

*Reinventing
the Regulation of*

DRUGS MADE FROM
BIOTECHNOLOGY



PRESIDENT BILL CLINTON
VICE PRESIDENT AL GORE

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**REINVENTING THE
REGULATION OF DRUGS MADE
FROM BIOTECHNOLOGY**

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OVERVIEW

Introduction

In March 1995, President Clinton announced a series of regulatory reform initiatives designed to reduce the burden of FDA regulations on the drug and device industries without sacrificing any of the health and safety protections that the American people rightly expect for these products. The report, *Reinventing Drug and Medical Device Regulations*, issued by Vice President Gore's National Performance Review, announced initiatives that will streamline the regulation of drugs and medical devices.

Today's report focuses on FDA's efforts to reform the regulation of biotech drugs used for therapy. The changes outlined in this report represent the most significant overhaul of the regulation of biotech drugs the FDA has ever attempted. FDA will in essence harmonize its regulation of biotech drugs that qualify as "well-characterized," making uniform the requirements of its two product centers responsible for helping to ensure the safety and effectiveness of biologic drugs: the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). According to the biotechnology industry, these changes will save their companies millions of dollars, reduce the required paperwork by thousands of pages, and cut drug development time by months. At the same time, the agency believes that these modifications will not diminish the safety and effectiveness of biotech drugs.

For well-characterized, therapeutic biotechnology-derived drugs—a definition that includes most biotech drugs—FDA will:

- eliminate CBER's existing requirement that manufacturing facilities be separately licensed; and
- eliminate the existing policy under which CBER evaluates and releases individual lots of biotech drugs after the drugs have been approved.

For all biologics, including biotech drugs regulated by CBER, FDA will:

- replace with one form the 21 different approval application forms for biotech drugs, blood, vaccines, and other drugs;

- eliminate the current requirement that promotional labeling be approved prior to the launch of a biologic and for 120 days following its approval;
- decide within 30 days whether newly submitted information supports the initiation or continuation of a human investigation that the agency has put on hold; and
- permit a corporation to designate more than one person to act as a "Responsible Head" in dealings with CBER.

These initiatives will greatly streamline the regulation of biotech drugs, harmonize the requirements with respect to manufacturing, and facilitate the development and marketing of new biotech drugs.

Background

Two FDA operating components regulate drugs: CBER, which regulates blood, vaccines, human tissues and many drugs derived from living organisms, principally under the Public Health Service Act; and CDER, which regulates other drugs under the Federal Food, Drug, and Cosmetic Act.

The drugs made from living organisms regulated by CBER are subject to statutory requirements in addition to those governing all other drugs. For statutory reasons, and historical reasons, the two centers have approached the regulation of biotech drugs somewhat differently. For example, CBER has required two separate licenses for every biotech drug that it regulates: (1) a product license; and (2) an establishment license for each facility in which the drug is manufactured. CBER has also required "lot-by-lot release" for the biotech drugs that it regulates, which means that CBER authorizes the release of individual lots.

The agency is now proposing to harmonize the two centers' policies and requirements for therapeutic biotech drugs that qualify as "well-characterized," which includes most biotech drugs.

FDA'S PROPOSALS FOR REFORM

Elimination of the Requirement for an Establishment License Application for Most Biotech Drugs

Background: Section 351 of the Public Health Service Act, which is administered by CBER, requires that biologics be manufactured in establishments holding a license. CBER currently requires manufacturers of all biologics, including the biotech drugs it regulates, to obtain approval of an establishment license application for each facility in which a biologic is to be manufactured. In addition, both CBER and CDER require drug manufacturers to obtain approval of a separate product application prior to marketing a new drug or a new biologic. According to companies that manufacture biotech drugs, complying with the establishment license application requirement can cost millions of dollars, require the filing of thousands of pages of information, and delay the submission of an application to the agency by several months. Thus, the requirement for establishment license applications places a significant burden both on industry, which must produce them, and on the agency, which must review them.

Technical advances over the last 15 years have greatly increased scientists' ability to control the manufacture of many biotech drugs. After over a decade of experience with these drugs, the agency has found that it can review the safety, purity, potency, and effectiveness of most biotech drugs regulated by CBER without requiring a separate establishment license.

Proposal: CBER will eliminate the requirement for submission and approval of establishment license applications for therapeutic biotech drugs that are "well-characterized." In place of the establishment license application, CBER will evaluate the adequacy of manufacturing facilities by inspection for compliance with good manufacturing practices and through the use of a new chemistry, manufacturing, and controls section of a newly revised product license application. The format and content of the product license application will be harmonized with a slightly revised new drug application for the well-characterized biotech drugs regulated by CDER. (The new drug application revision will consist of the addition of a simple one-page floor plan sufficient to allow an FDA reviewer to visualize the production of the drug, but will not require a detailed description of equipment placement.) CDER and CBER will use the same technical guidance documents.

The harmonization across centers of the chemistry, manufacturing, and controls format and content will also reduce the amount of information that biotech companies will need to provide in the product license application. For example, in many instances manufacturing facility information will not be submitted to the agency, but will be reviewed during good manufacturing practice inspections.

Preapproval inspections for biotech drugs regulated by CBER will continue to be done jointly by headquarters and field staff. These inspections will be comparable to the inspections currently conducted for biotech drugs regulated by CDER. To ensure that inspection procedures for biotech drugs will be consistent across the centers and the field, the FDA will train its scientists and inspectors using the same principles.

As described in the National Performance Review's report on *Reinventing Drug and Medical Device Regulations*, FDA has already begun reducing requirements for preapproval of manufacturing and site changes. Under this proposal, manufacturing and site change requirements for biotech drugs will be harmonized across CBER and CDER. To implement this proposal, the agency will develop a definition of "well-characterized" biotech drugs. The agency anticipates that most therapeutic biotech drugs regulated by CBER will fall within this definition and, therefore, will be exempted from the requirement to submit and have approved a separate establishment license application. To refine the agency's definition of well-characterized biotechnology-derived biologic drugs eligible for these streamlining efforts, FDA is also sponsoring a public scientific workshop on Dec. 11-13, 1995.

The agency anticipates that the workshop may identify additional product classes that could be exempted from the establishment license application requirements.

FDA believes that these changes in regulatory procedures and requirements will not diminish the safety, purity, potency, and effectiveness of biotech drugs. This is because with in-process control and process validation, the identity of the drugs to which the changes apply can be determined, their purity can be controlled and quantified, their activity and quantity can be measured, and both the manufacture and the end-product release specifications can be validated.

Impact: Companies developing and manufacturing most biotech drugs regulated by CBER will no longer have to prepare establishment license applications and submit them to the agency for approval. The amount of information that companies will need to provide in the product license application will also be reduced. These proposed changes will get biotech drugs to market faster and will enable companies to devote more resources to developing drugs and ensuring that they are manufactured appropriately, and fewer resources to submitting documentation to the agency. This change will especially benefit small biotechnology companies that lack experience in preparing establishment and product license applications. According to companies, the establishment license application

requirement adds substantially to the cost of biotech drug approval.

These proposed changes will also harmonize the requirements across the agency concerning a company's ability to contract out manufacture of its well-characterized therapeutic biotech drugs. These proposals will eliminate the requirement that each separate contract facility engaging in significant production steps obtain its own establishment license. Instead, each such biotech drug will be covered by only one marketing application, which lists all manufacturing locations, regardless of how many separate companies are involved in its manufacture.

Implementation and Timeline: Within 45 days, the agency will issue a proposed rule under which companies manufacturing "well-characterized biotechnology-derived drugs" would not be required to obtain a separate establishment license. The proposal will allow 30 days for comment. The agency will publish a final rule 75 days after the close of the comment period.

Elimination of Lot Release Requirements for Biotech Drugs

Background: Biologics have traditionally been complex mixtures of substances produced primarily from living organisms, and have been difficult to define by precise tests. They include vaccines, products made from human or animal blood, and other products made from a variety of materials. Because of the inherent variability of these products, each individual lot of most biologics has been subject to evaluation and testing by FDA.

Historically, the lot release requirement has served an important role in the regulation of biological drugs and has prevented the distribution of unacceptable lots. Greater control has been achieved by manufacturers over the production of biotech drugs through in-process controls, process validation, and recent advances in analytical techniques. For well-characterized therapeutic biotech drugs, the agency has found that once a company has demonstrated its ability to consistently produce acceptable lots, and has procedures in place that will prevent the release of lots that do not meet release specifications, it is not necessary for FDA to verify that each manufactured lot is acceptable for release.

Proposal and Justification: Once a well-characterized therapeutic biotech drug has been licensed for marketing and its manufacturing process has been validated, it will not be subject to lot-by-lot release by FDA. The agency will monitor companies' compliance with the requirement that they assay each lot and release only those that meet release specifications. In light of the developments in manufacturing and testing for well-characterized biotech drugs, FDA's lot-by-lot release is not necessary.

Impact: The elimination of lot-by-lot release of biotech drugs will result in a significant savings of time and resources for both the industry and the agency. There will be no significant additional risk to public health because these drugs are well-characterized and do not warrant direct agency participation in quality-assurance testing.

Implementation and Timeline: The agency will immediately begin sending letters to affected companies advising them of the change in the lot-by-lot release policy. Within 30 days, the agency will issue a notice describing the elimination of lot-by-lot release for well-characterized therapeutic biotech drugs.

Harmonized Application Format for All Drugs and Biologics

Background: CBER currently uses 19 different product license application forms and a separate establishment license application form. In addition, CDER has a separate new drug application form. This is confusing for the industry.

Proposal and Justification: The agency will consolidate the 21 different application forms into one. The harmonized form will contain a technical section on the establishment, which will be applicable only to those biologics for which establishment application review will continue to be necessary. The agency also intends to include some elements from the European Community format in order to facilitate international harmonization of applications.

In addition to a harmonized application form, the technical requirements and guidance documents will be the same across the agency for well-characterized therapeutic biotech drugs, regardless of which center regulates them. Also, the agency will harmonize its procedures regarding contracting out manufacture of drugs and biologics.

Impact: Companies will be able to provide higher quality submissions. Time to prepare applications will be reduced because forms will be standardized.

