substantial evidence necessary for new drug approval, the applicant cannot submit new studies at the hearing to be considered in the first instance by the administrative law judge; to do so would effectively shield an applicant's data from the initial scrutiny of staff experts. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

On hearing to determine threshold issue of safety of double-blind tests for new drug, it was

appropriate to require Commissioner, as an exception to usual case, whichever way he decides threshold issue, to hold a full evidentiary hearing on "all" relevant issues relating to approvability of new drug application, where drug manufacturer had first filed new drug application over six years prior thereto and in the interim its application had been denied on three separate occasions without an opportunity for hearing despite direction to contrary from court. *Edison Pharmaceutical Co., Inc. v. Food and Drug Administration, Dept. of Health, Ed. and Welfare*, 1975, 513 F.2d 1063, 16 U.S.App.D.C. 273, rehearing denied 517 F.2d 164, 170 U.S.App.D.C. 350.

The Food and Drug Administration may withdraw a drug from the market without a hearing when, and only when, it appears conclusively from the applicants' "pleadings" that the new drug application cannot succeed. *Sterling Drug Inc. v. Weinberger*, C.A.2, 1974, 503 F.2d 676.

Word "applicant" or "respondent" in subsec. (g) of this section refers only to holders of new-drug applications; thus, said subsection did not require Secretary personally to notify drug manufacturers which produced anorectic drugs containing amphetamines and which did not hold new-drug applications covering combination amphetamine products of hearing regarding Secretary's withdrawal of approval of such applications. *North American Pharmacal, Inc. v. Department of Health, Ed. and Welfare, C.A.8, 1973, 491 F.2d 546.*

Publication in Federal Register of notice of hearing regarding the withdrawal of approval of new-drug applications covering combination amphetamine products gave manufacturers, which produced anorectic drugs containing amphetamines and which did not hold new-drug applications covering combination amphetamine products, sufficient opportunity to be heard; and failure personally to notify each manufacturer of hearing did not deprive them of due process. *North American Pharmacal, Inc. v. Department of Health, Ed. and Welfare, C.A.8, 1973, 491 F.2d 546.*

Petitioner was not entitled to hearing before Commissioner on question of whether or not its product constituted new animal drug within meaning of this section. *Agri-Tech, Inc. v. Richardson, C.A.8, 1973, 482 F.2d 1148.*

Opportunity to be heard administratively is not prerequisite to prosecution for introduction of a "new drug" into interstate commerce without approval of a new drug application. *Durovic v. Richardson, C.A.III.1973, 479 F.2d 242*, certiorari denied 94 S.Ct. 232, 414 U.S. 944, 38 L.Ed.2d 168, rehearing denied 94 S.Ct. 611, 414 U.S. 1088, 38 L.Ed.2d 494.

Where drug manufacturer's applications for marketing a line of drugs had been approved pursuant to prior law but Commissioner of Food and Drugs proposed, without a hearing, to withdraw that approval on basis of a new standard and new information, together with evidence available when approval was originally granted, it was incumbent upon Commissioner, before calling upon manufacturer for additional evidence establishing a right to a hearing, to state facts and reasons showing at least prima facie that the evidence before him raised no material

issue of fact which would justify a hearing. *U.S.V. v. Pharmaceutical Corp. v. Secretary of Health, Ed. and Welfare*, 1972, 466 F.2d 455, 151 U.S.App.D.C. 284.

In circumstance in which the Food and Drug Administration publishes in Federal Register the required notice to drug manufacturers of opportunity for hearing and proposed withdrawal of drugs from market and manufacturers then fail to avail themselves of opportunity for the hearing within required 30 days, withdrawal of drugs from market is required by this section governing withdrawal of drugs and is purely a ministerial duty, and failure to withdraw constitutes agency action unlawfully withheld. *American Public Health Ass'n v. Veneman, D.C.D.C. 1972, 349 F.Supp. 1811.*

Hearing on withdrawal of a new drug application is to be scheduled as soon as practicable after request by drug manufacturers for such a hearing; and, while some agency discretion is conferred in scheduling the hearing, interminable delay is not contemplated. *American Public Health Ass'n v. Veneman, D.C.D.C.1972, 349 F.Supp. 1811.*

17a. Jurisdiction

Jurisdictional question whether a drug product is a "new drug," which is defined in section 321 of this title as a drug not generally recognized among experts is effective as well as safe for its intended uses, involves a determination of technical and scientific questions by experts, and agency is therefore appropriately the arm of government to make threshold determination of issue of coverage. *CIBA Corp. v. Weinberger, N.J.1973, 93 S.Ct. 2495, 412 U.S. 640, 37 L.Ed.2d 230.*

Food and Drug Administration has jurisdiction in an administrative proceeding on proposed withdrawal of an effective new drug application because of lack of substantial evidence of efficacy to determine jurisdictional question whether a drug product is a "new drug" within this chapter which defines a new drug as a drug not generally recognized among experts as effective as well as safe for its intended uses. *CIBA Corp. v. Weinberger, N.J.1973, 93 S.Ct. 2495, 412 U.S. 640, 37 L.Ed.2d 230.*

Food and Drug Administration has jurisdiction to decide "new drug" status of product and district court may refer new drug issue to Food and Drug Administration for resolution, but court may exercise its concurrent jurisdiction to adjudicate status of product. *Premo Pharmaceutical Laboratories, Inc. v. U.S., C.A.N.Y.1980, 629 F.2d 795.*

Limited "new drug" issue was sufficiently clear to warrant district court's exercise of its subject-matter jurisdiction, especially where to refer issue to Food and Drug Administration at the late date would be wasteful and duplicative. *Premo Pharmaceutical Laboratories, Inc. v. U.S., C.A.N.Y.1980, 629 F.2d 795.*

Decision of Commissioner that Laetrile is a "new drug" subject to premarketing approval under this chapter was properly within Food and Drug Administration's primary jurisdiction. *Carnohan v. U.S., C.A.Cal.1980, 616 F.2d 1120.*

Initial determination of whether drug is new animal drug is within jurisdiction of Commis-

sioner, and he may summarily deny hearing on issue whether drug is generally "recognized" and therefore exempt from withdrawal provisions if he finds there is no "substantial evidence" raising issue of fact. *Agri-Tech, Inc. v. Richardson*, C.A.8, 1973, 482 F.2d 1148.

Since Congress has created primary jurisdiction in Food and Drug Administration to determine in first instance safety and efficacy of new drug with such administrative determinations subject to review in appropriate court of appeals, as a jurisdictional matter district courts have no role to play in determining whether a new drug should be approved by Food and Drug Administration. *Hanson v. U.S.*, D.C.Minn.1976, 417 F.Supp. 30, affirmed 540 F.2d 947.

