whose interests are imputed to them under the statute, have a financial interest, if the particular matter will have a direct and predictable effect on that interest.

(b) *Specific waiver available.* A NASA employee may request a waiver of this prohibition. NASA may grant a specific waiver of the prohibition only if the Agency determines that the employee's financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services. The waiver must be obtained before the employee participates in the matter.

(c) *Officials authorized to make waiver determinations.* (1) For the employees listed below, waivers must be approved by the Administrator or Deputy Administrator. No further delegation is authorized.

(i) Employees who are required by 5 CFR 2634.202 to file Public Financial Disclosure Reports;

(ii) Employees who are appointed under authority of section 203(c)(2) (''NASA Excepted Positions'') or section 203(c)(10) (''Alien Scientists'') of the National Aeronautics and Space Act of 1958, as amended (42 U.S.C. 2473(c)(2) and 2473(c)(10));

(iii) Astronauts and astronaut candidates;

(iv) Chief Counsel; and

(v) Procurement Officers.

(2) For all other Headquarters employees, the Associate Administrator for Headquarters Operations may approve waivers of 18 U.S.C. 208. This authority may not be redelegated.

(3) For all other Center employees, the Center Director or Deputy Center Director may approve waivers of 18 U.S.C. 208. This authority may not be redelegated.

(d) *Procedures for specific waiver.* The employee's request for a waiver must be in writing. The request must describe the particular matter involved, the relevant duties of the employee, and the exact nature and amount of the disqualifying financial interest.

(1) *Headquarters employees.* (i) Those Headquarters employees described in paragraph (c)(1) of this section must submit their requests to the Official-in-Charge of the Headquarters office in which they are employed and to the General Counsel for concurrence. The Official-in-Charge will then submit the request to the Administrator with recommendations on the proposed waiver.

(ii) Other Headquarters employees must submit their requests to the Associate General Counsel (General) for concurrence, and to the Associate Administrator for Headquarters Operations for approval.

(2) *Center employees.* (i) Those Center employees described in paragraph (c)(1) of this section must submit their requests to the Center Chief Counsel for concurrence and then to the Director of the Center where they are employed. The Center Director will provide the request, with recommendations, to the appropriate Enterprise Associate Administrator and to the General Counsel for review and submission to the Administrator.

(ii) Other Center employees must submit their requests to the Center Chief Counsel for concurrence, and then to their Center Director or Deputy Center Director for approval.

(3) Copies of approved waivers must be forwarded to the Associate Administrator for Human Resources and Education, the General Counsel, and the Office of Government Ethics.

(e) *Cross-references.* For regulations concerning general waiver guidance and exemptions under 18 U.S.C. 208, see 5 CFR part 2640.

3. Add § 1207.103 to subpart A to read as follows:

§ 1207.103 Designations of responsible officials.

(a) *Designated Agency Ethics Official.* The General Counsel of NASA is the Designated Agency Ethics Official and is delegated the authority to coordinate and manage NASA's ethics program as set forth in 5 CFR 2638.203.

(b) *Alternate Designated Agency Ethics Official.* The Associate General Counsel (General) is the Alternate Designated Agency Ethics Official.

(c) *Deputy Ethics Officials.* The following officials are designated as Deputy Ethics Officials:

(1) The Deputy General Counsel;

(2) The Associate General Counsel (General);

(3) The Senior Ethics Attorney assigned to the Associate General Counsel (General); and

(4) The Chief Counsel at each NASA Center and Component Facility.

(d) *Agency Designee.* As used in 5 CFR part 2635, the term ''Agency Designee'' refers to the following:

(1) For employees at NASA Headquarters, or for matters affecting employees Agencywide, the Associate Deputy Administrator, the Designated Agency Ethics Official, the Alternate Designated Agency Ethics Official, or the Chief of Staff; and

(2) For Center employees, the Center Director, who may delegate specific responsibilities of the Agency Designee to the Center Chief Counsel or to another official who reports directly to the Center Director.

(e) *Cross-references.* For regulations on the appointment, responsibilities, and authority of the Designated Agency Ethics Official, Alternate Designated Agency Ethics Official, and Deputy Ethics Officials, see 5 CFR part 2638. For the responsibilities of the Agency Designee, see 5 CFR part 2635.

[FR Doc. 01–29425 Filed 11–26–01; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 607, and 807

[Docket No. 98N–1215]

RIN 0910–AB21

Foreign Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend its regulations pertaining to the registration of foreign establishments and the listing of human drugs, animal drugs, biological products, and devices. The final rule requires foreign establishments whose products are imported or offered for import into the United States to register with FDA and to identify a United States agent. The final rule implements section 417 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) as it pertains to foreign establishment registration.

DATES: This rule is effective February 11, 2002.

Compliance date: FDA will begin enforcing the requirements in 21 CFR part 207 on May 28, 2002, and in 21 CFR part 807 on April 26, 2002.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of May 14, 1999 (64 FR 26330), FDA published a proposed rule to implement section 417

of FDAMA (Public Law 105–115). Section 417 of FDAMA amended section 510(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)) to require, in part, that:

(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

(2) The establishment shall also provide the information required by subsection (j). (Section 510(j) of the act pertains to product listing.)

Generally speaking, before FDAMA's enactment, foreign establishments could, but were not required to, register with FDA. FDA, through its regulations, did require foreign establishments to list their products regardless of whether the foreign establishment was registered (see, e.g., former section 510(i) of the act, 21 CFR 207.40(a), 38 FR 6257, 6258 through 6259, and 6262 through 6263 (March 7, 1973) (final rule implementing the Drug Listing Act of 1972)). This difference in registration and listing requirements confused some foreign establishments and led some to not comply with the listing requirement. Additionally, the lack of registration information on foreign establishments sometimes made it difficult to determine the source of specific imported products, particularly products that were impure, counterfeit products, or products whose safety or efficacy had not been established.

FDAMA changed this situation by requiring all foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States to register. It also emphasized that foreign establishments must list their products and required, for the first time, foreign establishments to identify a United States agent.

Consequently, the proposed rule sought to amend the establishment registration and listing regulations in part 207 (21 CFR part 207) (human and animal drugs and biologics), part 607 (21 CFR part 607) (human blood and blood products), and part 807 (21 CFR part 807) (human devices). In general, the proposal removed the distinctions between domestic and foreign establishments where appropriate, required foreign establishments to identify a United States agent, and described some of the United States agent's duties.

The proposal also made minor technical amendments, such as updating addresses of FDA offices and the names of marketing applications, to be consistent with current FDA practices.

The comment period for the proposed rule was originally scheduled to end on July 28, 1999. On July 23, 1999, the Government of Canada requested that FDA extend the comment period for 60 days, stating that the proposed requirements could present significant cost and compliance burdens on small and medium-sized Canadian establishments. The Government of Canada requested the extension so that it could: (1) Ensure that affected Canadian establishments were aware of the proposed rule, and (2) prepare informed comments. The request arrived too late for FDA to announce an extension of the comment period, so FDA published a document in the **Federal Register** of August 9, 1999 (64 FR 43114), reopening the comment period from August 9, 1999, to October 8, 1999.

II. Comments on the Proposed Rule

FDA received over 35 comments on the proposed rule. Domestic and foreign establishments, particularly Canadian establishments, submitted most comments, although the Government of Canada, the trade agency for the Government of Ontario, Canada, Canadian and American trade associations, law firms, and FDA employees also submitted comments.

To make it easier to identify comments and FDA's responses to the comments, the word Comment in parenthesis, will appear before the description of the comment, and the word Response in parenthesis, will appear before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. General Comments

Several comments addressed general issues that were not directed to any particular codified provision.

(Comment 1) Two comments expressed general support for the rule. One comment said that the rule brings a'' desired level of consistency in requirements for both domestic and international manufacturing activities'' and will enable FDA to identify and locate firms and products made abroad, thus enhancing public health and safety.

In contrast, one comment, submitted by a law firm in the United States, asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. As an example, the comment said the rule should not apply if the product is sent to a foreign trade zone. The comment acknowledged that section 510(i) of the act does not expressly say that the product must be imported or offered for import into the United States ''for commercial distribution,'' but claimed that section 510(j) of the act suggests that only those who manufacture, prepare, propagate, compound, or process products for commercial distribution must register. The comment further claimed that excluding some foreign establishments from the registration requirement would also be consistent with FDAMA because FDAMA sought to reduce regulatory burdens.

(Response) FDA agrees, in part, with the comment, but only to the extent that it involves products that are shipped to foreign trade zones and never enter domestic commerce. In brief, a foreign trade zone (also known as a Free Trade Zone) is a federally sanctioned site where foreign and domestic goods are considered to be outside of the U. S. Customs territory. While in a foreign trade zone, the goods can be stored, tested, sampled, displayed, repaired, manipulated, assembled, salvaged, repackaged, cleaned, processed, relabeled, mixed, destroyed, or inspected (and, if approved by the foreign trade zone board, manufactured). If the goods are reexported from the foreign trade zone, no customs duties are paid, but if the goods enter U. S. commerce, duties would apply.