FDA will reduce 21 applications to one application. The standard format should expedite review by FDA staff and can be used as a basis for electronic submissions.

Implementation and Timeline: Within 60 days, CBER will make available a draft form which companies may choose to use for product license applications for well-characterized therapeutic biotech drugs. Within six months, FDA will publish a proposed revised application form for all drugs and biologics.

Elimination of the Preapproval Requirement for Promotional Labeling

Background: CBER currently requires preapproval of promotional labeling prior to launch of a new biologic and for 120 days following approval of a new biologic. This is inconsistent with what is required by CDER, which requires companies to send such information to the agency at the time the company disseminates it.

Proposal and Justification: CBER will change its current policy that labeling in connection with the launch of a new product be approved.

Impact: Industry will no longer need to await approval of promotional labeling prior to disseminating it. Agency resources will be freed up to accomplish other review activities.

Implementation and Timeline: Effective immediately, the agency will no longer require preapproval of promotional labeling. The agency will promptly issue a *Federal Register* notice announcing this new policy.

Agency Responses to Data Submitted Regarding Clinical Holds

Background: Companies or individuals that intend to study investigational drugs or biologics in humans must first submit an investigational new drug (IND) application to the agency. They may proceed with the study 30 days after the agency receives the application, unless FDA puts the study on clinical hold. A clinical hold is a directive issued by FDA that prevents the clinical study from proceeding. Thus, a researcher or company that intends to begin testing a new biologic or drug in humans, or is in the process of testing a new biologic or drug in humans, may not begin or continue the study until FDA releases the clinical hold. Currently, FDA has no internal requirements regarding how much time it may take to evaluate data submitted by the sponsor in response to the clinical hold. While the agency has generally responded in a timely manner, sponsors would like the predictability engendered by an agency commitment to respond within a specified time frame.

Proposal and Justification: FDA will commit itself to review and respond to data submitted in response to a clinical hold within 30 days of receiving the submission. Unless FDA responds within that period, the investigation may proceed. FDA believes that the 30-day period will meet the needs of sponsors, and is within the resource capabilities of the agency.

Impact: The proposed change will prevent delays in agency review of data submitted in response to a clinical hold on an IND, and thus prevent unnecessary delays in the start or continuation of clinical studies.

Implementation and Timeline: FDA will publish within six months a guidance document establishing new procedures for reviewing data submitted in response to clinical holds on INDs.

Revision of the Requirements for a Responsible Head for Biological Establishments

Background: Manufacturers of biological products are required to name a "Responsible Head" who is to exercise control of the manufacturing establishment in all matters relating to compliance with the regulations and who is to represent the manufacturer in all dealings with FDA. This individual must have an understanding of the scientific principles and techniques related to the manufacture of biological products.

In the past, biological product manufacturers typically were small companies, such as blood banks, that made products at one location. The requirement that a single responsible head represent the company was practical for such small operations. Today, however, manufacturers of biological products tend to be larger firms with more manufacturing locations and more complex corporate structures. Most companies do not have one person with the knowledge to represent a company in all matters, but instead have several people with expertise in regulatory affairs, manufacturing, and medical issues.

Proposal and Justification: FDA proposes to revise its requirements for a "Responsible Head" to allow more flexibility to assign control and oversight responsibility within a company. The revisions will still ensure the proper oversight and accountability within a firm, but will conform to the way biological firms assign responsibilities to their senior experts.

Impact: Firms will be able to divide management responsibility among appropriate regulatory, medical, or manufacturing staff. These individuals will be able to directly communicate with the agency on official matters related to biological products they manufacture.

Implementation and Timeline: FDA will publish a proposal to revise the regulation within nine months.

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Reinventing

F O O D

Regulations



PRESIDENT BILL CLINTON
VICE PRESIDENT AL GORE

JANUARY 1996

*Reinventing
the Regulation of*

C A N C E R
D R U G S



PRESIDENT BILL CLINTON
VICE PRESIDENT AL GORE

MARCH 1996

**REINVENTING THE REGULATION
OF CANCER DRUGS**

ACCELERATING APPROVAL AND EXPANDING ACCESS

**President Bill Clinton
Vice President Al Gore**

National Performance Review

March 1996

OVERVIEW

Introduction

The Food and Drug Administration has demonstrated a longstanding commitment to the prompt consideration and, when appropriate, early approval of new therapies for cancer patients. However, the overall process of developing a new agent is a complex one, and a substantial period exists between the first introduction of the agent into humans and the completion of clinical trials leading to formal submission of an application.

Faster Approvals

In order to speed up the entire process further, FDA is adopting a uniform policy that will permit accelerated approval of a significant number of new cancer therapeutics. In the past, FDA has approved cancer therapies on the basis of an agent's ability to produce an effect on the well-established and long-recognized criteria such as survival, improved quality of life, and relief of symptoms, as well as objective disease regression. When partial response of disease (measurable but incomplete tumor shrinkage) has been noted in patients who have extensive or metastatic cancer, it has often correlated with the other approval criteria. Because of this experience, FDA believes that for many cancer therapies it is appropriate to utilize objective evidence of tumor shrinkage as a basis for approval, allowing additional evidence of increased survival and/or improved quality of life associated with that therapy to be demonstrated later. By utilizing objective response as a surrogate endpoint in cancer clinical trials, FDA will decrease the total time needed for marketing approval in many situations.

Expanded Access

FDA is also committed to helping provide greater patient access to potentially effective cancer treatments even before full marketing approval, wherever possible. So-called "expanded access" mechanisms, such as Treatment Investigational New Drug (IND) protocol, the Group C Program, and "compassionate use" (single patient) protocols have been successfully utilized. They permit patients to receive promising but not yet fully studied or approved cancer therapies—that are undergoing clinical testing—when no other satisfactory options exist. To facilitate this availability even more, FDA is adopting a policy that will actively encourage the submission of expanded access protocols for U.S. patients for therapies that are approved in other countries. This policy will help ensure that

promising new therapies are available in the United States near the time of their availability in other countries and will ease the burden on commercial sponsors of preparing an expanded access protocol submissions.

Listening to Patients/Removing Barriers

FDA is undertaking two additional efforts that should positively affect the review of new cancer therapies. One policy will improve the representation of patients with disease-specific perspectives on FDA's cancer-related advisory committees. The second policy will reduce the number of IND Applications required for additional studies of already approved therapies.

FDA is undertaking these initiatives after carefully considering suggestions and advice offered by patients and their advocates, pharmaceutical industry representatives, physicians, and researchers. The Agency will continue to seek their views, as well as those of FDA advisory committees and the National Cancer Institute. FDA's intention is to foster expanded access to promising cancer treatments because cancer is among the greatest public health problems facing the United States. These initiatives are also prompted by the increasingly large number of cancer therapies being developed by the pharmaceutical and scientific communities and the demonstrated willingness of these communities to find the best use of new agents by continuing to study them after initial approval. FDA wishes to encourage the rapid development and availability of these and future therapies.

FDA'S PROPOSALS FOR REFORM

Accelerating Approval of Cancer Therapies For Primary and Secondary Indications

Background: Currently, FDA may utilize the "accelerated approval" process to allow marketing of therapeutics for patients with serious and life-threatening diseases. Under existing regulations, a new drug or biologic agent that is intended to provide a meaningful therapeutic benefit over existing therapies may be approved on the basis of:

adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval under this section will be subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit, where there is uncertainty about the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome. Postmarketing studies would usually be studies already underway. When required to be conducted, such studies must also be adequate and well-controlled. The applicant shall carry out any such studies with due diligence.

(21 CFR § 314.510 and 21 CFR § 601.41.)

Although the accelerated approval provisions have been applicable to promising treatments for cancer patients who do not benefit from or cannot tolerate available therapy, this approval mechanism has not been frequently utilized, largely because general agreement on reasonable surrogate endpoints has been lacking.

Until now, therapies for cancer patients have usually been approved on the basis of objective response to the agent (tumor shrinkage) together with direct evidence that the therapy produces measurable clinical benefit. Typical approval endpoints have included response rate together with increased patient survival, decreased recurrence rate, increased disease-free interval, and/or improved quality of life. It has been assumed that durable, complete clinical response (complete disappearance of detectable tumor) is a valid surrogate for such clinical benefit, but it is only infrequently achieved. Much more commonly, partial tumor shrinkages are induced, and evidence has accumulated that such responses are often directly linked to longer or better patient survival. In fact, for certain new agents, FDA has already begun to rely on a reasonably high rate of verifiable objective partial response to the

therapy as a basis for approval of agents to treat refractory malignancies, without requiring evidence of improved survival or quality of life. Subsequently, additional trials have been conducted to confirm or expand the product's indications. While the predictive value of partial responses may still be a matter of discussion and study for all types of cancer patients, FDA has concluded that for patients with refractory malignant diseases or for those who have no adequate alternative, clear evidence of anti-tumor activity is a reasonable basis for approving the drug. In these cases, studies confirming a clinical benefit may appropriately be completed after approval.

Proposal and Justification: Under this initiative, FDA will substantially expand the use of the accelerated approval process for cancer treatments, based upon verified and recognized demonstration of objective tumor shrinkage. For approval, the potential effectiveness of the treatment should outweigh its toxicities. FDA will also apply the accelerated approval provisions to certain products intended to remove a serious or life-threatening toxicity of cancer treatment.

For products approved on the basis of tumor shrinkage, post-approval studies will usually be required to further define the utility of the new agent for the approved and/or other indications, either alone or in combination with other agents.

For accelerated approval of products that remove treatment-associated toxicities, post-approval studies will be required, as appropriate, to study the effect of the therapy on survival, and/or to demonstrate that the surrogate measures correspond to clinical benefit.

A post-approval study will not necessarily be required in the exact population for which the approval was granted. For example, where a product was approved to treat patients with refractory malignancy, additional information from that population may not, for example, be as useful as randomized, controlled trials in a previously untreated population.