Under section 1337 of Title 28 giving the district courts original jurisdiction of any civil action or proceeding arising under any act of Congress regulating commerce, the district court had jurisdiction of class action brought against the United States and the Secretary of Health, Education and Welfare by cancer victims, and their spouses, seeking an order directing the Federal Drug Administration to desist from precluding the administration of laetrile to patients in the United States suffering from cancer, as the prohibiting language of this section stems from and has to do with commerce powers of the United States, and as plaintiffs were being precluded from transporting laetrile in commerce. *Rutherford v. U.S.*, D.C.Okla.1975, 399 F.Supp. 1208, affirmed and remanded on other grounds 542 F.2d 1137, on remand 424 F.Supp. 106.

18. Persons entitled to bring suit

Drug company met "zone of interests" test for prudential standing to bring action to prevent Food and Drug Administration (FDA) from approving generic versions of Intal Nebulizer Solution (cromolyn) without requiring specific testing, as Congress intended Hatch-Waxman Amendments which govern FDA's approval of applications for generic versions of pioneer drugs to benefit pioneer drug manufacturers. *Fisons Corp. v. Shalala*, D.D.C.1994, 860 F.Supp. 859.

Claim of AIDS (Acquired Immunodeficiency Syndrome) sufferer that drug manufacturer and university acted illegally when they terminated investigation into use of drug Ampligen as treatment for the disease and ceased providing him with the drug as part of their clinical studies did not arise under the Federal Food, Drug, and Cosmetic Act so as to give court jurisdiction over his claim as the civil action arising under an act of Congress regulating commerce. *DeVito v. HEM, Inc.*, M.D.Pa.1988, 705 F.Supp. 1076.

Drug manufacturer which marketed drug under trademark and which filed pioneer new drug application for that drug had standing to file action challenging Food and Drug Administration's approval of new drug application to British manufacturer and distributor of drug called "ibuprofen" on its claim of competitive market position and its claim that trade secret data and information contained in its pioneer new drug application was made subject to public disclosure due to approval of challenged new drug application. *Upjohn Mfg. Co. v. Schweiker*,

D.C.Mich.1981, 520 F.Supp. 58, affirmed 681 F.2d 480.

Threat of injury to plaintiffs, whose claim was not that they would in fact consume unsafe or ineffective drugs, but that they were being subjected to risk to their health on account of marketing of Category III drugs, was both real and immediate and, hence, was sufficient to give plaintiffs standing in suit for declaratory and injunctive relief against regulations of Food and Drug Administration governing the over-the-counter drug market. *Cutler v. Kennedy*, D.C.D.C.1979, 476 F.Supp. 838.

Action wherein plaintiff consumers challenged regulations adopted by Food and Drug Administration for policing the nation's over-the-counter drug market met the ripeness requirement in that the issue whether the regulations were consistent with the statutory scheme pursuant to which they were promulgated was fit for judicial resolution and both litigants would suffer a hardship from further delay in resolving that issue. *Cutler v. Kennedy*, D.C.D.C.1979, 476 F.Supp. 838.

Where individual and corporate defendant had actual notice that Food and Drug Administration considered subject drugs "new drugs" and knew that there was no effective new drug application permitting sale of subject drugs, defendants were not entitled to claim that this section prohibiting sale of new drugs without approval of new drug application by FDA was unconstitutionally vague and could not support a conviction. *U.S. v. Marcen Laboratories, Inc.*, D.C.N.Y.1976, 416 F.Supp. 453, affirmed 556 F.2d 562.

As the named plaintiff, a cancer victim, and those similarly situated were wholly without means or resources to comply with provisions of this section pertaining to filing an application with the Secretary of Health, Education and Welfare for approval to introduce a new drug into interstate commerce, the named plaintiff and those similarly situated, in being thus denied freedom of choice for treatment by the drug laetrile to alleviate or cure their cancer, were deprived of life, liberty or property without due process of law. *Rutherford v. U.S.*, D.C.Okla.1975, 399 F.Supp. 1208, affirmed and remanded on other grounds 542 F.2d 1137, on remand 424 F.Supp. 105.

Consumer organizations were without standing to institute suit against drug companies on behalf of themselves, their members and all other purchasers of certain allegedly ineffective drugs to recover money spent by purchasers of such drugs and to obtain punitive damages where such organizations had not purchased any of drugs involved and had not themselves been injured in fact, and where individualized proof would be necessary to establish each particular purchase and resulting damages incurred by each member and individual damage claims would be governed by common law of each state in which drug sales took place. *Consumer Federation of America v. Upjohn Co.*, D.C.App.1975, 346 A.2d 725.

18a. Discretion of court

Trial court did not abuse its discretion in dismissing, on forum non conveniens grounds,

suit brought by individual against drug company, on behalf of himself and other purchasers of allegedly ineffective drugs to recover money spent in purchase of such drugs and to obtain punitive damages. *Consumer Federation of America v. Upjohn Co.*, D.C.App.1975, 346 A.2d 725.

19. Res judicata

Doctrine of res judicata did not preclude Federal Food and Drug Administration from proceeding to withdraw approval of drug on theory that drug had not been proved effective as single active component drug, though administration had previously determined that drug had not been shown to be effective as fixed combination drug. *Sterling Drug Inc. v. Weinberger*, C.A.N.Y.1975, 509 F.2d 1236.

20. Estoppel

Drug manufacturer could be collaterally estopped from litigating, in seizure proceeding, whether Fiorinal with codeine was "new drug" that could not be marketed without Food and Drug Administration (FDA) approval, in view of determination in prior seizure proceeding concerning related drugs that differed only in amount of codeine they contained; amounts of codeine in drugs was immaterial to new drug determination, factual and legal issues in proceedings were almost identical, findings of other court were necessary to outcome of prior proceeding, and manufacturer had full and fair opportunity to litigate in other proceeding. *U.S. v. Sandoz Pharmaceuticals Corp.*, C.A.6 (Ohio) 1990, 894 F.2d 825, certiorari denied 111 S.Ct. 45, 498 U.S. 810, 112 L.Ed.2d 21.

Prior litigation between consumers of over-the-counter drugs and Food and Drug Administration in which it was determined that consumers had standing to challenge Food and Drug Administration's regulations, which went unappealed by Food and Drug Administration, precluded Food and Drug Administration from attempting to assert that consumers had no standing to challenge rule implementing Food, Drug, and Cosmetic Act, under doctrine of collateral estoppel, in absence of evidence of change in controlling facts sufficient to justify exception to collateral estoppel principles. *Cutler v. Hayes*, 1987, 818 F.2d 879, 260 U.S.App.D.C. 230.

Since Food and Drug Administration had no authority to approve marketing of drug product without new drug application, Government was not estopped from asserting that that drug product and related product were "new drugs" under section 321 of this title. *U.S. v. Articles of Drug . . . HORMONIN*, D.C.N.J.1980, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.