It is important to note that, while the U. S. Customs Service does not assess duties on goods in a foreign trade zone, those goods are subject to FDA's jurisdiction. However, FDA agrees that if a foreign establishment sends human drugs, animal drugs, devices, or biological products to a foreign trade zone and the product is re-exported from the foreign trade zone to another country without ever entering U. S. commerce, the foreign establishment is not required to register or list the products that were sent to the foreign trade zone. (These foreign establishments may voluntarily register and list their products, but the final rule does not require them to do so).

If the goods do enter U. S. commerce from a foreign trade zone, the foreign establishment must register and list its products. In this situation, the foreign establishment is like any other foreign establishment that exports a product to the United States. In other words, if the

goods are sold in the United States, the fact that those goods may have initially entered the United States through a foreign trade zone does not relieve the foreign establishment from registration and listing requirements.

FDA, therefore, has amended the foreign establishment registration and listing provisions at §§ 207.40(a), 607.40(a), and 807.40(a) to exclude drugs and devices that enter a foreign trade zone and are re-exported from the United States without ever entering domestic commerce.

(Comment 2) The same comment, in asking FDA to exempt foreign establishments from registration and listing requirements if their products are imported into the United States but are not marketed in the United States, suggested registering these foreign establishments is ''simply not necessary'' and that FDA defer to foreign authorities in such cases. The comment stated that foreign countries, whether exporting or receiving a product, can impose their own registration requirements on foreign manufacturers. The comment added that FDA is authorized to enter cooperative arrangements with foreign countries to determine whether drugs or devices should enter the United States.

(Response) FDA agrees, in part, and disagrees, in part, with the comment. The agency agrees that it is unnecessary to require a foreign establishment to register and list its products provided that the product enters the United States through a foreign trade zone and is later re-exported without ever entering domestic commerce. However, the fact that a foreign country may have its own registration requirements or that FDA may enter cooperative arrangements with foreign countries does not, by itself, justify an exemption from the act's registration and listing requirements. Foreign registration requirements may differ considerably from FDA's requirements or may not exist at all; likewise, cooperative arrangements may not exist or would have to be negotiated in order to obtain registration information from a foreign government.

(Comment 3) One comment asked FDA to work with the U. S. Customs Service in order to prevent any unnecessary interruption in the flow of goods and to facilitate communications between agencies at ports of entry.

(Response) FDA has worked and will continue to work closely with the Customs Service on various issues affecting the importation and exportation of FDA-regulated products and will notify the Customs Service about this final rule. Additionally, FDA will ''phase-in'' the rule so that foreign establishments will have an opportunity to adjust to these regulatory requirements. (Details concerning registration schedules for parts 207, 607, and 807 appear later in this document in section II.F entitled ''Registration Schedules.'') Consequently, the rule should not create any ''unnecessary interruption'' in imports of human drugs, animal drugs, biologics, blood and blood products, or devices.

B. Comments on the United States Agent Requirement

1. Comments on the Number of United States Agents, Including Requests to Exempt Firms in Certain Countries From Having a United States Agent

As stated earlier, section 510(i) of the act requires foreign establishments to identify a United States agent. The preamble to the proposed rule explained that FDA interpreted this provision as requiring the agent to be an individual, firm, or company physically located in the United States (see 64 FR 26330 at 26331). The preamble to the proposed rule added that the United States agent could not be a mailbox, answering machine or answering service, or any other place where an individual acting as the foreign establishment's agent is not physically present and that FDA interprets section 510(i) of the act as requiring only one agent for each foreign establishment.

(Comment 4) Some comments would amend the rule to allow or to require more than one agent per establishment. Two comments advocated one agent per product, and one of these comments said that foreign establishments should identify the United States agent as part of a drug master file or veterinary master file. One comment supported requiring one United States agent for each product and U. S. customer. Other comments suggested that a foreign establishment should be able to designate more than one agent or as many agents as it wished. In general, these comments explained that a foreign establishment may supply multiple U. S. companies or have multiple U. S. distributors. The comments said that, under these circumstances, a foreign establishment cannot select one company or distributor as its United States agent due to potential conflicts of interest, potential harm to the foreign establishment's proprietary interests, or frequent changes in its distributors. Some comments said that a distributor could not be a United States agent for more than one foreign establishment. One comment also argued that FDA already has names and addresses of agents for each product as part of a drug master file, so FDA should allow foreign establishments to have more than one United States agent.

(Response) Section 510(i) of the act clearly and unequivocally requires foreign establishments to register the name of a United States agent. As stated in the preamble to the proposed rule, FDA interprets section 510(i) of the act as allowing only one United States agent for each foreign establishment because section 510(i) of the act refers to the United States agent in singular, rather than plural, terms (see 64 FR 26330 at 26331). FDA continues to believe that this interpretation is efficient (because FDA would communicate or interact with only one United States agent rather than multiple agents who represent, or purport to represent, the same foreign establishment) and consistent with the statutory language. Thus, FDA declines to amend the rule to increase the number of United States agents per foreign establishment.

FDA also declines to amend the rule to have foreign establishments identify the United States agent as part of their drug master files or veterinary master files. Section 510(i)(1) of the act considers the United States agent to be part of a foreign establishment's registration requirement, so requiring a foreign establishment to name its United States agent as part of the registration process is consistent with the act.

(Comment 5) Many comments, particularly from Canadian sources, objected to having any United States agent. These comments would revise the rule to eliminate or suspend a United States agent requirement, either for Canadian firms or for firms in countries meeting certain criteria. The comments offered numerous reasons why FDA should not require certain foreign firms, particularly Canadian firms, to have a United States agent. The reasons cited most often were (in no particular order): (a) The requirement will be expensive; (b) the requirement results in a competitive disadvantage for Canadian firms doing business in the United States because Canada does not impose similar obligations on U. S. firms; (c) an agent will not be as knowledgeable as company officials concerning the company's products or training an agent to be knowledgeable will be burdensome, expensive, and time-consuming; (d) Canada and the United States share time zones, business ethics, language, and communications capabilities so a United States agent will not significantly enhance communications between FDA and Canadian firms; (e) FDA has not shown any need for a United States agent; (f)

firms with a history of good communications with FDA should be exempt from the United States agent requirement; and (g) the requirement will act as a trade barrier between Canada and the United States. One comment said a United States agent is unnecessary because FDA can work with the U. S. Customs Service to prevent unapproved devices from entering the United States. Some Canadian firms indicated that they would ask the Canadian Government to impose similar requirements against U. S. firms if FDA did not create an exemption.

A few comments suggested that FDA create exemptions for Canadian firms or firms in countries meeting certain criteria. One comment from an United States trade association advocated an exemption from the United States agent requirement for ''establishments in those countries with whom the United States has negotiated free trade agreements,'' arguing that FDA's ''interpretation'' of section 417 of FDAMA may pose an ''unreasonable barrier to trade,'' that registration and listing information should be enough to protect consumers, and that ''we run the risk of our partners in these agreements placing similar burdens on American companies.'' Other comments would exempt firms in countries that have no communications problems with the United States or FDA; countries that do not have a similar agent requirement that applies against U. S. firms; or countries where English is spoken and where firms can communicate directly with FDA.

(Response) FDA appreciates the concerns expressed by the comments. However, section 510(i) of the act does not contain any mechanism or any criteria for exempting certain foreign establishments or foreign establishments located in certain countries, in geographical regions, or in countries with no communications problems with the United States or FDA. Neither does it provide for a deferral of the United States agent requirement. The statutory language is clear—a foreign establishment ''shall register * * * the name of the United States agent for the establishment'' (see section 510(i) of the act). The most logical interpretation of the term, ''United States agent,'' is that the agent must be in the United States. If Congress intended foreign establishments to be able to designate agents outside the United States, the words ''United States'' would be unnecessary in section 510(i) of the act. Indeed, if Congress intended to require foreign establishments to be able to designate agents outside the United States, there would be no need for any agent at all because FDA could simply contact the foreign establishment directly. It is a well settled principle of statutory interpretation that, ''Absent clear congressional intent to the contrary, we will assume the legislature did not intend to pass vain or meaningless legislation'' (*Coyne* & *Delany* v. *Blue Cross* & *Blue Shield of Virginia*, 102 F.3d 712, 715 (4th Cir. 1996); see also *Halverson* v. *Slater*, 129 F.3d 180, 185 (D.C. Cir. 1997) (Congress cannot be presumed to do a futile thing).) Thus, the most straightforward reading of section 510(i) of the act is that foreign establishments must register the name of a United States agent and that the United States agent must be in the United States. So, despite the assertions made by one comment, one cannot fairly criticize FDA's ''interpretation'' of the act as being erroneous or claim that FDA's interpretation of the act is creating an ''unreasonable barrier'' to trade.

FDA sees no need to alter the rule based on those comments claiming that the United States agent requirement will create competitive disadvantages or trade barriers, increase costs to foreign establishments, or lead foreign countries to impose similar requirements against U. S. firms. The United States agent requirement is consistent with U. S. trade obligations under the relevant international agreements.

(Comment 6) One comment explained that small businesses might find the United States agent requirement to be economically feasible if multiple foreign establishments could share the same agent.