In many instances, additional studies would be already under way at the time the accelerated approval is granted. If such studies are adequate and well-controlled (either utilizing proper historical controls or randomization), they may fulfill the accelerated approval requirements for post-approval studies. All required post-approval studies should be carried out with due diligence. Failure to do so would constitute grounds to withdraw approval of the product application. (21 *CFR* § 314.530(a) or 21 *CFR* 601.43(a).) FDA may also withdraw approval of the application if studies fail to demonstrate clinical benefit. *Id.*

Supplemental Applications: The greater utilization of the accelerated approval provisions for cancer treatments should have an important impact not only on original applications but also on supplemental applications for secondary indications. FDA recognizes that the actual use of cancer agents may be far

broader than the approved indications, and that, because of the nature of cancer therapy, the approved label does not necessarily convey all the medical conditions for which the agent is used and may be useful. Nevertheless, for a variety of reasons, the FDA-approved label should accurately convey as many of the agent's uses as are properly supported by data. FDA encourages the submission of supplemental applications for secondary indications and believes that this initiative will significantly expedite the time to marketing approval.

Impact: This new policy is designed to make it easier to study cancer therapies and shorten the total time for first and subsequent marketing approvals for a wide range of cancer therapeutics. The broader use of accelerated approval will provide an important benefit to patients by permitting the marketing of promising cancer therapies at an earlier time than was previously possible. Although the complete success of this initiative depends upon the commitment of product sponsors, clinical investigators and patients to complete crucial studies after marketing, it is FDA's experience that in the field of oncologic therapy there is a tradition of continuing to study approved products.

Implementation and Timeline: This initiative is effective immediately.

Expanded Access to Investigational Cancer Therapies That Have Been Approved in Other Countries

Background: FDA recognizes that many cancer patients who have exhausted standard therapeutic options, or who do not have such options available, seek access to new treatments that may offer some hope of benefit. They may be willing to accept some risk from products still under study and with potentially dangerous toxicities. While most new agents are available in the United States at about the same time as in other countries, if not earlier, there are occasional exceptions. Cancer patients may feel particular frustration when new cancer treatments are approved elsewhere in the world before they are approved in the United States.

Although the primary purpose of the investigational use of a new product is to generate sufficient data to establish safety and effectiveness, several mechanisms currently exist to allow patients "expanded access" to such products (i.e., to allow patients access to the experimental agent primarily for the purpose of treatment rather than data gathering). These mechanisms include Treatment INDs, Group C drugs made available through the National Cancer Institute, and "compassionate use" (single patient) protocols. Ordinarily, these expanded access options become available after the product has been studied in the United States in a substantial number of patients.

Proposal and Justification: FDA believes that when a cancer therapy is under study in the United States in a controlled clinical trial and has been approved by an identified regulatory authority in a foreign country, there may be an adequate basis to allow early expanded access based on the data package submitted to the foreign regulatory authority. Therefore, whenever a cancer therapy for patients who are not curable or well-treated by currently available therapies is approved by a recognized foreign regulatory authority, FDA intends to contact the U.S. sponsor and encourage the submission of an expanded access protocol, regardless of the length of time that the product has been studied in the United States.¹ The expanded access protocol will be directed at the same general type of patient condition and similar dosage and schedule as formed the basis for the foreign approval. An English-language version of the relevant data submitted to the foreign regulatory authority will be accepted as providing the information needed to consider the expanded access protocol application. If these data are adequate, FDA will permit use of the therapy for appropriate patients under the expanded access protocol.

Recognized Acceptable Regulatory Authorities: For consideration under this policy, a foreign regulatory authority is to be identified as having review practices, review standards, and access to

¹ If there is currently no U.S. sponsor, the FDA will contact the foreign sponsor and encourage it to file an IND. Once the IND is filed, FDA will encourage submission of an expanded access protocol.

specialized expertise in the evaluation of agents for use in cancer treatment that are sufficient to allow FDA to conclude that a marketing approval action by that authority is likely to provide an adequate basis for proper consideration of an expanded access protocol for U.S. patients.³

Types of Treatments to Which This Policy Applies: FDA will encourage submission of expanded access protocols for therapeutic products under study in the United States that have been approved in a foreign country for treatment of patients with forms and stages of cancer that are not adequately treated by therapies currently approved in the United States. The route, dose and schedule of administration of the agent will generally be similar to that approved by the foreign regulatory authority, unless the sponsor is able to provide data supporting the safety and potential efficacy of an alternate dosing regimen.

Pursuit of Marketing Approval: To ensure that this process does not become a substitute for obtaining full marketing approval, the sponsor of the product will be required to demonstrate that it is pursuing marketing approval—accelerated or otherwise—with due diligence. (See 21 *CFR* §312.42(b)(4)(vii).) Due diligence requires that the sponsor has begun, or made credible plans for, the early initiation of studies designed to obtain data needed for submission of a marketing application. Such studies should be designed in conjunction with FDA to optimize study designs. There is a risk that the availability of expanded access protocols for an unapproved cancer agent may interfere with the enrollment of patients in the trials intended to support marketing approval. It is therefore imperative that the trials intended to support marketing approval be designed to efficiently enroll patients. FDA believes that one of the best mechanisms for ensuring adequate enrollment is to design the trials so that they offer a hope of personal benefit to the patient-volunteers that is at least equal to the hope of benefit associated with treatment under the expanded access protocol.

Impact: This policy will help make experimental cancer therapies available to patients shortly after they are approved in other countries even if they are early in their U.S. development. Reliance on the data submitted to the foreign authority could also ease the burden on sponsors of preparing a U.S. expanded access application. Under an expanded access protocol, the required data collection from the enrolled patients would usually be relatively limited. Nonetheless, this information has sometimes in the past provided important data for marketing applications. To ensure that this process does not become a substitute for obtaining marketing approval, the sponsor of the therapy will be required to demonstrate that it is pursuing marketing approval—accelerated or otherwise—with due diligence. FDA will work with the sponsor to develop an expanded access protocol that does not interfere with the enrollment of patients in the studies that will support approval.

³For purposes of initiating this policy, countries which use the English language and are identified in Section 802(b)(4)(A) of the Federal Food, Drug and Cosmetic Act will be contacted first.

Implementation and Timeline: To implement this initiative, FDA will establish a system to monitor the approval of new cancer therapies by foreign countries with identified regulatory review authorities. Information from the U.S. FDA about U.S. approvals of new cancer therapeutics will be communicated to them to foster a bilateral exchange. FDA will make initial contact with the identified foreign regulatory authorities within 30 days.

Patient Representation on FDA's Cancer-Related Advisory Committees

Background: FDA relies on several advisory committees to provide the Agency with advice on the consideration of cancer treatments. These panels are composed of individuals from outside the Agency, whose training, skills, and/or experience enable them to offer the Agency needed expertise in making decisions about new medical treatments. Currently, many of these committees include a "technically qualified" public representative who is identified broadly with consumer interests and has been nominated and recommended by a consumer-oriented organization. This individual serves as a liaison with interested consumers and their organizations, as well as other potential constituencies served by FDA, and attempts to represent the perspectives of these groups on issues and actions that come before the committee.

Because there are so many different cancers, the number of appropriate perspectives is larger than a single consumer can represent. As a result, organized patient advocacy groups have requested that their interests be more specifically represented on the advisory committees that consider cancer therapies by the addition of ad hoc representatives who have experience with the specific cancer for which a therapy is under consideration. For certain other advisory committees that review products for other life-threatening diseases, FDA already includes an ad hoc patient representative for the specific condition for which a product is indicated.

Proposal and Justification: It has been FDA's experience that well-informed and motivated representatives of the patient's perspective provide a valuable contribution to the decision making associated with the review of new cancer therapies. FDA has therefore concluded that an ad hoc patient representative with experience in the specific malignancy for which a therapeutic product is under consideration should be included in the advisory committee deliberations concerning that product. This individual will be screened in the same manner as other full members. In order to properly develop a system for selection and service of patient representatives for all future advisory committee meetings on cancer therapies, the agency has enlisted the assistance of an external consultant with expertise in this area.

Impact: This proposal will make more uniform FDA's policy of including patient perspectives on new cancer treatments and responds to public interest in increased participation in the advisory committee process. In addition, the proposal is responsive to a recommendation of the Institute of Medicine's 1992 *Report on FDA Advisory Committees* "that the concept of consumer be expanded to include patients and patient-oriented organizations." Adding participation of ad hoc patient representatives to cancer-related advisory committees will also increase consistency with some other committees that consider products for life-threatening illnesses.

Implementation and Timeline: In order to establish an equitable and efficient framework, FDA is working with an external consultant to develop a model system for recruitment, assessment, selection, and utilization of patient representatives. In the interim, while this report is being considered, the cancer liaison staff in FDA's Office of AIDS and Special Health Issues (OASHI) will:

- Publish a notice in the *Federal Register* to seek greater patient representation on advisory committees that consider cancer therapies, and send letters to individuals and organizations on its cancer mailing list, which includes organizations representing cancer survivors. The letters will invite nominations for candidates to serve as ad hoc representatives to FDA's cancer-related advisory committees. Nominees will be asked to provide copies of their resumés with a brief statement of the disease-related topic for which they would be most appropriate and the details of any financial relationships that they have/had with the persons or companies involved in the manufacture or sale of drugs, biologics and devices.
- When it is decided which products will be considered at an upcoming meeting, the FDA Cancer Liaison Program staff will select appropriately screened and approved nominees for each meeting. The Cancer Liaison Program staff will contact the nominee for each topic, notify the nominee of the general topic to be discussed, and request that the nominee reserve the date of the meeting.
- When specific meeting dates are announced by FDA, the Cancer Liaison Program staff will notify the nominees of the meeting details, ask about conflicts of interest, and confirm availability. The staff will notify the executive secretary of the advisory committee and relevant FDA officials which nominee has been selected.

Clarification of Policy on INDs for Studies of Marketed Cancer Products

Background: Currently, FDA does not require the submission of an IND to study a new use of a marketed drug or biological product, where the agent will be used in generally the same patient population and in generally the same manner for which the agent was approved, and the study is not intended to support approval of the new use or to support a significant change in the labeling or advertising of the product. (21 *CFR* §312.2(b).) Notwithstanding this regulatory exemption, physician-investigators frequently submit INDs for exploratory studies of marketed drugs and biological products for so-called "off-label" uses in situations where an IND is not strictly required. There seem to be two major reasons for these unnecessary submissions: (1) the physician-investigator or Institutional Review Board incorrectly believes that an IND is required, or (2) the pharmaceutical manufacturer agrees to provide the product free-of-charge, but is mistakenly concerned that, unless there is an IND, FDA will view the manufacturer's donation of the product as a promotional activity.