United States was not estopped from bringing an enforcement proceeding to prevent further shipment of drug X—Otag Plus in interstate commerce without first obtaining an approved new drug application or abbreviated new drug application despite claim that, because of refusal of Food and Drug Administration to follow its own regulations, abbreviated new drug application submitted by manufacturer for X—Otag Plus was rejected. *U.S. v. X—Otag Plus Tablets*, D.C.Colo.1977, 441 F.Supp. 105, affirmed in part, remanded in part, on other grounds 602 F.2d 1387.

Food and Drug Administration could not ban use of laetrile under grandfather clause if in fact laetrile had been used prior to the cutoff date in treatment of cancer and without ill effect, it was not necessary that the drug be shown to have been effective in treatment of cancer. *Rutherford v. U.S.*, D.C.Okla.1977, 429 F.Supp. 506.

21. Burden of proof

Proponents of laetrile did not conduct the research and laboratory testing required under prevailing agency procedures and by this chapter, thus, they did not meet their burden to fulfill premarketing requirements. *Rutherford v. U.S.*, C.A.Okla.1980, 616 F.2d 455, certiorari denied 101 S.Ct. 336, 449 U.S. 937, 66 L.Ed.2d 160.

Where Federal Trade Commission sought an order requiring weight loss clinics to disclose in their advertisements the fact that one of the drugs being used in the program was a new drug which had not been determined by the Food and Drug Administration to be effective for obesity, FTC did not have the burden of proving that the weight loss clinics' program was unsafe or ineffective. *Simeon Management Corp. v. F.T.C.*, C.A.9, 1978, 579 F.2d 1137.

Those who seek to market a drug or food additive in interstate commerce have some burden of proving the safety and, for drugs, the effectiveness of their product. *U.S. v. Articles of Food and Drug Consisting of Coli-Trol 80, F4C-60 Feed Grade, Entrol-S Medicated, Entrol-P*, C.A.Ga.1975, 518 F.2d 743.

Those who seek to market a drug or food additive in interstate commerce have some burden of proving the safety and, for drugs, the effectiveness of their product. *U.S. v. Articles of Food and Drug Consisting of Coli-Trol 80, F4C-60 Feed Grade, Entrol-S Medicated, Entrol-P*, C.A.Ga.1975, 518 F.2d 743.

Burden is on sponsor of new drug to demonstrate its safety and effectiveness. *Edison Pharmaceutical Co., Inc. v. Food and Drug Administration*, Dept. of Health, Ed. and Welfare, 1975, 513 F.2d 1063, 168 U.S.App.D.C. 273, rehearing denied 517 F.2d 164, 170 U.S.App.D.C. 350.

Drug manufacturers must carry burden of showing by substantial evidence the claimed efficacy and safety of drugs. *North American Pharmacal, Inc. v. Department of Health, Ed. and Welfare*, C.A.8, 1973, 491 F.2d 546.

Physicians and patients challenging, by way of petition for preliminary injunction, decision of Secretary suspending new drug applications for phenformin hydrochloride on ground that drug posed an "imminent hazard" had burden of demonstrating substantial likelihood that decision was a clear error of judgment and that he failed to articulate any rational connection between facts submitted to him and choice he made. *Forsham v. Califano*, D.C.D.C.1977, 442 F.Supp. 203.

22. Evidence

"Substantial evidence," as used in this section, which directs the Food and Drug Administration to refuse approval of a new drug application or to withdraw any prior approval if substantial evidence that the drug is effective for its intend-

ed use is lacking, means adequate and well-controlled investigations from which experts may conclude that the drug will have the claimed effect. *CIBA Corp. v. Weinberger*, N.J. 1978, 93 S.Ct. 2495, 412 U.S. 640, 87 L.Ed.2d 230.

Phrase "lack of substantial evidence," in this section which directs Food and Drug Administration to refuse approval of a new drug application and to withdraw any prior approval if substantial evidence that drug is effective for its intended use is lacking, is not applicable only to proof of actual effectiveness of drugs that fall within definition of a new drug; hurdle of "general recognition" of effectiveness requires at least substantial evidence of effectiveness for approval of a new drug application. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Evidence submitted by drug manufacturer with respect to efficacy of drug for use in treatment of premature labor and habitual abortion, including a list of literature references, a copy of an unpublished study, and a representative sample testimonial letter on behalf of the drug, was sufficient to warrant a hearing on proposed withdrawal of effective new drug application because of lack of substantial evidence of efficacy of the drug. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

To prevail at a Food and Drug Administration hearing on proposed withdrawal of an effective new drug application because of lack of substantial evidence of efficacy, applicant must furnish evidence stemming from adequate and well-controlled investigations. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1973, 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Drug manufacturer's attempt to replace evidence of controlled investigation with testimony relating to personal experiences or clinical impressions arising from use of proposed new drug was inconsistent with this chapter as well as with accompanying regulations and explicit Supreme Court precedent. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

Substantial evidence including the testimony of three expert witnesses supported decision of the Commissioner that both animal studies and clinical testing offered by drug manufacturer in support of new drug application were insufficient and failed to demonstrate the safety of the new drug. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

A drug can be generally recognized as effective only if the expert consensus is based upon substantial evidence that the drug is effective for the labeled use; anecdotal evidence, such as testimonials by satisfied patients or statements by doctors that, based on their experience, they believe the drug is effective do not constitute adequate and well-controlled investigations and cannot provide substantial evidence of effectiveness. *Simeon Management Corp. v. F.T.C.*, C.A.9, 1978, 579 F.2d 1137.

Substantial evidence of effectiveness is a necessary but not a sufficient condition for approval of a new drug application. *Edison Pharmaceutical Co., Inc. v. Food and Drug Administration*, 1975, 517 F.2d 164, 170 U.S.App.D.C. 350.

Meaning of label is relevant to general recognition of safety of alleged new drug. *U.S. v. 1,048,000 Capsules, More or Less, "Afrodex"*, C.A.Tex.1974, 494 F.2d 1158.

Evidence supported order of Food and Drug Administration withdrawing approval of new-drug applications covering combination amphetamine products. *North American Pharmacal, Inc. v. Department of Health, Ed. and Welfare*, C.A.8, 1973, 491 F.2d 546.

Evidence warranted submission to jury of issue of whether "Aralen" (chloroquine phosphate) was sold for use in the treatment of lupus erythematosus without adequate testing to determine possible harmful side effects. *Hoffman v. Sterling Drug, Inc.*, C.A.Pa.1973, 485 F.2d 132, on remand 374 F.Supp. 850.

The "substantial evidence" standard as set out in this section and regulation with respect to showing required by manufacturers of drugs is directed only to question of efficacy, and a different standard applies where question of safety arises, and such different standard should be articulated by the Food and Drug Administration. *E. R. Squibb & Sons, Inc. v. Weinberger*, C.A.3, 1973, 483 F.2d 1382.

