

**Final FDA Rule on Over-The-Counter Drug Labeling**

- FDA's final over-the-counter drug labeling rule would establish standardized format and content requirements for the labeling of *all* OTC drug products. The rule is intended to help consumers read and understand the labels of OTC drugs so that they can use these products safely and effectively.
- The standardized format and content includes:
  - Specific headings and subheadings (e.g. "Warnings" and "Ask a doctor if you have...") which must be placed in a specified order;
  - Standardized graphical features (e.g. use of Helvetica type only and use of "bullets"); and
  - Minimum standards for type size and spacing;
- FDA received more than 1800 comments on the proposed rule, the majority of which generally supported the agency's initiative to standardize the format of OTC drug labeling (including NDMA and many individual drug manufacturers).
- However, three areas remain controversial:
  - (1) Many commenters raised significant concerns about the proposed rule's lack of flexibility for products marketed in small packages and products marketed as drug-cosmetics (such as Blistex and a range of products that contain sunscreen). FDA has provided some flexibility with a modified labeling format for certain small packages. However, many products will still not be able to meet the requirements without increasing their package size.
  - (2) There is also considerable controversy over whether or not pharmacists and other health professionals should be included in the label (e.g. "Ask your doctor or pharmacist if..."). FDA has included pharmacists in warnings concerning drug-drug or food-drug interactions but not warnings for persons with preexisting conditions or symptoms. FDA has not included the term "health professional" except with the existing pregnancy warning.
  - (3) The minimum type size proposed by FDA generated significant comment. Consumer groups believe that the proposed 6-point minimum font is the smallest font readable for certain population groups; many others (particularly from the industry) argue that FDA's minimum takes up too much space, particularly on small packages, and that greater flexibility should be provided in this area. FDA's final rule does not change the required minimum 6-point font.
- We think this is an important initiative and would make a good event. However, it may take us several more weeks to resolve our issues with FDA.

# New Standard Labeling Format

<b>Drug Facts</b>							
<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>						
Chlorpheniramine maleate 2 mg.....	Antihistamine						
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat							
<b>Warnings</b> Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives							
<b>When using this product</b> ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children							
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.							
<b>Directions</b> <table border="1"> <tbody> <tr> <td>adults and children 12 years and over</td> <td>take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours</td> </tr> <tr> <td>children 6 years to under 12 years</td> <td>take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours</td> </tr> <tr> <td>children under 6 years</td> <td>ask a doctor</td> </tr> </tbody> </table>		adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours	children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours	children under 6 years	ask a doctor
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<b>Drug Facts (continued)</b>
<b>Other information</b> ■ store at 20-25° C (68-77° F) ■ protect from excessive moisture
<b>Inactive ingredients</b> D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

## Existing Label

# Allergy Tablets

**INDICATIONS:** Provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies.

**DIRECTIONS:** Adults and children 12 years and over—1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours or as directed by a physician. Children 6 to 11 years—one half the adult dose (break tablet in half) every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours. For children under 6 years, consult a physician.

**EACH TABLET CONTAINS:** Chlorpheniramine Maleate 4 mg. May also contain (may differ from brand): D&C Yellow No. 10, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch.

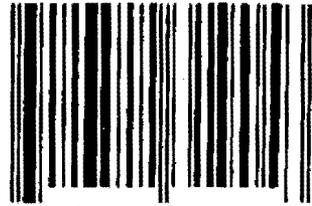
**WARNINGS:** May cause excitability especially in children. Do not take this product unless directed by a physician, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. May cause drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages, and do not take this product if you are taking sedatives or tranquilizers without first consulting your physician. Use caution when driving a motor vehicle or operating machinery. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Store at controlled room temperature 2°-30°C (36°-86°F).

Use by expiration date printed on package.

Protect from excessive moisture.

For better identification keep tablets in carton until used.



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*Office of Information and Regulatory Affairs  
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Room 10235  
Washington, DC 20503*

**FAX TRANSMITTAL**

FAX: 202-395-6974  
DATE: 7/3  
TO: Chris Jennings  
FROM: Wendy Taylor - 5-4815

Total number of pages (Including Transmittal Sheet): 3  
Recipient's Fax Number: 67431  
Recipient's Telephone Number: \_\_\_\_\_

Comments: Attached is the report language from the Committee on the pediatric studies provision. Hope this helps. I'm still trying to track down who the patent experts are within the EOP. The draft rule just arrived in my box. We'll move it as quickly as we can.