Proposal and Justification: FDA intends to reduce the effort of the clinical investigator by refusing to accept INDs for exempt studies of marketed drugs and biological products. Moreover, FDA will reemphasize that the provision, by a sponsor of a marketed drug or biological product for a study, does not, in and of itself, constitute promotional activity if the product is provided for a physician-initiated, bona fide clinical investigation.

(1) FDA will not accept an IND for the study of a lawfully marketed drug or biological product if the proposed study meets all the criteria specified in 21 *CFR* §312.2(b)(1), as follows:

- The study is not intended to support approval of a new indication or a significant change in product labeling or advertising.
- The study does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with use of the product. Information from previously conducted clinical trials that contain prior human experience relevant to the safety and effectiveness of the drug for a proposed use (e.g., use of larger than usual doses, or use in new combination) can be used to determine the degree of increased risk and the overall acceptability of the risk for the intended study population.
- The study meets the requirements for institutional review and informed consent, and does not commercialize the investigational product.

It is the responsibility of the investigator to determine whether an IND is necessary. Upon request, FDA will provide guidance to physician-investigators about the need for an IND in particular cases.

(2) FDA does not view the supply of a marketed product by the manufacturer or distributor for use in a study, in and of itself, as promotional activity, if the product is provided for a physician-initiated, bona fide clinical investigation. To assess the adequacy of a proposed study, the commercial manufacturer may request review of the investigator's proposed investigational plan. Nothing in this policy prevents FDA from finding that certain subsequent uses of physician-initiated studies by the manufacturer or distributor constitute promotional activity.

Impact: Clinical research will be fostered somewhat by the relief of burdens associated with filing and maintaining an IND. In addition, by not reviewing INDs for exempt studies, FDA will conserve resources that can be redirected to reviewing other applications for promising new therapies.

Implementation and Timeline: This initiative is effective immediately.

THE NEW SBA

Reinventing

SERVICE

TO THE
SMALL BUSINESS COMMUNITY



PRESIDENT BILL CLINTON
VICE PRESIDENT AL GORE

JUNE 12, 1995

THE NEW SBA

**REINVENTING
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THE NEW SBA
REINVENTING SERVICE TO THE
SMALL BUSINESS COMMUNITY

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THE NEW SBA
**REINVENTING SERVICE TO THE
SMALL BUSINESS COMMUNITY**

OVERVIEW

A New Strategy

The Clinton/Gore Administration has pursued an economic strategy that promotes economic growth, reduces the deficit, expands trade, invests in people, and reforms the Government to make it cost less and perform better. The results are clear. The combined rate of unemployment and inflation is at a 25-year low. The deficit has been reduced by \$600 billion. The Federal Government is being cut down to size -- and it is on its way to becoming the smallest it has been since President Kennedy was in office.

We have begun not only to shrink the size of Government, but to change the way Government operates and the way it regulates the private sector. Government must be a partner with business, and small businesses in particular, in creating jobs and expanding economic growth.

America's small business owners foster our Nation's economic growth and prosperity. They expect and deserve a Federal Government that lends a helping hand when it is needed and uses an even hand in applying its regulatory powers. With these goals in mind, President Clinton asked the Small Business Administration ("SBA") to work with small businesses to better understand their needs and to serve them more effectively. This outreach is working. SBA has expanded its loan programs, reduced its own paperwork and regulations, and championed a government-wide effort to streamline regulations. It will accomplish even more in the months to come.

This report contains a description of SBA's recent successes and proposed initiatives as it works to reinvent its own operations and to lessen small business regulatory burdens.

A New SBA

The Clinton/Gore Administration is committed to our Nation's small business community. It has fulfilled that commitment in part by maintaining a vibrant SBA that is expanding its assistance to small businesses and reducing taxpayer costs.

The number of small businesses is growing rapidly -- during the last decade, more than 600,000 new firms have been created annually. Just last year, more small businesses were created than at any time in our country's history. Throughout this period, small businesses created most of the Nation's new jobs. Today, they employ nearly 60 percent of the country's private work force. To help maintain and promote this growth, SBA has taken several important steps during the last two years and has plans to institute many more reforms. In doing so, the agency has worked closely with its customers to ensure that it is providing the right products for the small business marketplace.

In order to promote access to credit, SBA provides loan guarantees to participating lenders under a variety of programs. In fiscal year 1995, nearly \$11.5 billion in long-term credit and other financial assistance will be provided to more than 67,000 small businesses through SBA's network of participating banks, non-bank lenders, certified development companies, and SBA-licensed companies.

SBA has made significant reforms to expand its loan guarantee and capital formation assistance. For example, the new "LowDoc" program features an easy, one-page application and a rapid response, usually within two or three days, for Section 7(a) loan guarantees up to \$100,000. In fiscal year 1993, the year before the program was implemented, 30 percent of SBA's guaranteed loans were under \$100,000. Thus far in fiscal year 1995, the figure is 63 percent.

SBA has proposed legislation that would dramatically reduce the government's cost of the Agency's financing programs while expanding the number of small businesses served. If these proposals are adopted, SBA will provide financing to more than 92,000 small firms in fiscal year 1996 and reduce to zero the government's subsidy cost of providing small business loans under both the 7(a) and 504 programs.

SBA provides much-needed business education and training to small business owners. In 1994 the Agency provided counseling and training to more than 800,000 of its small

business clients through resource partners such as Small Business Development Centers (SBDCs) and the Service Corps of Retired Executives (SCORE). SBA is also leading efforts to create a "one-stop" electronic point of contact for all government business, economic and regulatory information that small businesses need to make informed decisions. This "U.S. Business Advisor" will soon be available to help make small businesses more efficient, productive and competitive in the global economy.

SBA acts as a strong advocate throughout the government on behalf of small businesses. It does so through specific programs, including the government contracting assistance programs and the Small Business Innovative Research program. But true advocacy must go beyond SBA's own programs to include the broad scope of federal government involvement with small businesses.

Accordingly, SBA has helped lead this Administration's efforts to reduce regulatory burdens on small business. In 1994, it co-sponsored an unprecedented interagency Small Business Forum on Regulatory Reform. Reflecting the serious work of 150 small business representatives and 80 government employees, the Forum produced a detailed list of findings and recommendations, many of which have already been implemented by the participating agencies. On March 16, 1995, President Clinton announced reform measures to give effect to the most important of those recommendations: a reduction in the paperwork burden on small businesses and a waiver of punitive actions against first-time violators of certain regulations. And, as part of a general review of regulations recently completed at the President's direction, SBA has committed to revise all of its regulations by the end of calendar year 1995, reducing their length by more than 50 percent.

SBA's disaster loans are the primary form of Federal assistance for non-farm, private sector disaster losses. This program is the only SBA assistance not limited to small businesses. During the program's 41 years of existence, SBA has approved more than 1.25 million disaster loans, comprising \$22 billion in assistance, for victims of physical disasters. During the last two years, SBA has taken several steps to simplify and expand access to its disaster loan program. Victims of disasters now find it easier than ever before to reach out to SBA for a helping hand.

President Clinton is determined to create a strong, efficient, cost-effective SBA that works with our Nation's small business community to expand access to credit and capital, provide needed training and assistance, and serve as an advocate and watchdog for small business owners. His efforts have shown significant and tangible results -- demand for SBA programs is up, paperwork and regulation are down; service and customer satisfaction is at an all-time high. The new SBA knows that even more can and should be done in the future; it will not cease its efforts to do more for the small business community in the months and years to come.

Ten Principles for Reinvention

SBA is committed to ten key principles:

1. Promoting better access to capital for small business owners.
2. Providing valuable small business education and training services.
3. Using government resources in an efficient and cost-effective manner.
4. Working closely with the private sector to better support and assist the small business community.
5. Reducing paperwork burdens on small businesses and streamlining regulations as much as possible.
6. Serving as an advocate for reform of government regulations so that they state clearly the rights and responsibilities of small business owners and the federal government.
7. Working to assure that affected small businesses are included at every important step in the regulatory development process.
8. Striving to improve communications between the federal government and affected small businesses to ensure that regulations are understood and followed.
9. Promoting voluntary small business compliance with regulations through flexible enforcement procedures.
10. Assuring access to government business, economic and regulatory information by using state-of-the-art information technology.

ACCOMPLISHMENTS AND NEW INITIATIVES IN SBA'S "PORTFOLIOS"

During the past two years, SBA has made a concerted effort to serve its constituency better. It has eliminated requirements that no longer made sense, reduced paperwork and forms that interfered with use of its credit programs, and streamlined internal procedures. Although SBA regulations are primarily designed to implement program delivery, rather than to regulate small business conduct, SBA's efforts have directly affected small business owners in vital areas, such as improved access to credit and business training. In its overall role as an advocate for small business interests, SBA has championed a government-wide regulatory reform effort. The accomplishments and continuing initiatives arising from these efforts are listed below under the four "portfolios" -- access to credit, business education and training, advocacy, and disaster loan assistance -- that describe SBA's programs.

Access to Credit

SBA expands access to capital by providing credit, through thousands of financial intermediaries, to small businesses unable to obtain loans to start-up or expand. Traditionally, small firms have faced serious problems obtaining long-term loans in the private credit marketplace. SBA has taken substantial steps in the last two years to ensure that its loan guarantee programs help the maximum number of small businesses at minimum cost.

1. **Low Documentation (LowDoc) Loan Program.** The paperwork and red tape associated with small SBA-guaranteed loans used to be an embarrassment. Today the LowDoc program features an easy, one-page SBA application and a rapid response, usually within two or three days, for loans up to \$100,000. In fiscal year 1993, the year before Low Doc was implemented, 30 percent of SBA's guaranteed loans were under \$100,000. As of May 1995, the fiscal year

overall management of the program are scheduled to be in place by August 1995.