Evidence that drug was, prior to Oct. 9, 1962, effective date of amendments to provisions of this chapter, prescribed and enthusiastically endorsed by a few physicians in one city and sold to no more than 150 to 200 doctors in two or three neighboring states was insufficient to establish that the drug was generally recognized as safe on the date in question, and thus drug was not entitled to "grandfather clause" exemption from present requirement of this chapter that drug not be shipped in interstate commerce without prior approval of a new drug application unless it is generally recognized as both safe and effective. *U.S. v. An Article of Drug "Bentex Ulcerine"*, C.A.Tex.1972, 469 F.2d 876, certiorari denied 93 S.Ct. 2772, 412 U.S. 938, 37 L.Ed.2d 397.

Decision of Commissioner of Food and Drugs relating to marketing order entered after a hearing will be upheld and sustained by any substantial evidence, but in determining whether Commissioner acted within limits of discretion on procedural question of whether hearing is to be allowed, test is whether there is any genuine and substantial evidence that supports position of applicant. *Hynson, Westcott & Dunning, Inc. v. Richardson*, C.A.4 1972, 461 F.2d 215, modified on other grounds 93 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 207.

Evidence in proceeding to withdraw approval of drug supported finding that manufacturer's studies of effect of drug, which was designed to reduce incidence of certain attacks of vertigo, were not sufficiently adequate and well controlled as to constitute substantial evidence of claims for efficacy. *Unimed, Inc. v. Richardson*, 1972, 458 F.2d 787, 147 U.S.App.D.C. 368.

Substantial evidence of safety and effectiveness of alleged new drug can be shown only by

adequate and well-controlled studies of product itself or by adequate and well-controlled studies which concern another drug with same active ingredients and which demonstrate bioequivalence of product and other drug. *U.S. v. Undetermined Quantities of an Article of Drug (Anucort HC Suppositories)*, D.N.J.1987, 709 F.Supp. 511, affirmed 857 F.2d 1464, 1466, certiorari denied 109 S.Ct. 864, 488 U.S. 1040, 102 L.Ed.2d 988.

Even if substantial evidence to support general recognition of safety and effectiveness of a combination drug exists concerning the individual components of the drug, there must also be substantial evidence of the safety and efficacy of the combination of the generally recognized components in order for the combination drug to transcend "new drug" status. *U.S. v. Articles of Drugs . . . HORMONIN*, D.C.N.J.1980, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.

Plaintiffs, who sought to establish their standing as consumers to challenge regulations adopted by the Food and Drug Administration with respect to policing the nation's over-the-counter drug market, were not required, through independent research, to monitor the Federal Register or similar means to keep abreast of precisely which of the thousands of the over-the-counter drug products contained conditions classifying Category III since such efforts would not alleviate the injury to their statutory interests any more than would decision to forgo the use of the drugs altogether. *Cutler v. Kennedy*, D.C.D.C.1979, 475 F.Supp. 838.

Fact that much of the raw data used by Bureau of Drugs in arriving at its conclusion that drug posed an imminent hazard had been available for some length of time did not preclude use of data in finding imminent hazard where magnitude of drug's risk was determined only after extensive reevaluation of data following hearing. *Forsham v. Califano*, D.C.D.C. 1977, 442 F.Supp. 203.

Even though testimony of general practitioners as to safety or efficacy of drugs may be less than compelling, court will not reject all clinical impressions by general practitioners in suit to condemn misbranded drug. *U.S. v. 1,048,000 Capsules, More or Less*, D.C.Tex.1972, 347 F.Supp. 768, affirmed 494 F.2d 1158.

Evidence in suit to condemn allegedly misbranded drugs was insufficient to meet claimant's burden of proving, as bearing on right to benefit of grandfather clause exemption from showing of effectiveness, that on October 9, 1962 the drug was generally recognized among qualified experts as safe for use under the conditions prescribed, recommended or suggested in the labeling as of that date. *U.S. v. 1,048,000 Capsules, More or Less*, D.C.Tex.1972, 347 F.Supp. 768, affirmed 494 F.2d 1158.

22a. Admissibility of evidence

At hearing on new drug application, administrative law judge properly excluded testimonial evidence which the drug manufacturer offered to demonstrate the efficacy of the new drug; personal testimonials simply did not meet the exacting standard of evidence required by this chapter and regulations. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of*

Health, Ed. and Welfare, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

At hearing on new drug application, administrative law judge correctly excluded evidence of tests that were not submitted with the new drug application where the drug manufacturer had failed to invoke the regulation which provides a procedure for filing new studies. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

At hearing on new drug application, administrative law judge properly excluded as irrelevant evidence concerning different treatment which the Administration allegedly gave to another drug. *Edison Pharmaceutical Co., Inc. v. Food and Drug Admin., Dept. of Health, Ed. and Welfare*, 1979, 600 F.2d 831, 195 U.S.App.D.C. 17.

24. Questions of fact

Factual question as to whether double-blind tests for new drug were too dangerous to perform was a sufficiently material fact in dispute to require an evidentiary hearing on drug manufacturer's new drug application before Commissioner could issue a final order. *Edison Pharmaceutical Co. Inc. v. Food and Drug Administration, Dept. of Health, Ed. and Welfare*, 1975, 518 F.2d 1063, 168 U.S.App.D.C. 273, rehearing denied 517 F.2d 164, 170 U.S.App.D.C. 350.

Whether Federal Food and Drug Administration had new information which would justify withdrawal of approval of new drug application in effect for prescription drug was factual determination to be made first by the Administration. *Sterling Drug Inc. v. Weinberger*, C.A.N.Y.1975, 509 F.2d 1236.

Affidavits stating that particular disease that drug was marketed as treatment for was hard to diagnose, ran variable course, and caused pain did not create factual question requiring Food and Drug Administration to conduct hearing as to whether testimonials of experienced physicians, rather than controlled studies, should be recognized as substantial evidence of drug's efficacy. *Cooper Laboratories, Inc. v. Commissioner, Federal Food and Drug Administration*, 1974, 501 F.2d 772, 163 U.S.App.D.C. 212.

Whether drug manufacturers violated this section by not submitting new drug application to Food and Drug Administration for "Aralen," their trade name for chloroquine phosphate, when the drug was offered for use in the treatment of lupus erythematosus was question for jury in user's action against manufacturers for loss of vision as result of using the drug. *Hoffman v. Sterling Drug, Inc.*, C.A.Pa.1973, 485 F.2d 132, on remand 374 F.Supp. 850.

Whether manufacturers' alleged violation of this section in the introduction of "Aralen" (chloroquine phosphate) without new drug statement for use in the treatment of lupus erythematosus was proximate cause of the user's loss of vision from use of the drug was question for the jury. *Hoffman v. Sterling Drug, Inc.*, C.A.Pa.1973, 485 F.2d 132, on remand 374 F.Supp. 850.