(Response) FDA has no objections to having one United States agent represent multiple foreign establishments. However, FDA reminds firms to select their United States agents carefully to guard against any conflict of interest and to account for any confidentiality or other business concerns.

2. Comments on the United States Agent's Duties or Responsibilities

(Comment 7) The preamble to the proposed rule cautioned foreign establishments to select their agents carefully due to potential conflicts of interest and issues involving trade secrets or confidential commercial information (see 64 FR 26330 at 26334). One comment acknowledged FDA's advice, but said that FDA's interest in enhanced communication and rapid acquisition of information would be best served if foreign establishments could determine the number of agents they need according to their business and proprietary needs. Another comment said that the rule would compel foreign establishments to designate persons other than their U. S. distributors as their United States agents because foreign establishments might be unwilling to give a distributor potential access to confidential information. The comment said this would increase costs of retaining a United States agent.

(Response) FDA disagrees with the comments. FDA expects to initiate most, if not all, communications between the agency and a United States agent. Thus, it would obviously be more efficient if FDA only had to contact one United States agent for a particular foreign establishment rather than sort through a list of agents to determine whether a foreign establishment had designated or authorized a particular agent to address a particular issue.

As for advising foreign establishments to select their United States agents carefully, FDA was emphasizing that its interactions with a United States agent could involve proprietary information, particularly in emergency situations (see 64 FR 26330 at 26334). FDA must be able to communicate freely with a United States agent in these situations; otherwise, if the United States agent is unable or unauthorized to speak to FDA, the United States agent has little or no value in serving as a contact between FDA and the foreign establishment. FDA takes no position whether a foreign establishment should select a U. S. distributor to be its United States agent.

(Comment 8) Several comments addressed the United States agent's duties under the rule. Under proposed §§ 207.40(c)(2), 607.40(d)(2), and 807.40(d)(2), the United States agent would be responsible for assisting FDA in communications with the foreign establishment, responding to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assisting FDA in scheduling inspections of the foreign establishment. The proposal also authorized FDA to provide information or documents to the United States agent if FDA is unable to contact the foreign establishment directly or expeditiously.

One comment said that the agent's duties were very flexible, reasonable, and represented a ''vast improvement'' over an earlier approach taken by FDA for device manufacturers, while another comment said the proposed rule appropriately imposed no duty on the agent to file annual submissions for devices. In contrast, other comments misinterpreted the rule as requiring the United States agent to submit all documents, such as premarket

notifications, annual certifications, and registration and listing information, to FDA, or to be the only contact between a foreign establishment and FDA. The comments argued that the agent would only become an obstacle to communications between FDA and foreign establishments or, in the case of device firms, would be performing the same duties as the firm's official correspondent.

(Response) FDA intentionally imposed very few duties on the United States agent. Thus, contrary to the views expressed in some comments, FDA is not requiring the agent to submit all documents—or any particular document—to FDA on behalf of a foreign establishment or to be a foreign establishment's sole contact with FDA. The final rule, like the proposal, only requires that the agent assist FDA in communications with the foreign establishment, to respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and to assist FDA in scheduling inspections of the foreign establishment. The final rule also authorizes FDA to provide information or documents to the United States agent if FDA is unable to contact the foreign establishment directly or expeditiously. Foreign establishments have the discretion to give their United States agents additional tasks and may always contact FDA directly, with or without their United States agents.

FDA does wish to clarify, however, that the United States agent, as established in section 510(i) of the act and this final rule, is different, both in the underlying legal authority for the requirement and its application to FDA-regulated products, from the ''U.S.-designated agent'' in the existing § 807.40(c). The ''U.S.-designated agent'' applied solely to device manufacturers, and FDA stayed the effective date of the ''U.S.-designated agent'' requirement in the **Federal Register** of July 23, 1996 (61 FR 38345). (In fact, because this final rule rewrites § 807.40 entirely, the ''U.S.-designated agent'' language from § 807.40 no longer appears.) In contrast, the United States agent requirement applies to human drug, animal drug, biologics (including blood and blood products), and device establishments, and is required by section 510(i) of the act. Section 510(i) of the act did not create any specific duties for the United States agent, and so FDA, under this rulemaking, prescribed very few duties for the United States agent.

(Comment 9) One comment stated that, at the port of entry, the importer of record has the burden of resolving any import problems. The comment said that because the U. S. Customs Service and FDA regulate imports, it is unclear how regulatory differences between the Customs Service and FDA would be reconciled. The comment said that if a foreign establishment selects company A as its United States agent, company A's role in resolving import problems would be unclear if another company was the importer of record.

(Response) The comment misinterprets the rule. The United States agent, under parts 207, 607, and 807, has no duties or responsibilities to the Customs Service. Furthermore, with regard to imported products, the final rule requires the United States agent to respond to questions regarding the foreign establishment's products that are imported or offered for import into the United States (see, e.g., § 207.40(c)(2)). The preamble to the proposed rule indicated that these questions might concern the product's distribution in the United States (see 64 FR 26330 at 26333). In other words, the rule does not require the United States agent to respond to inquiries from the Customs Service. The final rule does not require the United States agent to resolve any import problems alone or to resolve any import problems immediately at a port of entry. The final rule does not require the United States agent to be responsible for legal issues surrounding the product's admission into the United States. In the comment's hypothetical example, FDA regulations would not require company A to resolve import problems raised by FDA or the Customs Service, although FDA believes that the United States agent could play an important role in resolving such problems by facilitating communication with the foreign establishment, working with the importer of record, or even, when appropriate, helping resolve the problem.

3. Miscellaneous Comments Regarding the United States Agent Requirement

(Comment 10) Several comments asked about the United States agent's liability. One comment asked FDA to clarify that FDA would not hold the agent legally responsible if, after the agent had made reasonable attempts to transmit documents or information to the foreign establishment, the foreign establishment failed to respond adequately to FDA. The comment suggested that FDA revise the rule to limit the agent's liability to ''a fulfillment of the agent's responsibility * * * on behalf of the foreign firm'' and to not hold the agent liable for any violation of the act by the foreign firm. Another comment expressed a similar opinion, stating that FDA had not considered whether a United States agent would be liable for the foreign establishment's actions.

Another comment expressed concern about the United States agent's exposure to litigation from parties in the United States who sue the foreign establishment. Two other comments said that they had surveyed various U. S. firms or contacted U. S. attorneys and found that none were willing to act as a United States agent; one comment indicated that U. S. firms were concerned about their potential legal liability.

(Response) In general, FDA does not intend to hold the United States agent responsible for violations of the act committed by a foreign establishment. FDA wants the United States agent to assist in communications with the foreign establishment, to respond to questions about the foreign establishment's products, and to help schedule inspections of the foreign establishment. If a foreign establishment violates the act, FDA would pursue action against that foreign establishment. Examples of instances where FDA might take action against the United States agent would be where the agent submitted false information to FDA or the agent and the foreign establishment were effectively the same entity. Given the limited nature of the United States agent's potential liability to FDA, the agency declines to amend the rule to address liability issues.

As for the United States agent's liability in third party litigation (i.e., situations where a private party sues the foreign establishment and attempts to attach or enforce a judgment by attaching the United States agent's assets), such issues are beyond the scope of this rule. FDA does not have authority to insulate United States agents from such litigation, and such litigation would be a matter of State, rather than Federal, law.

(Comment 11) One comment asked FDA to provide additional support and details on the United States agent requirement. The comment suggested that FDA should identify persons who can serve as United States agents and make that information publicly available through FDA's website or other publications. The comment also said FDA should consider its enforcement needs regarding office location, personnel qualifications, and necessary communications capabilities.

(Response) Given the final rule's broad, general descriptions of the United States agent's duties, details regarding the United States agent's office location, the agent's personnel qualifications, and communications

capabilities are not necessary at this time. If such details become necessary or desirable in the future, FDA will consider whether additional documents, such as a guidance document or rulemaking, are needed.

As for identifying persons who might serve as United States agents, FDA's Center for Devices and Radiological Health is considering whether to list persons who have expressed an interest in being United States agents. The list would be made available over the Internet, but FDA cautions that the list should not be interpreted as endorsing any person on the list or as suggesting that those persons are particularly trained or qualified to act as United States agents.

(Comment 12) The proposed rule would require a foreign establishment to report changes in the United States agent's name, address, or phone number within 5 days of the change. The preamble to the proposed rule invited comment as to whether a United States agent should be able to report such changes to FDA itself (see 64 FR 26330 at 26333). The preamble to the proposed rule explained that, on rare occasions, FDA has contacted individuals whom their establishments had identified as their agent or representative only to find that the individual had terminated its relationship with the establishment or was unaware that the establishment had designated that individual as its representative (id.).

One comment would permit a United States agent to notify FDA about changes to its name or address or even whether a person no longer serves as a foreign establishment's United States agent.

(Response) FDA agrees and has revised §§ 207.40(c)(3), 607.40(d)(3), and 807.40(b)(3) so that United States agents may report changes themselves.