5. **Women's Pre-Qualification.** The Women's Pre-Qualification Loan Pilot Program was launched in June 1994 to help increase the number of loans made to women business owners by assisting them to pre-qualify for SBA guarantees. The program simplifies the loan process for women business owners and makes it more user-friendly. Selected nonprofit loan packagers pre-screen and present credit requests from women entrepreneurs to SBA. If SBA finds the borrower qualified, it issues a pre-qualification letter which the loan applicant can take to a commercial lender. At the time the pilot was launched, women, who own about 38 percent of all small businesses, were receiving about 14 percent of SBA loan guarantees. A year later, the percentage is 24 percent, with further progress anticipated.
6. **Export Working Capital Program.** In October 1994, the SBA reorganized its trade loan effort as the Export Working Capital Program (EWCP) to help small businesses obtain export financing. Most commercial lenders consider small trade loans too risky and time-consuming, particularly for transactions under \$1,000,000. In conjunction with the Export-Import Bank, SBA's EWCP offers streamlined application procedures, a simplified application, a higher guarantee and two kinds of loans, both well-suited for export financing.
7. **Small Business Investment Companies.** The Small Business Investment Company (SBIC) program is a unique partnership of public and private funds, in which SBA supplements the capital of private venture capital firms. During the past two years, SBA has worked with the private venture capital industry to completely revise SBIC regulations, virtually rebuilding the SBIC program, strengthening oversight, management screening and credit review, and creating a new class of larger, better capitalized SBICs that will provide a profit participation to the government. In 1994, the SBIC program attracted more private capital (\$520 million) than in the previous 10 years combined.

8. **CAPlines.** All of SBA's short-term and revolving lines of credit operate under the new CAPlines umbrella. Under the various CAPlines components, the SBA provides financing for asset-based, seasonal, contract and builders' lines of credit. Recently, the SBA took steps to make its asset-based lending program more customer-friendly by introducing a new, less complicated, and less costly program to handle asset-based revolving lines of credit in amounts up to \$200,000.
9. **Computer-Generated SBA Loan Forms.** SBA has proposed rules that would allow lenders participating in the business and development company loan programs to utilize computer-generated facsimile copies of SBA application and closing forms in making SBA guaranteed loans. With advances in technology, SBA recognizes that its forms may be reproduced as exact copies by computers. The use of these reproductions may in many cases help expedite the processing of SBA guaranteed loans.
10. **Proposed Loan Program Reforms.** SBA has proposed legislative changes that would dramatically reduce the government's cost of the Agency's financing programs, while expanding the number of small businesses served. Current demand for the Agency's Section 7(a) and 504 loan programs far exceeds fund availability. Through the institution of adjusted guarantee percentages and marginal fee increases, SBA can eliminate all federal subsidy costs, thereby assisting more small businesses while decreasing taxpayer costs. If SBA's proposals are adopted, SBA expects to provide financing to more than 92,000 small firms in fiscal year 1996.

Business Education and Training

SBA provides business and education training to small business owners through resource partners such as the Small Business Development Centers (SBDCs) and the Service Corps of Retired Executives (SCORE). These programs, in addition to SBA's Business Information Centers, training seminars and publications, often make the difference between success and failure for small businesses.

SBA is at the center of the government-wide effort to create a "one-stop" electronic point of contact and access for all the business, economic and regulatory information that small businesses need to make informed decisions. An electronic information and service delivery system for businesses in the United States -- the "U.S. Business Advisor" -- will soon offer initial solutions to make small businesses more efficient, productive and competitive in the global economy. Initially, the U.S. Business Advisor will access selected sources of important government information, including health, safety and environmental regulations, the Unified Agenda of Federal Regulations, the National Trade Data Bank and EPA and OSHA regulatory, guidance and compliance assistance. When fully developed in the regulatory area, it will allow easy access to a broad range of regulatory guidance and compliance assistance.

SBA's Business Information Centers (BICs) offer the latest in high-technology hardware, software and telecommunications to assist small business. In addition, at BICs small business owners receive one-on-one counseling with seasoned business people through the Service Corps of Retired Executives (SCORE). SBA is working to expand its network of BICs. With the recent openings of BICs in Fairmont, West Virginia, El Paso and Charleston, SBA now has 16 BICs in operation.

SBA's Cosponsorship program provides training and counseling for small businesses through joint activities with the private sector. SBA's standard operating procedures (SOP) for the program were complex and inhibiting, micromanaging the process from the central office and imposing considerable paperwork burdens upon cosponsors. SBA has thoroughly streamlined the SOP, reducing it from 76 pages to 26, increasing field office flexibility and responsibility, removing financial and paperwork constraints from private sector partners and slashing internal paperwork requirements by more than 75 percent.

The Small Business Development Center program is a cooperative effort of the private sector, the educational community and federal, state and local governments to enhance economic development by providing management and technical assistance to small businesses. Since the enactment of the program in 1980, it has been operating under direct statutory authority, without regulations. Responding to industry requests for the promulgation of regulations, SBA published proposed regulations on October 28, 1994.

Praised by the private sector as a clear, concise and understandable codification of program procedures, the final regulations will be published in the Federal Register this week. In addition, SBA's reinvention legislative proposal would streamline the administration of the SBDCs, reduce costs, and consolidate the women's and minority training assistance programs under the SBDC program.

Advocacy

SBA has championed Administration efforts to reduce regulations on small businesses as part of its government-wide advocacy role. The President's recent regulatory reform announcements reflected recommendations from the unprecedented interagency forum that SBA helped launch last year. Many other regulatory reform recommendations identified through SBA regulatory reform efforts are now being announced and implemented by other agencies as part of the National Performance Review's second phase.

Regulatory Reform Successes

The President recently directed each Federal agency to review all of its regulations for effectiveness and clarity of language. He also issued two specific directives aimed at simplifying the regulatory process.

1. **General Regulatory Review.** On March 4, 1995, President Clinton issued a directive to all Federal agencies to examine regulations for effectiveness and clarity of language. In response, SBA brought together attorneys, program officials and front-line regulators from across the country. They met with the regulated community -- bankers, small business owners, government contractors -- to discuss ways to improve SBA regulations in all program areas. These efforts have resulted in plans to clarify and streamline existing SBA regulations, reducing them in length by more than half. Implementation of the suggested changes has already begun and should be completed by the end of the year.
2. **Waiver of Fines and Right to Cure.** On April 21, President Clinton issued a Memorandum on Regulatory Reform directing agencies to waive up to 100

percent of any punitive fine on a small business if the small business corrects the violations within an appropriate time period. The government also will offer small businesses an opportunity to avoid punitive action by applying any fine actually levied towards correcting the violations leading to the fine. These policies apply to first-time violations and those that do not threaten safety and health or involve criminal wrongdoing.

3. **Reduced Paperwork Requirements.** In that same April 21 Memorandum, President Clinton directed that many regularly scheduled reports to the Federal Government now be required only half as often (quarterly reports will be semi-annual, semi-annual reports will be annual, etc.). This will help small business owners significantly.

Continued Reform Efforts

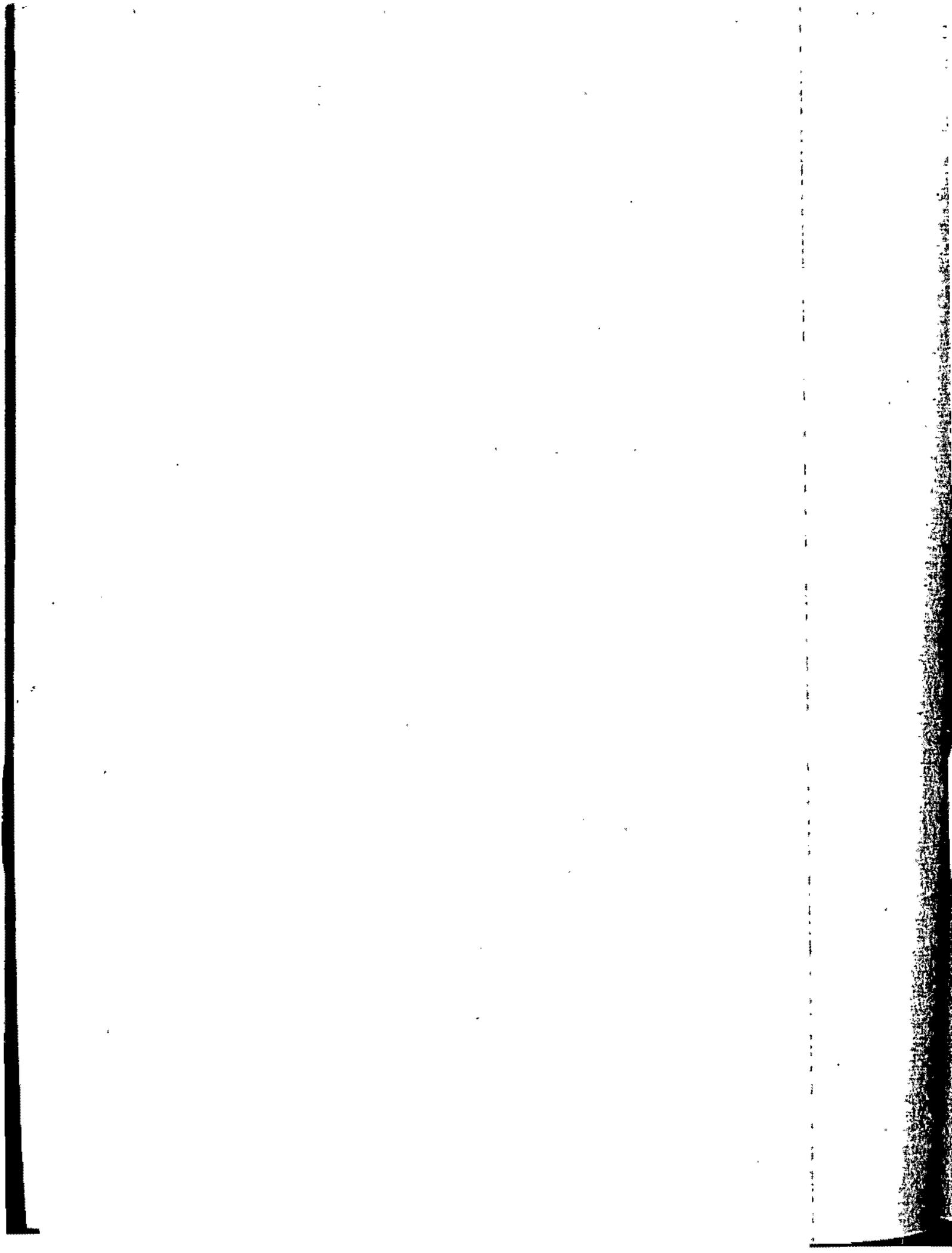
SBA will continue to work with EPA, OSHA and other agencies to address small business concerns as part of the President's reinventing government initiative:

1. **Regulatory Development.** A regulating agency should attempt to identify the affected community very early in the regulatory process. Mechanisms and procedures should be established for effective two-way communication and interaction with affected small businesses at every important step in the development process. Such businesses are and should be encouraged to provide comments, data and other information for use in the underlying regulatory studies, evaluations, and analyses. If potential adverse impacts and unintended consequences can be identified and mitigated, future compliance problems and litigation can be reduced.
2. **Communications.** To help improve communications between agencies and small businesses, SBA is working with those agencies to develop strategies for disseminating regulatory information to affected industries on a regular basis. The electronic "U.S. Business Advisor" should play a valuable role in this regard.