25. Injunction

Corporation which acquired title to new drug application was not in contempt of order enjoined

ing previous holder of application from infringing plaintiff's drug patents; plaintiff failed to show that corporation, which acquired title to application and which was not a party to patent infringement case, was an instrumentality of previous holder designed to evade injunction or acted in concert or in participation with original defendants in patent infringement action, and new drug application was not equivalent to product addressed and did not authorize anyone to make, use or sell drug. *Eli Lilly and Co. v. Prema Pharmaceutical Laboratories, Inc.*, C.A.Fed. (N.J.) 1988, 843 F.2d 1378.

Where court's recall order did not address particular violation of this chapter from which injury might be presumed, an independent showing of irreparable harm was required to warrant issuance of such order. *U.S. v. Spectro Foods Corp.*, C.A.N.J.1976, 544 F.2d 1175.

Questions as to whether laetrile was marketed on October 9, 1962, as a cancer drug and was then generally recognized as safe, or whether it was recognized or used as a cancer drug under the same conditions of present use during the period when the Food and Drug Act of 1906 [Act June 30, 1906, Ch. 3915, 34 Stat. 768] was in effect, and thus question of whether laetrile is exempt as a new drug under this section were sufficiently substantial, difficult and doubtful to support grant of preliminary injunction against interference with cancer patient's personal use of the drug. *Rutherford v. U.S.*, C.A.Okla.1976, 542 F.2d 1187, on remand 424 F.Supp. 105.

District court did not abuse its discretion in refusing to enjoin United States authorities from interfering with distribution of specified vitamin which had not been approved for distribution by the Food and Drug Administration, in absence of showing by distributors that there was substantial probability of success with respect to their claim that such vitamin was not a substance subject to control within meaning of this chapter. *Hanson v. U.S.*, C.A.Minn.1976, 540 F.2d 947.

Pharmaceutical company was not entitled to injunctive relief prohibiting Food and Drug Administration from granting approval of generic copies of drug product Desyrel, trazadone HCL within ten-year period of nonpatent marketing exclusivity provided by 1984 amendments to the Federal Food, Drug, and Cosmetic Act; there was no substantial likelihood that pharmaceutical company could demonstrate that letter of December 24, 1981, which stated that drug "is approved" and which approval would except drug from ten-year period of nonpatent marketing exclusivity, was not approval letter, pharmaceutical company did not demonstrate existence of imminent injury in connection with disclosure of safety and effectiveness data, and pharmaceutical company failed to demonstrate that granting of injunctive relief would not significantly harm other interested parties. *Mead Johnson Pharmaceutical Group v. Bowen*, D.D.C.1986, 655 F.Supp. 53, affirmed 838 F.2d 1332, 267 U.S.App.D.C. 322.

Absent showing that probable injury to drug manufacturer without preliminary injunction outweighed harm to Food and Drug Administration and competitor with preliminary injunction or showing of likelihood of success on merits,

antibiotic drug manufacturer was not entitled to preliminary injunction to compel Food and Drug Administration to withhold approval of competitor's application to market generic version of manufacturer's new antibiotic drug; public interest was best served by allowing agency to interpret its own regulations and to operate unimpeded by courts in such matter. *Glaxo, Inc. v. Heckler*, D.C.N.C.1985, 623 F.Supp. 69.

Even if placement of an over-the-counter drug in Category III, absent grandfather status or coverage by a new drug application, was tantamount to a finding of illegality under this chapter, it was not necessary to issue an injunction requiring the commissioner to take the drugs off the over-the-counter market, but only necessary to issue an injunction prohibiting the commissioner from implementing the offensive aspects of the subject regulations. *Cutler v. Kennedy*, D.C.D.C.1979, 475 F.Supp. 838.

Litigation by Food and Drug Administration of new drug status of two products manufactured by plaintiff in pending condemnation actions would not be preliminarily enjoined given serious question as to correctness of dictum in *Lanett* decision permitting a generic or "me-too" drug to be marketed without premarketing approval if its therapeutically active ingredients are identical to a recognized drug both chemically and quantitatively. *Pharmadyne Laboratories, Inc. v. Kennedy*, D.C.N.J.1979, 466 F.Supp. 100, affirmed 596 F.2d 568.

Plaintiff who was dying from cancer of the pancreas and who sought to enjoin the Food and Drug Administration from interfering with importation or interstate transportation of Laetrile for purposes of his own consumption raised right of privacy issue sufficiently serious to be fair grounds for litigation, warranting preliminary injunction. *Rizzo v. U.S.*, D.C.N.Y.1977, 432 F.Supp. 356.

Plaintiff who was dying from cancer and who sought to enjoin Food and Drug Administration from preventing importation or interstate transportation of Laetrile for purposes of his own consumption raised due process question in regard to requirement of filing and prosecution of a "new drug" application of sufficient seriousness to make it fair grounds for litigation, warranting preliminary injunction. *Rizzo v. U.S.*, D.C.N.Y.1977, 432 F.Supp. 356.

Balance of equities tipped decidedly in favor of granting temporary injunction to plaintiff, a cancer patient, who sought to enjoin Food and Drug Administration from preventing importation or interstate transportation of Laetrile for purposes of his own consumption and plaintiff sufficiently demonstrated possibility of irreparable injury by death. *Rizzo v. U.S.*, D.C.N.Y. 1977, 432 F.Supp. 356.

Since plaintiff class, all terminally ill cancer patients, was in danger of suffering irreparable injury if relief in form of allowing such patients who wished to import laetrile for use was postponed or denied and the potential loss to the Food and Drug Administration from granting of relief was slight and record disclosed indications that laetrile was exempt from new drug classification under grandfather clause, court would grant temporary injunction to permit class to import and use laetrile while the Food and Drug

Administration developed proper administrative record to support its claim that laetrile was a new drug. *Rutherford v. U.S.*, D.C.Okla.1977, 429 F.Supp. 506.

In cancer patient's action for preliminary injunction to restrain government or its agents from barring patient's importation of Laetrile solely for his personal use, plaintiff failed to demonstrate substantial probability of success with respect to his claim that Laetrile was not "new drug" within meaning of this section prohibiting importation of such drug until approval of new drug application by Food and Drug Administration. *Gadler v. U.S.*, D.C.Minn.1977, 425 F.Supp. 244.

Proper procedure for manufacturers and distributors of prescription drug involved in proceeding to withdraw approval of new drug applications was to raise defense of res judicata in the administrative proceedings and then have the agency determination on that issue, should it be contrary to their claim, reviewed on appeal to court of appeals from whatever adverse final decision the FDA might make with respect to withdrawal proceedings and manufacturers and distributors were not entitled to circumvent the administrative channels by seeking to enjoin the proceeding. *Sterling Drug, Inc. v. Weinberger*, D.C.N.Y.1974, 334 F.Supp. 557, affirmed 509 F.2d 1236.

26. Record

Food and Drug Administration must produce an administrative record to support its determination that laetrile is a new drug; FDA must present substantial evidence to support the proposition that laetrile is not generally recognized among qualified experts as safe and effective and that its use is not grandfathered in. *Rutherford v. U.S.*, C.A.Okla.1976, 542 F.2d 1187, on remand 424 F.Supp. 105.