(Comment 13) Several comments supported discussions between FDA and its Canadian counterparts to reach an agreement that would eliminate the need for a United States agent for Canadian firms or let Canadian authorities act on FDA's behalf on matters involving Canadian firms. Another comment stated that it understood that the U. S. Department of Agriculture and FDA had a ''reciprocal relationship'' with the Canadian Food Inspection Agency (CFIA) that enables U. S. regulatory authorities to inspect Canadian firms where possible and, where geographically impossible, obtain information from Canadian authorities regarding a Canadian firm's products, their origin, inspection status, and other information.

(Response) Although FDA and its Canadian counterparts have a history of cooperation on regulatory matters of mutual interest, section 510(i) of the act and other laws administered by FDA do not contain a mechanism for exempting countries from the United States agent requirement. Consequently, negotiations seeking an administrative exemption from the United States agent requirement would not be productive.

Similarly, an agreement with a foreign country regarding inspection results does not relieve foreign manufacturers from complying with section 510(i) of the act. Neither does it relieve FDA from enforcing section 510(i) of the act.

(Comment 14) Several comments asserted that trade agreements restricted the ability of the United States to require foreign establishments to have a United States agent. Most comments referred to the North American Free Trade Agreement (NAFTA), the United States-Canada Free Trade Agreement, and/or the General Agreement on Tariffs and Trade (GATT) to declare that a United States agent requirement would hinder trade or would be an unreasonable barrier to trade. Other comments simply referred to unnamed trade agreements and did not explain how the United States agent requirement violated those trade agreements. One comment stated that NAFTA provides for recovery of lost profits under certain conditions and that FDA must consider NAFTA matters before issuing regulations that could affect North American trade. Another comment said that NAFTA prevents the United States from requiring foreign establishments to have a United States agent when Canada does not have a similar requirement for U. S. firms.

Other comments raised other trade issues, stating that the United States agent requirement will prompt some foreign establishments to withdraw from the U. S. market, resulting in an adverse effect on U. S. consumers. Some comments suggested that they would ask their governments to enact similar requirements against U. S. companies. A small number of comments feared that other countries, after discovering that the United States requires foreign establishments to have an agent, would enact similar legislation or claimed that their own foreign country did not impose such requirements on U. S. establishments.

(Response) FDA disagrees with the comments that suggested that the rule violates relevant trade agreements. Both GATT and NAFTA permit parties to adopt measures for the protection of human health as well as measures to secure compliance with permissible laws. The rule accurately implements the legitimate public health objectives of facilitating communication and scheduling of inspections with foreign establishments and is not a disguised restriction on trade. Furthermore, it does not violate the national treatment provisions of the trade agreements because the requirement parallels the domestic registration requirements of providing the name of an accessible individual responsible to the establishment.

As for those comments claiming that the rule will prompt some foreign establishments to withdraw from the U. S. market or lead to foreign legislation targeting U. S. companies, such matters are speculative and outside the scope of this regulation.

As for those comments claiming that their own country does not have a similar requirement that would apply against U. S. establishments, FDA is aware of several agent-like requirements imposed by foreign countries. These requirements vary in the obligations imposed and the industries affected, but, regardless of their nature, the existence or non-existence of foreign statutory requirements does not alter the fact that section 510(i) of the act requires foreign establishments to have a United States agent.

(Comment 15) Most comments did not object to requiring foreign establishments to register their establishments. The comments often explained that their own country's laws or regulations required establishments to register or that FDA would be treating domestic and foreign establishments alike. However, one comment objected to having a United States agent because, it argued, FDA does not require establishments in the United States to have an agent. The comment also criticized the ''U.S.-designated agent'' requirement (which never became effective) as treating foreign establishments differently than U. S. establishments.

(Response) Section 510(i) of the act clearly requires foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States to register and to name a United States agent. Although the comment is correct that the act does not impose a United States agent requirement on U. S. establishments, there would be no need to amend the act to impose such a requirement on U. S. establishments because, by virtue of being located in the United States, they already should have employees located

in the United States whom FDA can contact when necessary.

C. Comments on Proposed Changes to Part 207 (Human Drugs, Biologics, and Animal Drugs)

1. General Comments

(Comment 16) One comment said that foreign establishments that make a bulk chemical intermediate do not have to register or list because a bulk chemical intermediate is not a drug. The comment then suggested that, because a new drug application (NDA) holder processes both bulk chemical intermediates and bulk drug substances into a finished drug product, there is no valid basis for requiring a foreign bulk drug substance manufacturer to register if a foreign bulk chemical intermediate manufacturer does not register. The comment suggested that the NDA holder simply list both foreign suppliers in the NDA rather than require a foreign bulk drug substance establishment to register.

(Response) FDA declines to revise the rule as suggested by the comment. The comment's claim regarding different regulatory burdens between bulk chemical intermediate product manufacturers and bulk drug substance manufacturers is misleading because it neglects to consider the role of each substance in a drug. Chemical intermediates, in general, are materials that are produced during a manufacturing process and undergo further molecular change or processing before they become an active pharmaceutical ingredient. Bulk drug substances, under § 207.3(a)(4), are substances that are represented for use in a drug and that, ''when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or finished dosage form of the drug * * *.'' Thus, chemical intermediates and bulk drug substances are not alike.

In other words, a chemical intermediate undergoes one or more molecular changes during manufacturing to become a different chemical, but the chemical intermediate, in its original form, is not intended or suitable for use as an active ingredient. Requiring establishments that manufacture chemical intermediates to register and to list, therefore, would not provide much helpful information to FDA and, for that reason, is not necessary to protect the public health.

In contrast, if a firm makes a bulk drug substance, the bulk drug substance does not require molecular change to become pharmacologically active. Thus, because a bulk drug substance, like a finished drug, may provide pharmacological activity, it makes sense to require establishments that manufacture bulk drug substances to register and list.

(Comment 17) One comment asked FDA to clarify which biological products fall under part 207 and to explain the rationale for including or excluding biological products from part 207. The comment offered no reason why this clarification was necessary.

(Response) Deciding whether a biological product should be registered under parts 207, 607, or 807 depends largely on how the product is defined. In brief, section 201(g)(1)(B) and (g)(1)(C) of the act (21 U.S.C. 321(g)(1)(B) and (g)(1)(C)) defines ''drug'' as ''articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals'' and as ''articles (other than food) intended to affect the structure or any function of the body of man or other animals.'' Section 201(h) of the act, in part, defines ''device'' as ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory'' which is ''intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals'' or ''intended to affect the structure or any function of the body of man or other animals'' and ''which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.''

Section 510(i) of the act, in turn, requires foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to register the name and place of business of the establishment and the name of a United States agent and to provide listing information. Thus, if a biologic meets the definition of drug or device, as defined in the act, a foreign manufacturer for that biologic must register (including the name of its United States agent) and submit listing information. Implementing regulations for the registration and listing requirements in section 510 of the act are divided among parts 207 (drugs (including biologics) and animal drugs), 607 (blood and blood products), and 807 (devices).

It is impractical to explain further which biologics may or may not be regulated under part 207 or to explain the rationale for their inclusion or exclusion. FDA's experience demonstrates that, despite FDA's intentions to provide advice or clarity, whenever the agency attempts to provide complete descriptions of the products that are subject to a particular regulation or part, the descriptions are either misconstrued as being exhaustive or definitive (so that persons whose products are not identified or even slightly different from the products mentioned in the description claim that they are exempt from the rule) or must be constantly revised to add new products and to remove old products. FDA, therefore, finds it more practical, less confusing, and a better use of its resources to refrain from providing the detailed explanations sought by the comment. If an establishment is unsure which registration and listing requirements apply, it should contact the Center for Biologics Evaluation and Research (CBER).

2. Definitions (§ 207.3)

Proposed § 207.3 defined two terms: ''commercial distribution'' and ''United States agent.'' The proposal in § 207.3(a)(5) defined ''commercial distribution'' as:

> any distribution of a human drug except for investigational use under part 312 of this chapter, and any distribution of an animal drug or animal feed bearing or containing an animal drug for noninvestigational uses, but the term does not include internal or interplant transfer of a bulk drug substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term ''commercial distribution'' shall have the same meaning except that the term shall not include distribution of any drug that is neither imported nor offered for import into the United States.

FDA meant to clarify that, for foreign establishments, commercial distribution does not include distribution of a human or animal drug that is neither imported nor offered for import into the United States. This change was intended to reflect the statutory language limiting the registration requirement to those foreign establishments that are ''engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import *into the United States*'' (emphasis added), as well as the definition of ''interstate commerce'' in section 201(b) of the act.

(Comment 18) One comment sought further clarification of the term ''commercial distribution'' and how it determined who must register under

§ 207.20. The comment asked whether a foreign establishment that supplies a bulk active drug ingredient to the U. S. holder of an NDA for incorporation into a finished product must register and list its products and whether the act of supplying the bulk active drug ingredient was ''commercial distribution.'' The comment asserted that if FDA required the foreign bulk active ingredient establishment to register and list, it would impose a greater obligation on the foreign establishment than on an affiliated company of the NDA holder. The comment asserted that the transfer or shipment of bulk drug substances between affiliates does not constitute commercial distribution.