3. **Compliance and Enforcement.** Voluntary small business compliance with regulations is important for protecting health and safety. SBA is working closely with agencies to implement procedures, such as those already proposed by President Clinton, that emphasize cooperation and teamwork, rather than the use of intimidation and punitive enforcement to improve regulatory compliance. By working together, everyone benefits.

Disaster Loan Assistance

SBA's disaster loans are the primary form of Federal assistance for nonfarm, private sector disaster losses. SBA provides long-term, low interest loans to cover those losses not compensated for by private insurance. The disaster loan program is the only form of SBA assistance not limited to small businesses. SBA's disaster loans are available to homeowners, renters, businesses of all sizes, and nonprofit organizations. Given the rising Federal costs resulting from the tremendous level of disasters experienced over the last six years, SBA is participating in a Government-wide effort to reform the way it responds to disasters. During the last two years, SBA has taken steps to reinvent the program by simplifying the loan application process and increasing its loan limits. Its recent legislative proposal to Congress would greatly reduce the subsidy rate for disaster assistance, making more loans available at a lower cost to taxpayers.



APPENDIX:

**BRIEF DESCRIPTIONS OF SBA'S
ACCOMPLISHMENTS AND INITIATIVES**

Access to Credit

The Low Documentation Loan Program (LowDoc)

Action: Introduce an easy, one-page SBA application and a rapid response, usually within two or three days, for loans up to \$100,000.

Background: The need for a program like LowDoc became evident at a series of town hall meetings held around the country during the Spring of 1993. One complaint was heard time after time -- small businesses were unable to find lenders able or willing to provide loans in amounts under \$100,000.

Description: LowDoc is one of the best examples of the recent innovative changes SBA has made in the 7(a) lending program. The program was designed to increase the access that businesses have to smaller loans by reducing the paperwork burden imposed on lenders for these loans. The SBA LowDoc application is only one page. This single sheet is both the applicant's SBA loan application and the lender's request for an SBA guarantee. This application is a distillation of all the information previously required from applicants on a series of forms and required attachments. The lender still requests whatever additional information it requires to make an appropriate credit decision.

The LowDoc program was piloted in Texas beginning in December of 1993 and was expanded nationally last summer. During the expansion phase each SBA district office selected lenders within its market area to participate in LowDoc. Because the LowDoc application evaluation requires a high degree of experience and judgment on the part of the participant lender, lender selections were based on past and/or projected levels of activity, the degree of success achieved in the lender's SBA loan portfolio, and the lender's cooperativeness and dedication to meeting the financing need of small business. Expansion of the program nationally was accomplished over time with SBA certifying its personnel as

competent to process LowDoc applications only after they had taken an intensive two-day training course.

The program has been extremely well received by both SBA's borrowers and participating lenders. During fiscal year 1994, the SBA approved nearly 6,000 LowDoc loans totalling approximately \$316 million. As of April 10, 1995, the SBA had approved 18,296 LowDoc loans totalling approximately \$1 billion. SBA anticipates that approximately 35,000 LowDoc loans will be approved during fiscal year 1995.

Early reports show that loans made under the program are performing at a better rate than those made during the same period under the regular 7(a) program. Even though these preliminary results on program performance are good, SBA continues to monitor the LowDoc program closely. The results of examinations of the lenders' credit analyses are very positive. Future plans for the program call for on-going monitoring and sampling to assure that the same high quality performance by the lenders continues.

To improve the procedural efficiency of the LowDoc program, on May 1, 1995, SBA announced plans to centralize LowDoc processing at three sites: Sacramento, California; Madison, Wisconsin; and Melville, New York. The processing centers will enable the SBA to achieve economies of scale and to take advantage of the latest in technology. They will also help to assure a high degree of consistency in the loan consideration process. These centers will be operational in mid- to late July, 1995.

The FASTRAK Program

Action: Implement a pilot program that allows selected lenders who agree to share risks on a 50/50 basis to approve and service loans up to \$100,000, while using their own forms, documentation and procedures.

Background: In another effort to streamline the 7(a) program, SBA worked closely last year with some of its lending partners to develop an exciting new pilot program called FASTRAK. This pilot program is designed to increase the availability of smaller loans for SBA customers and to decrease the paperwork burden imposed on the Agency's lending partners.

Description: Under the FASTRAK pilot, which began on February 27 of this year and is scheduled to last two years, 18 selected lenders are authorized to make, service and liquidate loans in amounts up to \$100,000 using their own application and disbursement documents and processes. Lenders participating in the pilot program are given the ability to attach an SBA guarantee to an approved loan without having to submit the loan application to an SBA field office for a credit analysis or review. These loans are sent to a single location for assignment of an SBA loan number and a determination of borrower eligibility.

In exchange for the convenience of using their own forms and processes, lenders agree to limit the loan amount to \$100,000, accept a maximum guarantee of 50 percent, and waive payment on defaulted loans until after the lender has completed liquidation and SBA has reviewed the underlying documentation supporting the loan. As of April 28, 1995, SBA had approved 46 FASTRAK loans totalling \$2.0 million.

Repeal of the Media Policy (Opinion Molder) Rule

Action: Repeal the rule barring loan assistance to media-related small business concerns.

Background: The media policy rule was adopted in 1953 and prevented small media concerns such as booksellers, radio stations and television production companies from eligibility for SBA loan assistance. The rule remained in effect despite the fact that small media concerns often have difficulty raising capital or borrowing money.

Description: In October, 1994, SBA repealed the media policy rule, thereby extending loan eligibility to approximately 75,000 small business concerns it could not previously serve. This change in policy enables SBA to promote job growth and economic development by making financial assistance available to a larger number of small business concerns.

Repeal of this rule has created a very broad list of newly-eligible enterprises that includes broadcasters, movie theaters, publishers, producers, importers, exporters or distributors of all types of communications (such as newspapers, sheet music, posters, film, tape, theatrical productions, greeting cards, and books), plus transportation concerns limited to the distribution of such products.

Reinvention of the 504 Business Development Loan Program

Action: Streamline the 504 loan process from authorization to closing; establish the Accredited Lenders Program and the Premier Certified Lender program.

Background: SBA provides asset-based financing to small businesses through its 504 Certified Development Company program. The program makes loans available for acquiring land, buildings, machinery and equipment, and for building, modernizing, renovating or restoring existing facilities and sites.

A "certified development company" (CDC) is a private, public sector non-profit corporation that is set up to contribute to the economic development of its community or region. CDCs can sell 100 percent SBA-guaranteed debentures to private investors in amounts up to 40 percent of a project or \$750,000, whichever is less. The CDC program has in the past required cumbersome, resource-intensive review procedures.

Description: SBA is in the process of a complete streamlining of the 504 loan process from authorization to closing, including regulations, internal operating procedures, forms and agreements. On April 24, it implemented the first steps to expedite the processing of 504 loan closings. Any qualified CDC may now apply for approval to use this expedited procedure, which allows the CDC and its private counsel to perform document preparation and review. Specifically, SBA attorney review time will be reduced from a current average of four hours, to a new average of 20 minutes per loan package.

While it moves forward in its effort to streamline the closing process, SBA has taken steps to expedite the application stage of the program. On April 26, 1995, a final rule was published establishing an Accredited Lenders Program (ALP) for Certified Development Companies that provides for expedited processing of loan applications and servicing actions by SBA field offices. Development companies with a proven track record in the submission of documentation needed for making and servicing of sound loans may qualify as accredited lenders. Applications submitted by these lenders will be processed by SBA within three working days. The ALP is intended to build upon the successful Certified Lenders Program

for SBA's General Business Loan program and the pilot Accredited Lenders Program for CDCs which has been administered by SBA since 1991. The positive experience with the pilot led to its statutory authorization in The Small Business Administration Amendments Act of 1994, P.L. 103-403. The final rule implements the program.

The same law established a Premier Certified Lenders Program (PCLP) to be administered by SBA on a three-year pilot basis. The final rule implementing the PCLP was published on April 26, 1995. The program is modeled after the Preferred Lender Program for the SBA's General Business Loan Program. The PCLP development company will agree to share the risk of loan making, and in return SBA will delegate authority to the company for the purpose of authorizing, closing and servicing loans. The program responds to the significant increase in development company loan activity and recognizes the growing strength and capability of CDCs.

In addition, SBA is working closely with its CDC resource partners to improve its overall management of the 504 program. Working groups composed of SBA personnel and CDC representatives from around the country are in the process of examining the loan application process, credit analysis, loan closing and loan servicing. To streamline delivery of the program, SBA will clearly define and centralize the responsibility for data collection and maintenance, minimize paper flow, make maximum use of communications and database technology, and assure that access to database information will be integrated for ease of use. These changes are scheduled to be in place no later than August 31, 1995.