Record established that studies whereby 50 patients with herpes zoster were treated with drug while six received a placebo but without method of selecting patients to insure that subjects were suitable for purposes of study, without subjects being designed in such way as to minimize bias, and without comparability of pertinent variables being assured, and study whereby 34 patients with herpes zoster were treated with drug and ten with injections of Vitamin B12, were not "well-controlled" and were properly rejected by Food and Drug Administration as proof of efficacy of drug. *Cooper Laboratories, Inc. v. Commissioner, Federal Food and Drug Administration*, 1974, 501 F.2d 772, 168 U.S.App.D.C. 212.

Exclusion from administrative record of documents generated in course of Food and Drug Administration's compliance and enforcement activities did not preclude meaningful public comment on or judicial review of Administration's "current good manufacturing practice" regulations in view of their general, nontechnical nature, especially as administrative record did include descriptive summaries of the Administration's enforcement activities and most of the actual documents were available for public inspection either in the Administration's files or through requests under Freedom of Information Act, section 552 of Title 5. *National Ass'n of*

Pharmaceutical Manufacturers v. Department of Health and Human Services, D.C.N.Y.1984, 586 F.Supp. 740.

Record was inadequate to support finding that Food and Drug Administration abused its discretion by failing to exercise authority to immediately suspend drugs which present an imminent hazard to the public health. *American Public Health Ass'n. v. Veneman*, D.C.D.C.1972, 349 F.Supp. 1811.

27. Summary judgment

Study which compared new drug's efficacy against that of drug known to be effective and which observed that rate of remission for known drug was 56.5% and that for new drug was 27.6% and thus did not show new drug to be as effective as active control did not produce evidence of new drug's efficacy and thus did not meet Food and Drug Administration's regulatory standards for adequate and well-controlled investigations so as to preclude summary judgment order denying new drug application. *Holland-Rantos Co., Inc. v. U.S. Dept. of Health, Ed. and Welfare*, 1978, 587 F.2d 1173, 190 U.S.App.D.C. 276.

Food and Drug Administration's endorsement of Dexedrine as effective for short term management of obesity provided prima facie support for drug manufacturer's use of Dexedrine as active control in testing efficacy of new drug to be used in the control of obesity, precluding summary judgment order denying new drug application on ground that clinical trials testing drug's efficacy were deficient under FDA regulation requiring that study provide comparison of results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. *Smithkline Corp. v. Food and Drug Administration*, 1978, 587 F.2d 1107, 190 U.S.App.D.C. 210.

This section granting applicant's right to due notice and opportunity for hearing prior to withdrawal of approval to market new drugs in interstate commerce does not preclude use of summary judgment procedure by Food and Drug Administration in appropriate circumstances, but it does restrict application of that procedure to cases in which no material factual issue is presented and a hearing would be a hollow formality. *USV Pharmaceutical Corp. v. Secretary of Health, Ed. and Welfare*, 1972, 466 F.2d 455, 151 U.S.App.D.C. 234.

Manufacturer of hemorrhoidal suppositories with hydrocortisone acetate was not entitled to discovery of specific instances in which Food and Drug Administration approved drug based on extrapolation, in that studies of approved drug could not be extrapolated to newly marketed product simply on basis that new product contained same active ingredient as approved drug. *U.S. v. Undetermined Quantities of an Article of Drug . . . (Anucort HC Suppositories)*, D.N.J.1987, 709 F.Supp. 511, affirmed 857 F.2d 1464, 1466, certiorari denied 109 S.Ct. 864, 488 U.S. 1040, 102 L.Ed.2d 988.

In action brought against Secretary by physicians and patients who sought to preliminarily enjoin Secretary from implementing order suspending new drug applications for phenformin hydrochloride on ground that drug posed an imminent hazard, summary judgment in favor of

Secretary was precluded by existence of issues of material fact. *Forsham v. Califano*, D.C.D.C. 1977, 442 F.Supp. 203.

28. Review

While a Food and Drug Administration order denying a new drug application or withdrawing one is reviewable by the Court of Appeals under this section, an order declaring a "new drug" status is reviewable under the Administrative Procedure Act, sections 551 et seq. and 701 et seq. of Title 5, by the district court. *Weinberger v. Bentex Pharmaceuticals, Inc.*, S.C. 1978, 98 S.Ct. 2488, 412 U.S. 645, 37 L.Ed.2d 235.

Declaratory order of Food and Drug Administration that a drug is a "new drug" so as to require an effective new drug application before drug may be introduced into commerce is not reviewable in the Court of Appeals under subsec. (h) of this section, but is reviewable by the district court under Administrative Procedure Act, sections 551 et seq. and 701 et seq. of Title 5. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1978, 98 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 235.

In reviewing an order of the Commissioner denying a hearing on proposed withdrawal of an effective new drug application because of lack of substantial evidence of efficacy of the drug, a Court of Appeals must determine whether the Commissioner's findings accurately reflect study in question and if they do, whether the deficiencies he finds conclusively render the study inadequate or uncontrolled in light of the pertinent regulations. *Weinberger v. Hynson, Westcott and Dunning, Inc.*, Va.1978, 98 S.Ct. 2469, 412 U.S. 609, 37 L.Ed.2d 235.

Deference owed to political branches in military matters did not preclude judicial review of Food and Drug Administration (FDA) regulation permitting Defense Department to use unapproved, investigational drugs on military personnel, without service member's informed consent, in certain combat-related situations. *Doe v. Sullivan*, C.A.D.C.1991, 938 F.2d 1370.

District court could not reconsider the issue of drug's lack of effectiveness for alleviation of pain, and had no jurisdiction to reopen the case, where Court of Appeals had previously affirmed district court's affirmance of finding by the Food and Drug Administration with respect to the drug's lack of effectiveness. *Rutherford v. U.S.*, C.A.10 (Okla.) 1986, 806 F.2d 1455.

Action of Food and Drug Administration in withdrawing new drug application for muco-eva-cuant "Alevaire" on ground that it was not effective as a "fixed combination drug" was arbitrary and invalid where there was no mention of that theory as ground for proposed withdrawal in the notice of opportunity for hearing and the manufacturers were never given a meaningful opportunity to submit studies or data to contravene that theory. *Sterling Drug Inc. v. Weinberger*, C.A.2, 1974, 503 F.2d 675.

Where the nature of the Food and Drug Administration Interim Index and the basis on which listings thereon are made were not before the court of appeals and were not explored on appeal from Administration's orders which withdrew approval of new drug applications for

muco-eva-cuant drug "Alevaire," the court of appeals would deny manufacturers' motion to require the Administration to remove a listing of "Alevaire" as "ineffective" from the Administration's Interim Index. *Sterling Drug Inc. v. Weinberger*, C.A.2, 1974, 503 F.2d 675.