(Response) Section 510(i) of the act applies to any foreign establishment engaged in the ''manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States * * * .'' Section 201(g)(1) of the act defines ''drug,'' in part, as ''articles intended for use as a component'' of a drug. Thus, a foreign bulk drug manufacturer who ships bulk active ingredients to a U. S. firm is subject to section 510(i) of the act and must register the foreign establishment (including a United States agent) and list its products.

FDA disagrees with the comment's assertion that requiring a foreign bulk drug manufacturer to register and list would impose a greater duty than one that would apply to an NDA holder's affiliate company. Under § 207.3(a)(5), only internal or interplant transfers of bulk drug substances between registered establishments within the same parent, subsidiary, and/or affiliate company fall outside the definition of ''commercial distribution.'' Thus, under § 207.3(a)(5), an affiliate firm would have to be registered just like the foreign establishment.

(Comment 19) One comment sought additional definitions or explanations of terms in part 207. The comment said FDA should amend the definitions to state specifically that establishments, both foreign and domestic, that make biological products must register and list. The comment claimed that biologics manufacturers are sometimes unaware that they must register and list. The comment also asked FDA to clarify whether biologic source suppliers must register.

(Response) FDA declines to amend the rule to include an express reference to biologics establishments. Part 207 already contains sufficient indications to show that the requirements apply to biologics establishments, so further clarification is unnecessary, and the statutory definition of ''drug,'' in section 201 of the act, includes biological products.

Furthermore, revising part 207 to include an express reference to biologics establishments might increase any confusion in the biologics industry or force FDA to make similar changes throughout title 21 of the CFR each time the word ''drug'' appears. Otherwise, a biologics firm might argue that the absence of an express reference to biologics in any given regulation meant that the regulation did not apply to biologics. The result would be confusion as to which rules did or did not apply to biologics. While it might ultimately be beneficial for FDA to examine all of its regulations to clarify their scope or coverage, a large scale reexamination and editorial effort is outside the scope of this rule.

As for the question whether biologics source suppliers must register, registration is required if the product that is imported or offered for import to the United States meets the definition of ''drug'' in section 201(g) or ''device'' in section 201(h) of the act and if the foreign establishment is not otherwise exempt from the registration requirement.

(Comment 20) Proposed § 207.3(a)(11) defined ''United States agent'' as ''a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent.'' FDA received no comments on the definition in § 207.3(a)(11), but one comment did address the identical definition at § 807.3. The comment noted that the preamble to the proposed rule stated that the definition of ''United States agent'' excluded mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present (see 64 FR 26330 at 26331). The comment suggested that FDA revise the definition of ''United States agent'' to mention these exclusions.

(Response) FDA agrees with the comment and has revised the definition of ''United States agent'' in §§ 207.3(a)(11), 607.3(j), and 807.3(r) accordingly.

3. Establishment Registration and Product Listing for Human Blood and Blood Products and for Medical Devices (§ 207.7)

Proposed § 207.7(a) would revise the address for the office in CBER that receives the registration and listing information.

FDA received no comments on this provision and has finalized it without change.

4. Exemptions for Establishments (§ 207.10)

Proposed § 207.10 would delete the word ''domestic'' from its title, so that the provision pertains to exemptions for both foreign and domestic establishments. The proposal would also revise the description of establishments that are exempt from registration.

FDA received no comments on this provision and has finalized it without change.

5. Who Must Register and Submit a Drug List (§ 207.20)

Proposed § 207.20(a) would clarify that the exemptions are under section 510(g) of the act or subpart B (''Exemptions'') of part 207. This would be an editorial change to place all exemptions that apply to drug manufacturers in subpart B of part 207 and would remove all exemptions from subpart D.

The proposal would also revise paragraph (a) of § 207.20 so that the language requiring owners and operators to register their establishments and to list drugs, whether or not the output of the establishment or any particular drug so listed enters interstate commerce, would apply only to domestic firms. FDA proposed this change because it does not intend to require foreign establishments to list drugs that do not enter interstate commerce by being imported or offered for import into the United States.

The proposal would also make some minor edits to § 207.20(a) by: (a) Deleting the phrase ''at this time'' because the phrase is unnecessary, (b) moving the parenthetical language referring to Type B and Type C medicated feed so that it refers accurately to animal feeds bearing or containing an animal drug rather than to animal feeds generally, and (c) revising the parenthetical language so that it refers to Type B ''or'' Type C medicated feed. The proposed rule would also add ''abbreviated new drug applications'' and ''abbreviated new animal drug applications'' to the list of marketing applications in § 207.20(c). These applications were inadvertently omitted from previous rulemakings amending part 207.

(Comment 21) In the preamble to the proposed rule, FDA noted that § 207.20(a) permits a company to submit listing information on behalf of a parent, subsidiary, and/or affiliate company for all establishments when operations are

conducted at more than one establishment and there exists joint ownership and control among all the establishments. FDA interpreted this provision, and similar provisions at §§ 607.20(a) and 807.20(a), as including foreign establishments to which the same conditions apply (see 64 FR 26330 at 26332).

One comment asked FDA to explain what '' affiliate companies '' and '' joint ownership and control '' are. The comment said that the rule allows reporting by affiliate companies where there is joint ownership and control, but does not explain what those terms mean.

(Response) The act and a commonly used law dictionary can provide some help on interpreting the terms '' affiliate companies '' and '' joint ownership and control.'' Section 735(9) of the act (21 U.S.C. 379g(9)) defines ''affiliate,'' for purposes of fees relating to drugs, as meaning ''a business entity that has a relationship with a second business entity if, directly or indirectly—(A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has power to control both of the business entities.'' This definition is similar to one that appears in *Black's Law Dictionary*, which defines ''affiliation,'' in terms of corporations, as legally enforceable control of stock of corporations by the same interests (see *Black's Law Dictionary* 80 (4th ed. 1968)). Thus, an ''affiliate company'' is one that is legally controlled, directly or indirectly, by another company or can be controlled by another company; mere business links are not sufficient. *Black's Law Dictionary* defines ''joint owners'' as ''two or more persons who jointly own and hold title to property'' and ''control'' as ''power or authority to manage, direct, superintend, restrict, regulate, direct, govern, administer, or oversee'' (id. at 1260 and 399). Thus, ''joint ownership and control'' suggests that two or more persons own the companies at issue and share managerial or supervisory responsibilities.

(Comment 22) One comment suggested that FDA revise § 207.20(a) and similar language in §§ 607.20(a) and 807.20(a) to allow a foreign parent company to register and list on behalf of its foreign subsidiaries. The comment explained that the rule allows parent companies to list on behalf of their subsidiaries, but does not allow them to register their subsidiaries. The comment suggested that section 510(i) and (j) of the act give FDA the flexibility to allow parent companies to register on behalf of their subsidiaries and that this would also enable foreign establishments to name a single official who would be responsible for registration and listing information, thereby facilitating the development of a single, unified registration and listing system.

(Response) FDA agrees with the comment and has amended §§ 207.20(a), 607.20(a), and 807.20(a) to allow parent companies to register and list on behalf of their subsidiaries.

(Comment 23) One comment said that FDA should ''recognize'' that distributors may list drug products and that the manufacturers of those drug products, whether foreign or domestic, should not have to list the same drugs. The comment asserted that the Drug Listing Act of 1972 was not intended to require ''dual listing'' by a manufacturer if a distributor supplied the same information. The comment said FDA's current practice (which requires manufacturers to list drugs even if a distributor lists those drugs) is contrary to the Drug Listing Act of 1972, FDA's regulations at § 207.20(b), and the Paperwork Reduction Act. The comment said requiring ''additional'' listing has no practical utility, is wasteful to the regulated industry, and costly to consumers.

(Response) Although the comment is outside the scope of the rule in the sense that it has no direct bearing on foreign establishment registration, listing, or the United States agent requirement, FDA disagrees with the comment. Section 207.20(b) applies to owners and operators of establishments that are ''*not otherwise required to register under section 510 of the act*'' and that ''*distribute under their own label or trade name* a drug manufactured or processed by a registered establishment'' (emphases added). It states that these owners and operators may elect to submit listing information directly to FDA and to obtain a Labeler Code. The regulation, therefore, clearly states that these distributors: (1) Do not have to register (whereas manufacturers must register); (2) are distributing drugs under their own label or trade name (which will be different from the labels and names used by the manufacturer); and (3) have discretion to decide whether they wish to list the drugs (because § 207.20(b) says that these persons ''may elect'' to submit listing information to FDA).

More importantly, the comment overlooks the value in having these distributors and manufacturers list drugs. Section 207.20(b) applies where the distributor uses its own label or trade name on a drug, but does not manufacture the drug itself. So, if these distributors and drug manufacturers list the drugs that they put into commercial distribution, FDA will be able to link the distributor's drugs back to their manufacturer(s) even though the distributor is using a different label or name for the drug.