Women's Pre-Qualification Pilot Loan Program

Action: Implement a pilot program to increase the number of loans made to women business owners by assisting them to pre-qualify for SBA loan guarantees.

Background: Last year, SBA examined closely its record of lending to women-owned businesses and found that historically only approximately 10 to 12 percent of SBA loans and loan guaranties have gone to women-owned businesses. Statistics show that women-owned businesses constitute more than one-third of all small businesses and that women are starting businesses at a faster rate than their male counterparts. Therefore, SBA felt that it was necessary to look at new ways to improve its ability to meet the borrowing needs of women business owners.

Description: The Women's Pre-Qualification Pilot program allows SBA to review and pre-qualify loans for women-owned businesses prior to their submission to a participating lender. The SBA pre-qualification letter assures the lender that SBA has seen the loan application and has determined that, if the lender agrees to make the loan, an SBA guarantee will be available.

The pilot began June 1, 1994, and there are presently 16 pilot sites across the country. SBA has contracted with the Women's Business Development Center in Chicago to gather data and help evaluate the effectiveness of the first six months of the pilot's operations. The results of this evaluation will help SBA decide whether the program should continue as is, be changed, expanded, or discontinued.

The Export Working Capital Program

Action: Help small businesses obtain financing for export purposes by working with the Export/Import Bank on a one-year pilot program that streamlines procedures and offers a higher guarantee percentage.

Background: Trade loans are loans to exporters which cover specific transactions, or export deals. They are short term in nature (6 to 12 months in duration), and, unlike most regular business loans, collateral is generally the goods involved in the export deal:

Many private sector lenders have little or no experience with trade loans under \$1 million. Because they are not familiar with these loans, lenders believe that they are too risky and time-consuming to be commercially reasonable. Yet it is precisely these smaller loans that many small exporters need.

Description: SBA has refined its 7(a) program to meet this gap in private sector lending for export purposes. SBA has carefully designed a program to provide small business with the working capital necessary to support their export transactions. On October 1, 1994, SBA kicked off the Export Working Capital Program, which is operating on a one-year pilot basis.

In order to make this program operate most effectively, the Administration requested, and Congress approved, a harmonization, or blending, of the SBA export working capital program with the finance program of the U.S. Export-Import Bank (Eximbank). As part of this harmonization, SBA adopted Eximbank's practice of providing preliminary commitments to exporters with SBA, not the lender, reviewing the loan application first, in a manner similar to the Women's pre-qualification program.

SBA also revised its fee and interest rate policies to allow participating lenders a more reasonable return on their investment by assessing their risk and charging the appropriate market rate, usually 2 to 3 percentage points over prime. It recently authorized 16 participating lenders to process EWCP loans under the expedited Preferred Lenders Program. SBA worked with Eximbank to develop a simplified, user friendly, joint application form which now lets the exporter apply either to SBA or Eximbank depending on

the loan amount requested with the larger loans going to Eximbank and smaller loans going to SBA. It developed joint lenders' guides and instructions and, with the support of the Congress, obtained the legislative changes necessary to allow SBA to guarantee 90 percent of the EWCP loan and the authority to guarantee standby letters of credit, an increasingly common feature of many international sales contracts.

SBA is committed to making this program a success. It is carefully monitoring the program during the pilot period and will refine it wherever necessary to assure that it delivers a product that meets the needs of the small business exporting community. SBA has set a national goal for fiscal year 1995 of approximately 1,600 international trade-related loans under the 7(a) business loan program. Within that goal, SBA has a sub-target of 300 loans under the EWCP.

Small Business Investment Companies (SBICs)

Action: Revise Small Business Investment Company regulations, strengthen oversight, management screening and credit review, and create a class of larger, better capitalized SBICs.

Background: Small Business Investment Companies (SBICs) represent a unique public/private sector partnership for providing risk capital to small businesses. SBICs are privately-owned and managed investment firms (corporations or partnerships) licensed by SBA to provide equity and long-term subordinated debt financing to small businesses for their sound financing and to promote their growth, modernization or expansion. SBA supplements an SBIC's private capital by either guaranteeing their securities which are funded in the public markets or by purchasing their securities.

The program makes funding available to all types of manufacturing and service industries. Many investment companies seek out small businesses with new products or services because of the strong growth potential of such firms. Some SBICs specialize in the field in which their management has special knowledge or competency. Most, however, consider a wide variety of investment opportunities.

Description: The Small Business Equity Enhancement Act of 1992 restructured the SBIC program, making it more effective in providing risk capital to small businesses than at any time in its 35-year history. In addition, over the last two years SBA has worked with the private venture capital industry to completely revise SBIC regulations. Oversight has been strengthened, management and credit review have been enhanced, and a new class of larger, better capitalized SBICs has been created. As a result, in 1994, the SBIC program attracted more private capital (\$520 million) than in the previous 10 years combined.

CAPlines

Action: Implement nationally an enhanced revolving line of credit program for small businesses.

Background: SBA has traditionally offered a long-term loan guarantee program. Access to long-term financing by small businesses has historically been more difficult than for larger businesses, which often have other financing vehicles available to them. Over the past several years, it has become more and more common for SBA to hear small businesses complain that short-term credit sources have also become difficult to access.

Description: SBA offers short-term and revolving lines of credit under the new CAPlines umbrella. Under the various CAPlines components, SBA provides financing for various needs including asset-based, seasonal, contract and builders' lines of credit. These programs help to finance the short-term cyclical needs of many small business borrowers. CAPlines are not subject to the \$500,000 maximum gross loan amount limitation currently in place, but are limited to an SBA maximum share of the lesser of 75 percent of the loan amount or \$750,000.

The heart of SBA's asset-based lending program is its ability to support lenders in their efforts to provide businesses with short-term financing, based on the business' cash cycle rather than its cash flow over an established period of time. Based on its cash needs, the borrower may take advances from the line of credit and must repay the line from cash received, throughout the term of the loan. This assures that the loan will truly revolve.

Recently, SBA took steps to make its asset-based lending program more customer-friendly. Responding to criticism that the monitoring requirements of the program were too stringent and too expensive for smaller asset-based revolving loans, SBA introduced a new, less complicated, and less costly program to handle asset-based revolving lines of credit in amounts up to \$200,000.

Computer-Generated SBA Business Loan Forms

Action: Propose rules to authorize SBA participating lenders and development companies to use computer-generated facsimile copies of SBA forms in submitting loan applications and closing documents.

Background: SBA has required that its participating lenders and development companies use SBA-provided forms in the SBA business and development company loan programs. With advances in technology, SBA recognizes that such forms may be reproduced as exact copies by computers and that use of these reproductions may in many cases help expedite the processing of SBA guaranteed loans.

Description: Under the proposed rules for the business loan and development company programs, lenders and development companies would be authorized to use SBA application and closing forms that they generate on the computer or from software prepared by third parties. This is an effort by SBA to allow participating lenders and development companies to take advantage of available technologies to expedite the processing of loans. The copies must be exact; lenders and development companies that use computer-generated forms agree to accept liability for a substantial SBA loss due to deficiencies in the forms.

The proposed rule for business loans was published in the Federal Register on March 3, 1995. The proposed rule for the 504 Development Company Loan Program was published in the Register on March 24, 1995.

General Loan Program Reforms

Action: Increase customer access to SBA loan guarantee programs while reducing the cost to taxpayers.

Background: A crucial aspect of SBA's reinvention effort has been to seek ways to enhance its existing programs and at the same time reduce costs to the Federal Government. Presently, Congress must appropriate an amount that anticipates the subsidy cost of loan guarantees made by SBA in the upcoming fiscal year. Often, a supplemental appropriation is required because loan demand is greater than Congress expected. As a result, lenders and borrowers experience uncertainty about loan availability.

Description: The Clinton Administration has submitted legislation that will reduce to zero the SBA's subsidy rate for the 7(a) and 504 loan programs. These changes will allow SBA to serve more small firms and to provide loans in slightly larger amounts, while substantially reducing the program's cost to the taxpayers.

The zero subsidy rate will be achieved through a series of adjustments to SBA's guarantee percentages, interest rates, and program fee structures. These changes will allow SBA to increase its maximum guarantee amount to \$1 million, thus allowing small business borrowers with larger funding needs to receive SBA assistance. Care was taken to assure that the fees charged to borrowers would not make the program too expensive and that the fees charged to lenders and the reductions in guarantee percentages would not be so great as to make use of the programs commercially impractical. SBA believes it has struck the proper balance, and that the proposed changes would allow it to continue to do more for small business, with less reliance on taxpayers' funds.

Business Education and Training

The U.S. Business Advisor

Action: Develop in cooperation with other federal agencies a "one-stop" electronic point of contact that small businesses can use to obtain business, economic and regulatory information.

Background: Through more effective use of technology and productive public/private partnerships, small businesses can increase productivity and cut costs. In the new information-age economy, knowledge and communication are fundamental sources of wealth. Current and emerging technology is revolutionizing the way business is done -- and is indispensable to managing change. In future years, no successful business will be without access to the Internet, a sprawling "place" where over a billion electronic-mail messages go back and forth monthly among 35 million users.

Description: SBA is at the center of a government-wide effort to create a "one-stop" electronic point of contact and access for all business, economic and regulatory information that small businesses need to make informed decisions. An electronic information and services delivery system for businesses in the United States -- the "U.S. Business Advisor" -- will soon be available to offer initial solutions to make small businesses more competitive in the global economy.

Consisting of several divisions, the U.S. Business Advisor will be accessed through the Internet and offer government-wide access to financial and regulatory information and resources, all in one place. Responding to the small business community's need for better access to regulatory information and compliance assistance, the first division to open will be the Regulatory Assistance Center (RAC).

Initially, RAC will access selected sources of important government information, including federal and state environment, safety and health statutes and regulations; the Department of Commerce's National Trade Data Bank, which contains information on

overseas markets, how-to guides for exporters, general information on foreign countries, and over 60,000 foreign business contacts; a global electronic commerce system for environmental technology; EPA and OSHA compliance guides and assistance; IRS forms; and Customs import regulations. As it evolves, RAC will become the one-stop place to go for everything a business might require to address its regulatory, reporting and compliance needs. It will allow easy access to a full range of plain-language regulatory guidance and compliance assistance information to help businesses understand regulatory requirements, including self-assessment tools, forms, training modules, expert systems and best management practices.