- Wendy

is no different for food contact substances being marketed subject to a PMN.

Section 617(c) specifies that this legislation shall be effective following 18 months from the date of its enactment. PMNs may be filed after this period (and become effective 120 days after their receipt by FDA) without regard to whether FDA has issued regulations implementing this legislation.

*Sec. 617. Health Claims For Food Products.*

Section 617 amends section 403(r)(3) (21 USC 343(r)(3)) of the FFDCA. It provides an alternative to the current standard and review process by allowing health claims to be made based on information published by authoritative U.S. government scientific bodies. The new provision will allow a health claim in food labeling without FDA authorization, if it consists of or will otherwise summarize or reflect information contained in a publication of a Federal Government scientific organization or some component of the National Academy of Sciences. If any such health claim is made, it must be submitted to FDA, along with the published information on which it is based, at least 120 days prior to its appearance in the marketplace. A claim meeting the requirements may be made until a final regulation, prohibiting or modifying the claim, becomes effective, or a U.S. District Court determines that the nutritional claims requirements have not been met.

*Sec. 618. Pediatric Studies Marketing Exclusivity.*

Section 618 amends Chapter V (21 USC 351 et. seq.) of the FFDCA by creating new section 505A--Pediatric Studies of Drugs. If, prior to the approval of a new drug, the Secretary determines that information about the drug will produce health benefits in a pediatric population, and makes a written request for pediatric studies, and the studies are completed and accepted, then the sponsor or manufacturer can qualify for up to 6 months of extra market exclusivity. If the Secretary makes a written request for pediatric studies of an already marketed drug, and those studies are completed, then the manufacturer can be granted up to 6 months of increased market exclusivity as well.

Within 180 days of enactment, the Secretary, after consultation with experts, must develop and publish an initial list of approved drugs for which additional pediatric information may produce health benefits. When the Secretary has formally requested pediatric studies those studies must be conducted by a written protocol agreed to by the sponsor, patent holder, and the Secretary. Less than 60 days after the pediatric studies have been submitted, the Secretary must determine whether the studies were done properly and notify the sponsor or holder. In addition, the provision contains a section describing other means by which the study protocol requirements can be met.

This section contains a sunset provision that states that no market exclusivity will be granted based on pediatric studies begun after January 1, 2004. In addition, the Secretary must complete a study and report to Congress no later than January 1, 2003, the agency's experience under the program. The report must address the program's effectiveness, the adequacy of its incentives, the program's economic impact, and any suggestions for the program's modification.

Sec. 619. Positron Emission Tomography.

Section 619 amends the FFDCA to include the regulation of compounded positron emission tomography (PET) drugs. The provision defines compounded PET drugs to mean drugs that exhibit spontaneous disintegration of unstable nuclei; includes nonradioactive reagents, nuclide generators, accelerators, electronic synthesizers, or associated software used to prepare any such drug; and, which have been compounded in accordance with State law by or on the order of a practitioner licensed in that State or in a federal facility in accordance with the laws of the State in which it is located. The Act is amended to stipulate that a compounded PET drug is adulterated, and thus subject to regulatory and/or legal action by FDA if it is not compounded, processed, packed, or held in accordance with the PET compounding standards and official monographs of the United States Pharmacopoeia (USP).

The act is further amended to provide that neither a New Drug Application (NDA) nor an Abbreviated New Drug Application (ANDA) is required by a licensed practitioner to produce a compounded PET product in accordance with USP standards. Within 30 days of enactment, the Secretary must publish in the Federal Register a notice revoking all previously published efforts by FDA to provide industry guidance and regulatory standards for PET products.

TITLE VII-FEES RELATING TO DRUGS

Sec. 701. Short Title.

Section 701 provides that this title be cited as the "Prescription Drug Users Fee Reauthorization Act of 1997."

Sec. 702. Findings.

Section 702 sets forth four congressional findings: (1) the prompt approval of safe and effective new drugs and other therapies is critical to improve public health; (2) additional resources augmenting the Food and Drug Administration's (FDA) review of human drug applications serve the public health; (3) the successful Prescription Drug User Fee Act of 1992 (PDUFA) program reduced drug review times; therefore it should be reauthorized for an additional 5 years and should be carried out by FDA with more ambitious and comprehensive regulatory goals; (4) fees authorized by amendments will be used to expedite the drug