To illustrate how this works, assume that a distributor, named Delta, distributes two drugs that it calls Alpha and Beta. Alpha is made by a U. S. manufacturer, named Domestic Co., which sells Alpha under the name X, while Beta is made by a foreign manufacturer, named Foreign Co., and sold under the name Y. If, as the comment apparently requests, Delta—but not Domestic Co., or Foreign Co., had to list the drugs, FDA might find it difficult to link Alpha and Beta to their respective manufacturers. If, on the other hand, the manufacturers, but not Delta, had to list the drugs, FDA might find it difficult to know that drug X and Alpha are the same or that drug Y and Beta are the same. When viewed from this perspective, the drug listing information from both the distributor and manufacturers serves the practical purpose of providing a link between seemingly different drugs, and so, contrary to the comment, the drug listing information is not redundant or unnecessary.

(Comment 24) One comment said that FDA, in the past, has allowed foreign drug establishments to authorize a representative to register and list on its behalf. The comment asked FDA to clarify that foreign drug establishments may continue this practice.

(Response) Foreign drug establishments may continue to have representatives register and submit drug listing information on their behalf. Neither section 510(i) of the act, nor this final rule, requires foreign drug establishments to complete or to submit registration and listing information themselves, but foreign drug establishments are responsible for the accuracy of the information submitted to FDA and for complying with the registration and listing requirements.

(Comment 25) One comment suggested that if a biologic intermediate is licensed, then the license holder for the intermediate and the license holder for the final product must register and list the product.

(Response) In general, if an establishment has a licensed biological product, the establishment, whether foreign or domestic, must register and list its products. FDA would consider the product to fall within the definition of ''drug'' or ''device'' in section 201(g) or (h) of the act, so section 510(i) of the act would require registration and product listing.

(Comment 26) One comment asked whether biologics source suppliers must register.

(Response) As stated earlier, registration is required if the product that is imported or offered for import to the United States meets the definition of ''drug'' or ''device'' in section 201(g) or (h) of the act and if the establishment is not otherwise exempt from the registration requirement.

If the establishment is unsure about whether or not they should register, they should contact the appropriate product review division in CBER. If the establishment is unsure about which product review division to contact, they should contact the Office of Compliance and Biologics Quality at 301–827–6190 for assistance.

(Comment 27) One comment claimed that, because the rule excluded establishments whose drugs are not imported or offered for import into the United States, the rule contradicted FDA's ''Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics'' (hereinafter referred to as ''the cooperative manufacturing policy''), which appeared in the **Federal Register** on November 25, 1992 (57 FR 55544). The comment focused on foreign manufacturers of bulk substances who sell their products to other foreign manufacturers who use them in making a finished product.

(Response) The cooperative manufacturing policy discussed several types of manufacturing arrangements for establishments who wish to cooperate in the manufacture of a licensed biological product and made no distinctions between foreign and domestic manufacturers. FDA drafted the policy statement to describe the then-current licensing policies in CBER ''for meeting the increased demand for flexible manufacturing arrangements'' (57 FR 55544).

The first manufacturing arrangement discussed in the policy concerned short supply arrangements. In a short supply arrangement, a manufacturer obtains materials from another facility under certain conditions because the manufacturer needs to obtain source materials only due to ''unusual circumstances where the source material is scarce or growth requirements so peculiar that production is uncommon'' (57 FR 55544 at 55545). The policy was silent as to whether firms who provide source material under a short supply arrangement must register or list, so it neither supports nor conflicts with this rule. FDA advises foreign establishments who provide source material under a short supply arrangement to register and to list if they meet the terms in section 510(i) of the act and this final rule. In other words, registration and listing is required if the foreign establishment is engaged in manufacturing, preparing, propagating, compounding, or processing a drug or device that is imported or offered for import into the United States (and the establishment does not otherwise qualify for an exemption from the registration and listing requirements).

The second arrangement discussed in the policy concerned divided manufacturing arrangements where two *registered* manufacturers jointly participate in manufacturing a product (emphasis added). Under this scenario, both manufacturers are manufacturing the product, so, even if the manufacturers were both foreign establishments, they would be subject to the registration requirements in this rule because they are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States. So, the policy, as it applies to divided manufacturing arrangements, does not conflict with the rule.

The third and fourth arrangements discussed in the policy pertain to shared and contract manufacturing arrangements. In shared manufacturing arrangements, two or more manufacturers may perform different manufacturing tasks, but are not licensed to perform all manufacturing aspects. The policy advised manufacturers in shared manufacturing arrangements to register and to list in accordance with part 207. If the manufacturers are located in a foreign country, FDA considers both to be manufacturing a product to be imported or offered for import into the United States and would expect both manufacturers to register and to list the products that are being imported or offered for import. Consequently, the policy does not conflict with the rule.

As for contract manufacturing arrangements, these arrangements involve a licensed manufacturer who engages another manufacturing facility (referred to as the ''contract manufacturer'') to perform all or some of the steps to manufacture a biological product (see 57 FR 55544 at 55546). Clearly, the licensed manufacturer, as the entity who obtains marketing approval and sells the product, must register and list its product even if the licensed manufacturer is a foreign establishment. Registration and listing would be required because, under section 510(i) of the act, the licensed manufacturer is manufacturing, preparing, propagating, compounding, or processing a drug that is imported or offered for import into the United States. The same would be true for foreign contract manufacturers; if a foreign contract manufacturer's manufacturing steps can be considered to be manufacturing, preparing, propagating, compounding, or processing a drug that is imported or offered for import into the United States, then the foreign contract manufacturer falls within section 510(i) of the act and must register and list.

FDA further notes that the cooperative manufacturing policy statement simply represents FDA's advice whereas this rule implements section 510(i) of the act and creates enforceable obligations. Therefore, even if there were any conflict between the policy statement and this rule, foreign establishments must comply with this rule.

6. Times for Registration and Drug Listing (§ 207.21)

Proposed § 207.21 would correct an administrative oversight by adding ''abbreviated new drug applications'' and ''abbreviated new animal drug applications'' to the list of marketing applications in that section. The effect would be to state, expressly, that an owner or operator of an establishment that has just begun manufacturing or processing drugs should register within 5 days after submitting an NDA, abbreviated new drug application, new animal drug application, abbreviated new animal drug application, medicated feed mill license application, antibiotic application, or a biologics license application to manufacture a biological product.

(Comment 28) One comment said FDA failed to address biological manufacturing sites that are currently licensed, but not registered. The comment asked when these firms should register.

(Response) FDA recently began efforts to create an electronic registration program for all establishments, both foreign and domestic, that are subject to part 207. As a result, FDA is amending § 207.21(a) to delete the registration schedule and its reference to Form FDA–2656 (Registration of Drug Establishment).

Foreign establishments subject to part 207 should register by May 28, 2002.

(Comment 29) One comment said that FDA should create a special schedule for foreign establishment registration, rather than use the existing schedule, because foreign establishments might find it difficult to register quickly or immediately (depending on when the

rule becomes effective). The comment said FDA should also consider the implications of company mergers, name changes, burdens of complying with new registration schedules, and multiple product types.

(Response) As stated above, foreign establishments subject to part 207 should register by May 28, 2002. This should give foreign establishments sufficient time to comply with the registration and listing requirements even if they are aware of impending mergers, name changes, or other future business considerations.

7. Information Required in Registration and Drug Listing (§ 207.25)

Section 207.25(b)(2) requires the numbers for various marketing applications to be included in the drug listing information submitted to the agency. For example, if an NDA were assigned number 20–570, the application number that would be included in the drug listing information would be NDA 20–570.

The proposed rule would add abbreviated new animal drug applications to the list of marketing applications in § 207.25. This action was necessary because abbreviated new animal drug applications were inadvertently omitted.

(Comment 30) One comment asked whether § 207.25(b)(3), which requires an establishment to provide the ''license number of the manufacturer'' as part of the drug product listing form, applies to numbers assigned to biologics license applications.

(Response) When FDA approves a biologics license application, the applicant receives a United States license number. The United States license number is different from the biologics license application number and is the number that should be reported on the drug listing form for biological products in § 207.25(b)(3).

8. Inspection of Registrations and Drug Listings (§ 207.37)

Proposed § 207.37(a) would update the addresses in the Center for Drug Evaluation and Research (CDER) where copies of registration forms filed by establishments are available for inspection and would state that copies of registration forms submitted by foreign establishments are available for inspection at the Office of Compliance in CDER. Copies of forms submitted by domestic establishments would continue to be available for inspection at FDA district offices and at the Office of Compliance in CDER.

The proposal would also update the addresses in § 207.37(b).

(Comment 31) One comment claimed the current procedures for examining drug listing information are ''cumbersome and inconvenient'' and that FDA should makes its processes more transparent and its procedures readily available. The comment said FDA should post the information on the Internet.

(Response) In general, FDA has taken various steps to make information more readily available. The agency will take the comment's suggestion under advisement, but, due to resource limitations and other agency priorities, it cannot, at this time, make drug listing information available electronically or estimate when it will be able to do so.