Issue of whether anorectic drugs containing amphetamines were "grandfathered" by 1982 amendments to this chapter was initially a matter for determination of the Food and Drug Administration, subject to review in district court pursuant to the Administrative Procedure Act, sections 551 et seq. and 701 et seq. of Title 5, and could not be determined by the Court of Appeals in action by manufacturers of such drugs to set aside order of Administration withdrawing approval of new-drug applications covering combination amphetamine products. *North American Pharmacal, Inc. v. Department of Health, Ed. and Welfare*, C.A.8, 1978, 491 F.2d 548.

Court of Appeals did not lack jurisdiction to review merits of petition by manufacturers of anorectic drugs containing amphetamines to set aside order of Food and Drug Administration withdrawing approval of new-drug applications covering combination amphetamine products because manufacturers were not holders of such applications but manufactured drugs which were identical, similar or related to drugs covered by another manufacturer's new drug application. *North American Pharmacal, Inc. v. Department of Health, Ed. and Welfare*, C.A.8, 1978, 491 F.2d 548.

In suit for damages and injunctive relief based on alleged conspiracy by defendants to keep plaintiffs' drug off interstate market by influencing the Administration to deny fair consideration of new drug applications, district court should not be inhibited from considering conclusions reached by the Administration with respect to safety and efficacy of drug for interstate sale in light of whatever showing plaintiffs make of the existence of a conspiracy, unfairness, or conflict of interests on part of defendants. *Israel v. Baxter Laboratories, Inc.*, 1972, 466 F.2d 272, 151 U.S.App.D.C. 101.

District court's review of decision of Secretary to suspend phenformin hydrochloride as an imminently hazardous drug was limited to determination of whether Secretary's decision was arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law. *Forsham v. Califano*, D.C.D.C.1977, 442 F.Supp. 203.

Any error made by Food and Drug Administration in its consideration of a new drug application or an abbreviated new drug application for drug X—Otag Plus manufactured by defendant was not for consideration of district court in enforcement proceeding brought by United States, but was for consideration of court of appeals after a final agency determination on status of drug. *U.S. v. X—Otag Plus Tablets*, D.C.Colo.1977, 441 F.Supp. 105, affirmed in part, remanded in part on other grounds 602 F.2d 1387.

Whether FDA had "new information" justifying withdrawal of approval of new drug application in effect for prescription drug was factual determination which should first be made by FDA and, only after that determination was

made and it became clear on what specific information FDA relied for its conclusion, could court determine whether data used constituted new information. *Sterling Drug, Inc. v. Weinberger*, D.C.N.Y.1974, 384 F.Supp. 557, affirmed 509 F.2d 1236.

Complaint seeking determination as to whether drug was a "new drug" was an inappropriate vehicle to determine issues of case as, if plaintiffs were to seek judicial review of any Food and Drug Administration order, complaint would have to be withdrawn and petition for review substituted. *Carolina Brown, Inc. v. Weinberger*, D.C.S.C.1978, 365 F.Supp. 310.

28a. Standards of review

The Food and Drug Administration's denial of claimant's request for relabeling of medical device was an informal adjudicatory process, as to which Administration was not required to conduct an "on the record" hearing to produce record that was basis of action, the basic requirement for substantial evidence review, and thus, decision to deny relabeling was subject to review under the arbitrary and capricious standard contained in 5 U.S.C.A. § 706(2)(A). *U.S. v. An Article of Device ... Diapulse, C.A.7 (Ill.)* 1985, 768 F.2d 826.

29. Declaratory judgment

Where order of Commissioner on Food and Drugs withdrawing drug manufacturer's new drug applications had not become final prior to district court assuming jurisdiction of manufacturer's suit for declaratory judgment that its drugs were exempt from efficacy requirements, and in fact the Court of Appeals had reversed the Commissioner's decision and proceedings on remand were pending before the Commission, manufacturer was not barred from proceeding in the district court. *USV Pharmaceutical Corp. v. Weinberger*, Va.1978, 98 S.Ct. 2498, 412 U.S. 640, 37 L.Ed.2d 230.

Drug manufacturer, who had opportunity to litigate jurisdictional question whether drug product was a "new drug" before Food and Drug Administration and to raise issue on appeal to a court of appeals to review withdrawal order, could not relitigate the issue in a separate proceeding for a declaratory judgment. *CIBA Corp. v. Weinberger*, N.J.1978, 98 S.Ct. 2495, 412 U.S. 640, 37 L.Ed.2d 230.

Plaintiffs who were in commercial business of selling laetrile, who did not need drug, and who did not allege that they were unable to afford new drug application procedures, were not entitled to relief in their action for declaratory judgment that laetrile is a food and is not a new drug and for order decreeing that no agency of United States has right to interfere with importation and distribution of laetrile on theory that it is unconstitutional to deny consumer of laetrile opportunity to obtain it because consumer cannot afford costly procedures required for new drug application. *Hanson v. U.S.*, D.C.Minn.1976, 417 F.Supp. 30, affirmed 540 F.2d 947.

Where issue of whether drug is "new drug" was matter within the primary jurisdiction of the Food and Drug Administration and judicial review would be available following the adminis-

trative determination, the district court, in exercise of its sound discretion under Declaratory Judgment Act, section 2201 et seq. of Title 28, would refuse to take jurisdiction of action for declaration that particular drugs were not "new drug." *National Ethical Pharmaceutical Ass'n v. Weinberger*, D.C.S.C.1978, 365 F.Supp. 735, affirmed 503 F.2d 1051.

30. Prescription drugs

Prescription drugs on market are subject to efficacy requirements of this chapter. *USV Pharmaceutical Corp. v. Weinberger*, Va.1978, 98 S.Ct. 2498, 412 U.S. 640, 37 L.Ed.2d 230.

Manufacturer of pioneer antibiotic drug was not entitled to protection of amendment to Federal Food, Drug and Cosmetic Act preventing any manufacturer of prescription pharmaceutical drugs from marketing generic version of drug for five years from date of pioneer drug's approval, where drug had not been submitted and approved pursuant to referenced section and had been approved pursuant to another section and only thereafter exempted and subsequently regulated under governing statute. *Glaxo, Inc. v. Bowen*, E.D.N.C.1986, 640 F.Supp. 933.

31. Drugs administered by physicians

Whether or not endocrine drug was a "new drug," operators of weight reduction clinics were not required to seek Food and Drug Administration approval for use of the drug in treatments administered by licensed physicians. *F.T.C. v. Simeon Management Corp.*, D.C.Cal.1975, 391 F.Supp. 697, affirmed 532 F.2d 708.

The Food and Drug Administration does not have jurisdiction to regulate the administration of a drug by a physician. *F.T.C. v. Simeon Management Corp.*, D.C.Cal.1975, 391 F.Supp. 697, affirmed 532 F.2d 708.