Increasingly, small businesses are demanding better, faster, and more timely service from the Federal Government. Creating a customer-driven, results-oriented Government that offers quality service is an important goal of the Clinton Administration. Through technology and productive partnerships, SBA and other federal agencies can become more accessible and more responsive to small businesses. "Opening" the U.S. Business Advisor is an important part of that process. SBA will seek to make the U.S. Business Advisor accessible to all small business owners, regardless of their technological capabilities. It will be made available via computer for those without access to the Internet. For those small business people without a computer, various options are being explored, including making the U.S. Business Advisor accessible at SBA's 950 Small Business Development Centers and sub-centers and its 16 Business Information Centers.

Business Information Centers

Action: Expand the network of Business Information Centers (BICs) to provide better access for small businesses to state-of-the-art technologies and information sources.

Background: During this time of rapid change, small businesses need access to the latest in high-technology hardware, software and telecommunications in order to compete effectively and grow.

Description: SBA's Business Information Centers provide one-stop state-of-the-art assistance and advice to small business owners plus one-on-one counseling and training through the Service Corps of Retired Executives (SCORE). BICs are now in sixteen locations across the country: Seattle, Atlanta, Houston, Los Angeles, St. Louis, Nashville, Chicago, Boston, Kansas City, Washington, D.C., San Diego, Baltimore, Fort Worth, El Paso, Charleston, South Carolina and Fairmont, West Virginia.

BICs use state-of-the-art personal computers, graphics work stations, CD-ROM technology and interactive videos, allowing small business owners access to market research databases, use of planning and spreadsheet software, and use of vast libraries of information to help them start or build businesses. The BICs offer electronic bulletin boards, computer data bases, on-line information exchange, periodicals and brochures, counseling, videotapes, reference materials, texts, start-up guides, application software, computer tutorials and interactive media.

BICs receive major private sector support from sponsors such as Apple Computer, Dell Computers, Dun & Bradstreet, Microsoft, U.S. Sprint and others. In cooperation with its private sector co-sponsors and SCORE, SBA has expanded the network of BICs recently in its continuing effort to ensure that America's small business people have access to the best available resources.

Cosponsorships

Action: Streamline the operating procedures for the Cosponsorship program and reduce the paperwork burden for SBA's private sector partners.

Background: SBA extends and expands the limited resources it has available for small business training and counseling through the Cosponsorship program. Cosponsorship enlists the aid of non-profit and for-profit entities, as well as federal, state and local government agencies.

Typical projects include training seminars and workshops, publications, conferences, and expos and fairs involving SBA programs. Topics include international trade, minority business opportunities, women's business ownership procurement opportunities, finance programs, rural initiatives, veterans and a wide variety of special endeavors such as computer training, workplace literacy, ethics, employee theft and drug-free work environments.

Description: SBA's standard operating procedures (SOP) for the Cosponsorship program were complex and inhibiting, micromanaging the process from the central office and imposing considerable paperwork burdens upon private sector cosponsors. SBA has thoroughly streamlined its SOP, reducing it from 76 pages to 26, increasing field office flexibility and responsibility, removing financial and paperwork constraints from private sector partners and slashing internal paperwork requirements by more than 75 percent.

Small Business Development Centers

Action: Promulgate regulations for the Small Business Development Center (SBDC) program and propose legislation that will streamline administration of the SBDCs, reduce costs, and consolidate the women's and minority training assistance programs under the SBDC program.

Background: The Small Business Development Center program is a cooperative effort of the private sector, educational institutions and federal, state and local governments to meet the basic and specialized needs of the small business community. The SBDCs' primary objective is to further economic development by providing counseling, training, research and specialized assistance in all aspects of business management. More than half of all SBA counseling and two-thirds of all training efforts are provided by Small Business Development Centers.

Description: In October of last year, SBA responded to industry requests that regulations be promulgated to govern administration of the program. Since creation of the program in 1980, it had been operating under direct statutory authority, without regulations. The new regulatory framework, which will be published in the Federal Register this week, codified and clarified the procedures under which the program had been operating. The regulations have been well received by the industry.

SBA's reinvention legislative proposal would streamline the administration of the SBDCs and reduce taxpayer costs. Under the proposal, other grant programs currently providing management and technical assistance to differing segments of the small business community would be consolidated under the SBDC program. The Women's Demonstration Project and Minority Business Training Program would be administered by the SBDCs, streamlining the delivery of services and reducing the overhead of these programs.

In order to maximize the services provided by SBDCs to the small business community, the proposal also allows SBDCs the flexibility to use various delivery mechanisms, including, but not limited to, institutions of higher learning and local non-profit

economic development organizations. SBDCs would retain the authority to receive funding from other Federal and state entities. The legislative proposal would keep existing eligibility requirements for SBDCs and add a requirement that SBDCs work closely with state governments in developing relationships with state and local economic development organizations to broaden the services provided.

Advocacy

General Regulatory Review

Action: Clarify and streamline SBA's regulations, revising or eliminating any duplicative, outdated, inconsistent or confusing provisions. As a result of this process, SBA regulations will be cut by more than 50 percent by the end of the calendar year.

Background: SBA has championed Administration efforts to reduce regulations on small businesses as part of its government-wide advocacy role. The SBA-sponsored Small Business Forum on Regulatory Reform made numerous recommendations and findings, including the need to revise or eliminate outmoded, confusing or duplicative regulations. On March 4, 1995, President Clinton directed all agencies to conduct a review of all regulations to determine what might be revised or eliminated.

Description: In response to the President's directive, SBA has completed a page-by-page and line-by-line review of each of its regulations. Individual regulations were analyzed to determine if they imposed any unnecessary burden on small businesses or if they more appropriately should be included in internal operating procedures. SBA has sought to ensure a less cumbersome and more efficient process, with an emphasis on enhanced customer service.

This three month review process has yielded impressive results. Agency teams reviewed the 700 pages of SBA regulations in detail, identifying specific ways to streamline and simplify. Overall, SBA will reinvent 100 percent of its regulations, resulting in the elimination of 355 pages of regulatory text -- or 51 percent of its regulations. Some of these changes are described elsewhere in this report in the descriptions of particular program reforms, but they will also include: consolidation of all discrimination regulations; simplification of size regulations; simplification of 8(a) program regulations to expedite

eligibility reviews and contracting actions; and the consolidation and redrafting of all business loan regulations into one section to facilitate use and save time.

Waiver of Fines and Right to Cure.

Action: The President has issued a Memorandum on Regulatory Reform directing agencies to modify or waive penalties for small businesses in certain situations.

Background: The SBA-sponsored Small Business Forum on Regulatory Reform recommended measures to encourage voluntary compliance with regulations and develop more flexible enforcement mechanisms.

Description: On April 21, 1995, President Clinton issued a Memorandum on Regulatory Reform, directing department and agency heads to implement two important policy initiatives. Agencies are directed to use their enforcement discretion to waive the imposition of all or a portion of a penalty when the violation is corrected within an appropriate time period. For those violations that may take longer to correct than the period set by the agency, federal agencies will waive up to 100 percent of the financial penalties if the amounts waived are used to cure the violation.

The Memorandum directs federal agencies to implement these new policies on or before July 14, 1995. As part of their implementation plan, the agencies must include information on how notification of the new policies will be given to small businesses. SBA is working with EPA and OSHA and other agencies to assist them in implementing and disseminating information about the policies.

Reduced Paperwork Requirements

Action: The President issued a Memorandum on Regulatory Reform that directs agencies to reduce the paperwork burden on small businesses.

Background: Included among the recommendations of the SBA-sponsored Small Business Forum on Regulatory Reform was the need to reduce the paperwork burden on small businesses.

Description: On April 21, 1995, President Clinton issued a Memorandum on Regulatory Reform directing agencies to reduce by one-half the frequency of the regularly scheduled reports that the public is required, by rule or by policy, to provide to the Government (from quarterly to semiannually, from semiannually to annually, etc.).

Each agency is required to submit a plan by June 15, 1995 to the Office of Management and Budget describing the actions it is taking to implement this paperwork reduction.

Disaster Loan Assistance

Action: Simplify the disaster loan assistance program by reducing filing requirements. Increase loan limits and propose legislation to reduce the subsidy rate for disaster loans, allowing SBA to quadruple the number of loans it makes with the same subsidy.

Background: SBA's disaster loans are the primary form of Federal assistance for nonfarm, private sector disaster losses. SBA provides long-term, low interest loans to cover those losses not compensated for by private insurance. The disaster loan program is the only form of SBA assistance not limited to small businesses. SBA's disaster loans are available to homeowners, renters, businesses of all sizes, and nonprofit organizations. Given the rising Federal costs resulting from the tremendous level of disasters experienced over the last six years, SBA is participating in a Government-wide effort to reform the way we respond to disasters.

Description: SBA has made many changes to simplify the disaster loan assistance program and make it more customer friendly. Specifically, it has:

- (1) Simplified the home loan filing requirements. SBA now requires certain information only after a loan is approved so that disaster victims are not required to do unnecessary paperwork.
- (2) Simplified the filing process and the requirements for disaster business loans. As a result of its experience in the Midwest floods, SBA has cut the length of its disaster loan application in half.
- (3) Increased the disaster home loan limits from \$100,000 to \$200,000 for real estate damage, and from \$20,000 to \$40,000 for personal property damage.
- (4) Modified the major source of employment criteria to permit consideration of waiver of the \$1.5 million business loan limit in more cases. (The law provides a maximum loan limit of \$1.5 million for any business in any one

disaster. It also permits SBA's Administrator to waive that limit for a "major source of employment", as defined in our regulations. The modification made it easier for businesses to qualify as major sources of employment.)

Furthermore, the reinvention legislative proposal SBA recently submitted to Congress would reduce the subsidy rate for disaster loans in fiscal year 1996 from its current level of over 31 percent to 8.46 percent. This reduction would permit SBA to make \$407 million in disaster loans with its requested subsidy authority of \$34 million as opposed to \$110 million in loans with the current subsidy rate.

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