9. Drug Listing Requirements for Foreign Drug Establishments (§ 207.40)

Proposed § 207.40(a) would require foreign establishments whose drugs are imported or offered for import into the United States to comply with the establishment registration and listing requirements in subpart C of part 207 (''Procedures for domestic drug establishments''), unless exempt under subpart B of part 207 (''Exemptions''). Proposed § 207.40(b) would prohibit the importation of drugs from unregistered foreign establishments, prohibit the importation of unlisted drugs, and require foreign establishments to submit registration and listing information, including labels and labeling, in English. Proposed § 207.40(c) would, among other things, require each foreign establishment to submit the name, address, and phone number of its United States agent as part of the establishment's initial and updated registration information, and to describe the United States agent's responsibilities.

(Comment 32 and Response) FDA, on its own initiative, is revising the reference to drugs imported for investigational use in § 207.40(b). The rule stated that drugs for investigational use must comply with 21 CFR part 312. FDA is revising the provision to add a reference to part 511 (21 CFR part 511) because investigational new animal drugs are subject to part 511. This change should have no effect on foreign establishments because the Center for Veterinary Medicine has not required foreign establishments to list investigational new animal drugs.

FDA is also revising § 207.40(b) and its prohibition on the importation or the offer to import drugs from unregistered foreign establishments. FDA is adding a reference to section 801(d)(3) of the act (21 U.S.C. 381(d)(3)) so that drugs imported under section 801(d)(3) of the act may be admitted into the United States even if the foreign establishment is not registered. The agency is taking this step because section 801(d)(3) of the act imposes very few restrictions on the admission of drug components that are imported into the United States for further processing or incorporation into a product that will be exported from the United States. The agency is making similar changes to §§ 607.40(b) and 807.40(c).

(Comment 33) Proposed § 207.40(c)(2) would require the United States agent to assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. One comment would revise the rule to allow multinational companies with many foreign affiliates to designate an employee at the foreign affiliate as the United States agent and to list an employee in the United States as an alternate. The comment said this would make communications between FDA and foreign establishments more efficient because the foreign employee would be able to answer questions more directly and schedule inspections more readily.

(Response) FDA declines to revise the rule as suggested by the comment. FDA reiterates that it interprets the term ''United States agent'' as meaning that the agent is physically located in the United States. If the United States agent could be located in any foreign country, section 510(i) of the act would not have to refer to a ''United States'' agent. Indeed, if the agent could be in any foreign country, the agent requirement might even by invalid or questioned as an intrusion into a foreign country's corporate or employment laws.

So, the rule does not prevent a multinational firm from designating an employee located in the United States as its agent who could, if necessary, consult a foreign employee to respond to any questions FDA might have, schedule an inspection, or work with a foreign employee on other issues relevant to the United States agent's duties.

(Comment 34) Proposed § 207.40(c)(3) would require foreign establishments to report changes in the United States agent's name, address, or phone number within 5 days of the change. One comment stated that there may not be an adequate number of firms or persons who can act as United States agents and that foreign establishments will have to identify and locate such persons. The comment asked FDA to provide 30 days,

rather than 5 days, for foreign establishments to identify its United States agent. Similarly, another comment said a 5-day period is too short and asked FDA to allow 10-business days or 14-calendar days.

(Response) FDA has revised § 207.40(c)(3), and similar requirements at §§ 607.40(d)(3), and 807.40(b)(3), to give foreign establishments and United States agents 10-business days to report changes.

(Comment 35) As stated earlier, one comment asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. The comment said that foreign establishments which send goods to a foreign trade zone and later re-export those goods from the United States without entering them into U. S. commerce should be exempt from registration requirements.

(Response) FDA agrees with the comment, but only as it pertains to foreign establishments who send products into foreign trade zones and whose products are re-exported from the United States without having entered domestic commerce. FDA, therefore, has amended §§ 207.40(a), 607.40(a), and 807.40(a) accordingly.

D. Proposed Changes to Part 607 (Human Blood and Blood Products)

1. Definitions (§ 607.3)

a. Definition of ''commercial distribution.'' Proposed § 607.3(e) would revise the definition of ''commercial distribution'' to state that, for foreign establishments, commercial distribution does not include distribution of any blood or blood product that is neither imported nor offered for import into the United States. The preamble to the proposed rule explained that this change was intended to make the definition, insofar as foreign establishments are concerned, consistent with the language of section 510(i)(1) of the act.

FDA received no comments on this provision and has finalized it without change.

b. Definition of ''United States agent.'' Proposed § 607.3(j) would define ''United States agent'' as ''any person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent.'' This definition was identical to that in proposed § 207.3(a)(11).

(Comment 36) FDA received no comments addressing proposed § 607.3(j). However, as stated earlier, the agency did receive a comment which sought to revise the identical definition at § 807.3 to expressly exclude mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

(Response) FDA agrees with the comment and has revised the definition of ''United States agent'' in § 607.3(j) and the identical definitions in §§ 207.3(a)(11) and 807.3(r), accordingly.

2. Establishment Registration and Product Listing of Blood Banks and Other Firms Manufacturing Human Blood and Blood Products (§ 607.7)

Section 607.7(b) and (c) provides an address for CBER from which registration forms may be obtained and to which they may be sent. The proposed rule would amend § 607.7(b) and (c) to update the address.

FDA received no comments on this provision and has finalized it without change.

3. Who Must Register and Submit a Blood Product List (§ 607.20)

Proposed § 607.20(a) would revise the description of owners and operators who must register their establishments and list their products. The proposal would clarify that only domestic firms must register and submit a list of every blood product in commercial distribution, ''whether or not the output of such blood product establishment or any particular blood product so listed enters interstate commerce.'' This would mean that foreign establishments do not have to list blood products that are not sold or offered for sale in the United States.

(Comment 37) As stated earlier, one comment suggested that FDA revise § 207.20(a) and similar language in §§ 607.20(a) and 807.20(a) to allow a foreign parent company to register and list on behalf of its foreign subsidiaries. The comment explained that the rule allows parent companies to list on behalf of their subsidiaries, but does not allow them to register their subsidiaries.

(Response) FDA agrees with the comment and has amended §§ 207.20(a), 607.20(a), and 807.20(a) to allow parent companies to register and list on behalf of their subsidiaries.

4. How and Where to Register Establishments and List Blood Products (§ 607.22)

Proposed § 607.22 would update the addresses from which registration and listing forms may be obtained. The proposal would also delete the language in § 607.22(b) concerning tapes for computer input and the submission of proposed formats for FDA review and approval because the option for using computer tapes was never used.

FDA received no comments on this provision and has finalized it without change.

5. Information Required for Establishment Registration and Blood Product Listing (§ 607.25)

Proposed § 607.25(a) would delete the word ''ZIP'' from the phrase ''post office ZIP code.'' FDA proposed this change because many foreign countries do not use the term ''ZIP'' code.

FDA received no comments on this provision and has finalized it without change. However, the agency, on its own initiative, is also amending § 607.25(b)(3) regarding the registration number of a parent establishment. Section 607.25(b)(3), as revised, now clarifies that for each blood product listed, the registration number of the parent establishment is required and that ''an establishment not owned, operated, or controlled by another firm or establishment is its own parent establishment.'' FDA is making this change to be consistent with changes to the Form FDA 2830 (Blood Establishment Registration and Product Listing).

6. Amendments to Establishment Registration (§ 607.26)

Currently, § 607.26 requires changes in individual ownership, ''corporate or partnership structure location or blood-product handling activity'' to be reported. The proposal would revise this language to read as ''Changes in individual ownership, corporate or partnership structure, location, or blood-product handling activity'' to clarify that changes in corporate or partnership structure or location or blood-product handling activity are to be reported.

FDA received no comments on this provision and has finalized it without change.

7. Additional Blood Product Listing Information (§ 607.31)

Proposed § 607.31(a) would authorize the Director of CBER, rather than the Commissioner of Food and Drugs (the Commissioner), to perform various actions, such as making a request or a finding, before requiring additional blood product listing information. The proposal reflected the fact that the center director, rather than the Commissioner, performs those functions.

The proposal would also delete § 607.31(b) that pertains to the voluntary reporting of information on the quantity

of blood product distributed. FDA proposed to delete the text in paragraph (b) of § 607.31 because the form specified in the rule, Form FD–2831 (Blood Establishment Resource Summary), is obsolete, and the provision has not been used.

FDA received no comments on this provision and has finalized it without change.

8. Notification of Registrant; Blood Product Establishment Registration Number and NDC Labeler Code (§ 607.35)

Section 607.35(a) currently states that the Commissioner will provide a validated copy of Form FD–2830 to the location shown for the registering establishment. The proposal would amend § 607.35(a) to state that a copy will also be sent to the reporting official if that official is at another address. The proposal would also substitute the ''Director of the Center for Biologics Evaluation and Research'' for the ''Commissioner'' because the center director, rather than the Commissioner, is the official who provides the validated copy.

FDA received no comments on this provision and has finalized it without change.

9. Inspection of Establishment Registrations and Blood Product Listings (§ 607.37)

Proposed § 607.37 would update the addresses where filed forms are available for inspection or where requests for information regarding blood establishment registration and listing should be sent.

FDA received no comments on this provision and has finalized it without change.