32. Notes of approval

Where Food and Drug Administration had issued and published in the Federal Register a new "Notice of Opportunity for Hearing" on proposal withdrawing approval of New Drug Applications for "Alevaire," a muco-eva-cuant drug, and the notice made specific reference to Court of Appeals decision which permitted the notice, the Administration would not be required to publish notice of reinstatement of approval of the new drug applications in the Federal Register. *Sterling Drug Inc. v. Weinberger*, C.A.2, 1974, 503 F.2d 675.

32a. Opinion letters

Issuance of opinion letter stating that particular drug product would not require clearance under "new drug" procedure was beyond statutory authority of Food and Drug Administration, which had no legal authority to permit marketing of the product without new drug application approved for safety and efficacy. *U.S. v. Articles of Drug ... HORMONIN*, D.C.N.J.1980, 498 F.Supp. 424, affirmed 672 F.2d 902, 904.

33. Remedy

This section which provides that court may order additional evidence to be taken and to be adduced upon hearing in such manner and upon such terms as to court may seem proper and that Commissioner may modify findings as to

facts by reason of additional evidence gives court broad authority to fashion a remedy capable of balancing fairness to new drug applicant against public's right to expeditious enforcement of this chapter. *Smithkline Corp v. Food and Drug Administration*, 1978, 587 F.2d 1107, 190 U.S.App.D.C. 210.

Creation of federal common-law damages remedy under this chapter was not necessary to enforcement of claims asserted in individual's suit against drug companies to recover damages arising out of purchase of allegedly ineffective drugs, since cause of action in question was of kind traditionally governed by state law. *Consumer Federation of America v. Upjohn Co.*, D.C.App.1975, 348 A.2d 725.

34. Remand

Where trial before district court should not have occurred, and its record was part of administrative record on remand solely for information it contained and as a matter of administrative convenience, the Food and Drug Administration, in proceeding on claimant's request for relabeling of medical devices, was not bound by findings of the district court, and fact that trial procedure took place did not transform the Administration's decision-making process into adjudicatory hearing. *U.S. v. An Article of Device* ... *Diapulse*, C.A.7 (Ill.) 1985, 768 F.2d 826.

There was no error in refusing to remand to the Food and Drug Administration for development of an administrative record in support of Food and Drug Administration's contention that drug was a new drug requiring approval of a new drug application, where the Administration had only instituted condemnation proceedings against a certain quantity of the drug and injunction proceedings against a single drug manufacturer, so that its action was not in the nature of a declaratory order, and where determination that the drug was a "new drug" for purposes of condemnation and injunction proceedings was made by the district court following trial. *U.S. v. X-Otag Plus Tablets*, C.A.Colo.1979, 602 F.2d 1387.

§ 356. Certification of drugs containing insulin

(a) The Secretary, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

[See main volume for text of (b) and (c)]

(As amended June 16, 1992, Pub.L. 102-300, § 6(b)(2), 106 Stat. 240; Aug. 13, 1993, Pub.L. 103-80, § 3(o), 107 Stat. 777.)

If Food and Drug Administration has not developed adequate administrative record to permit determination whether laetrile is properly classified as a new drug, appropriate procedure for district court is to remand the case to the FDA for proceedings adequate to develop the record; such proceedings should give laetrile proponents an opportunity to express their views. *Rutherford v. U.S.*, C.A.Ok.1976, 542 F.2d 1187, on remand 424 F.Supp. 105.

35. Investigatory drugs

Food and Drug Administration (FDA) had authority, under statute regulating new drug investigations, to impose recordkeeping requirements on clinical investigators of new drugs, in light of dangers incumbent in receipt of false data. *U.S. v. Garfinkel*, C.A.8 (Minn.) 1994, 29 F.3d 451.

Food and Drug Administration (FDA) regulation permitting Defense Department to use unapproved, investigational drugs on military personnel, without service member's informed consent, in certain combat-related situations, was within FDA's rule-making authority under Food, Drug, and Cosmetic Act, which provided for use of unimproved investigational drugs only on the informed consent of human subjects affected "except where [the experts administering the drug] deem [the human subject's consent] not feasible." *Doe v. Sullivan*, C.A.D.C.1991, 938 F.2d 1370.

36. Labeling information

Plaintiffs could not recover from name brand manufacturer for death of their daughter who died as result of ingesting generic equivalent of drug on theory that negligent misrepresentations on generic drug's label were merely copied, as permitted by federal law, from name brand manufacturer's label; manufacturer of generic drug was responsible for accuracy of labels placed on its products and name brand manufacturer's statements regarding its drug could not serve as basis for liability for injuries caused by another manufacturer's drug. *Foster v. American Home Products Corp.*, C.A.4 (Md.) 1994, 29 F.3d 166.

1 and Pub.L. 96-88 and Pub.L. 102-300, the amendment resulted in no change in text.

1992 Amendments

Subsec. (a). Pub.L. 102-300, § 6(b)(2), struck out "of Health, Education, and Welfare" following "The Secretary".

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L.

CODE OF FEDERAL REGULATIONS

Drugs composed wholly or partly of insulin, see 21 CFR 429.3.

§ 357. Certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin or any other antibiotic drug

(a) Regulations prescribed by Secretary; release prior to certification; "antibiotic drug" defined

The Secretary, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs (except drugs for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof. For purposes of this section and of section 352(l) of this title, the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

[See main volume for text of (b) to (d)]

(e) Exempted new drugs subject to section 355 of this title; request for certification of exempted drug; determination of compliance with sections 351(b) and 352(g) of this title

No drug which is subject to this section shall be deemed to be subject to any provision of section 355 of this title except a new drug exempted from the requirements of this section and of section 352(l) of this title pursuant to regulations promulgated by the Secretary. For purposes of section 355 of this title, the initial request for certification, as thereafter duly amended, pursuant to this section, of a new drug so exempted shall be considered a part of the application filed pursuant to section 355(b) of this title with respect to the person filing such request and to such drug as of the date of the exemption. Compliance of any drug subject to section 352(l) of this title or this section

96-88, Title VI, Oct. 17, 1979, 93 Stat. 696, set out as a note under section 3401 of Title 20, Education, deemed to refer and apply to the Department of Health and Human Services or the Secretary of Health and Human Services, respectively, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under Pub.L. 96-88, Title III, §§ 301 to 307; Oct. 17, 1979, 93 Stat. 677 to 681. See section 8441 to 8447 and 8508 of Title 20.

Federal Policy Regarding the Export of Banned or Significantly Restricted Substances

For provisions relating to the applicability of the term "banned or significantly restricted substance", as defined, and the Federal policy regarding the export of banned or significantly restricted substances, see section 1-101 of Ex. Ord. No. 12284, Jan. 15, 1981, 46 F.R. 4659, set out as a note under section 2403 of Title 50, Appendix, War and National Defense.

HISTORICAL AND STATUTORY NOTES

1993 Amendments

Subsec. (a). Pub.L. 103-80, § 3(a) directed

Secretary Administrator" and "Administrator"