10. Establishment Registration and Blood Product Listing Requirements for Foreign Blood Product Establishments (§ 607.40)

Proposed § 607.40(a) would require foreign establishments to comply with establishment registration requirements in addition to blood product listing requirements. To complement this change, the proposal would revise the title to § 607.40 to read as ''Establishment registration and blood product listing requirements for foreign blood product establishments.''

Proposed § 607.40(b) would enable FDA to prohibit the importation of blood products from unregistered foreign establishments, in addition to prohibiting the importation of unlisted blood products. This prohibition would be similar to § 207.40(b) and would be consistent with sections 301(p) and 501(a) (21 U.S.C. 331(p) and 351(a)), and 801(a) of the act. Proposed § 607.40(b) would also add establishment registration information to types of information that must be submitted in the English language.

Proposed § 607.40(c) would require foreign blood product establishments to submit the name and address of the establishment and the name of the individual responsible for submitting the establishment registration and product listing information as part of the establishment registration and blood product listing. Proposed § 607.40(c) would also require foreign establishments to report any changes in their registration or listing information.

Proposed § 607.40(d) would require each foreign blood product establishment to submit the name, address, and phone number of one United States agent as part of its initial and updated registration information and describe the United States agent's responsibilities. Changes to the United States agent's name, address, or phone number would, under proposed § 607.40(d), be reported to FDA within 5 days of the change.

(Comment 38) FDA received no comments on this provision, but, as stated earlier, one comment asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. The comment said that foreign establishments which send goods to a foreign trade zone and later re-export those goods from the United States without entering them into United States commerce should be exempt from registration requirements.

(Response) FDA agrees with the comment, but only as it pertains to foreign establishments who send products into foreign trade zones and whose products are re-exported from the United States without having entered domestic commerce. FDA, therefore, has amended §§ 207.40(a), 607.40(a), and 807.40(a) accordingly.

(Comment 39) FDA received no comments on § 607.40, but, as stated earlier, received comments on similar language in § 207.40 regarding the time period for reporting changes to the United States agent's name, address, or phone number. The comments would increase the time period to 10-business days or 14-calendar days.

(Response) FDA agrees with the comment and has revised §§ 207.40(c)(3), 607.40(d)(3), and 807.40(b)(3) to give foreign establishments and United States agents 10 business days to report changes.

11. Exemptions for Blood Product Establishments (§ 607.65)

Proposed § 607.65 would revise paragraphs (c), (d), and (e) so that the exemptions described in those paragraphs would apply to both foreign and domestic persons or establishments. For example, proposed § 607.65(c) would exempt domestic and foreign persons who manufacture blood products solely for use in research, teaching, or analysis, while proposed § 607.65(d) would exempt carriers, both foreign and domestic, who receive, carry, hold, or deliver blood products in their usual course of business. Proposed § 607.65(e) would exempt domestic and foreign persons who engage solely in the manufacture of in vitro diagnostic blood products and reagents that are not subject to licensing under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262).

FDA received no comments on this provision and has finalized it without change.

12. Miscellaneous Biologics Comments

(Comment 40) One comment said that the document entitled ''Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics,'' which appeared in the **Federal Register** on November 25, 1992 (57 FR 55544), discusses registration requirements for firms in cooperative manufacturing arrangements, but does not specifically address ''who was responsible for the registration process (i.e., the license holder of the final product versus the establishment owner of the bulk drug substance').''

(Response) FDA issued the cooperative manufacturing policy in 1992, 6 years before FDAMA amended section 510(i) of the act to require foreign establishments to register. While FDA is currently updating the policy, comments concerning the policy are outside the scope of this rule.

Yet with regard to the comment's cooperative manufacturing scenario, section 510(i) of the act requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to register the name and place of business of the establishment and the name of a United States agent for the establishment. Thus, in a cooperative manufacturing arrangement, if a foreign bulk drug substance establishment imports or offers to import the bulk drug into the United States, the foreign establishment must

register. Likewise, the license holder of the final product, whether foreign or domestic, must register because, by obtaining the license (and presumably intending to sell the drug), the license holder is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug (see section 510(a)(1), (b), and (i) of the act).

E. Proposed Changes to Part 807 (Devices)

1. Definitions (§ 807.3)

a. Definition of ''commercial distribution.'' Section 807.3(b) currently defines ''commercial distribution,'' in part, as ''any distribution of a device intended for human use which is held or offered for sale * * * .''

Similar to the proposed changes to §§ 207.3 and 607.3, the proposed rule would create a new § 807.3(b)(4) to state that, for foreign establishments, commercial distribution does not include distribution of a device that is neither imported nor offered for import into the United States.

FDA received no comments on this provision and has finalized it without change.

b. Definition of ''United States agent.'' Proposed § 807.3(r) would define a ''United States agent'' as ''any person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent.''

(Comment 41) As stated earlier, FDA received one comment on the definition of United States agent. The comment noted that the preamble to the proposed rule stated that the definition of ''United States agent'' excluded mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present (see 64 FR 26330 at 26331). The comment suggested that FDA revise the definition of ''United States agent'' to mention these exclusions.

(Response) FDA agrees with the comment and has revised the definition of ''United States agent'' in §§ 207.3(a)(11), 607.3(j), and 807.3(r) accordingly.

2. Who Must Register and Submit a Device List (§ 807.20)

Section 807.20(a) currently requires an ''owner or operator of an establishment not exempt under section 510(g) of the act'' or subpart D of part 807 who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use to register and to submit listing information. It also states that an owner or operator shall register and list devices ''whether or not the output of the establishments or any particular device so listed enters interstate commerce.''

Proposed § 807.20(a) would clarify that an owner or operator ''shall'' register and list (unless it is otherwise exempt from such requirements). The proposal would also clarify that the language requiring owners and operators to register their establishments and to list devices, even if the devices do not enter interstate commerce, applies only to domestic firms.

The proposal would also amend the title of subpart B of part 807, ''Procedures for Domestic Device Establishments,'' to remove the word ''domestic.'' This would reflect the fact that the act's registration and listing requirements now apply both to domestic establishments and to foreign establishments whose devices are imported or offered for import into the United States.

The proposal would also delete § 807.20(a)(6) pertaining to persons acting as the U.S.-designated agent.

(Comment 42) One comment asked if a foreign establishment that supplies components to U. S. manufacturers must register and list if the U. S. manufacturer incorporates those components into a device.

(Response) Section 807.65(a) states that a ''manufacturer of raw materials or components to be used in the manufacturer or assembly of a device who would not otherwise be required to register under the provisions of this part'' is exempt from the registration requirements.

(Comment 43) One comment asked if devices that are licensed under section 351 of the PHS Act must be listed and whether their manufacturers must be registered.

(Response) Section 510(i) of the act makes no distinction between establishments whose products are subject to the act or whose products are subject to the PHS Act. It requires all foreign establishments that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to register (including the name of a United States agent) and to list their products.

Consequently, if a foreign establishment has devices that are licensed under section 351 of the PHS Act, then that foreign establishment must register and list its products. Most devices that are licensed under section 351 of the PHS Act will contain or use blood or blood components, so establishments that manufacture such licensed products would be subject to the registration and listing requirements for blood and blood products (part 607) rather than the registration and listing requirements for devices. FDA has revised § 607.3(b) to state expressly that, for purposes of the blood and blood product registration and listing requirements, blood and blood products include products which meet the definition of a device under the act and are licensed under section 351 of the PHS Act.

(Comment 44) One comment asked FDA to clarify whether foreign establishments may continue to authorize an initial importer in the United States to list devices on the foreign establishment's behalf. The comment explained that, in the past, FDA has allowed initial importers to list devices if the foreign establishment certifies that it does not ship its devices to anyone else in the United States. The comment added that, under § 807.25(d), the official correspondent for the foreign establishment would remain as the contact point for registration and listing matters.

(Response) The final rule requires foreign manufacturers to register and to list. In other words, FDA is discontinuing its policy that allowed ''sole'' initial importers to list devices. FDA is discontinuing the policy because, even though importers believed they were the ''sole'' importer, FDA sometimes found there were multiple ''sole'' importers. Each importer listed devices, and the lists would differ. The submission of multiple, and sometimes different, device lists from persons who claimed to be the ''sole'' initial importer for a particular foreign establishment created confusion and uncertainty about the device lists. Therefore, FDA is requiring foreign establishments to register and to list their devices and will not accept lists from ''sole'' initial importers.

(Comment 45) One comment asked FDA to clarify whether contract manufacturers must register or list devices. The comment explained that proposed § 807.20(a)(2) suggests that contract manufacturers do not have to list devices, but does not expressly exempt contract manufacturers from the registration requirements. The comment added that § 807.20(c) appears to exempt contract manufacturers from registration requirements and suggested that both foreign and domestic contract manufacturers be exempt from registration requirements.

(Response) The comment is correct that § 807.20(a)(2) exempts contract manufacturers from the listing

requirements, while the language in § 807.20(c)(1) was intended to exempt contract manufacturers from registration and listing requirements. However, the agency is considering more substantial revisions to part 807, and these revisions will include changes to the requirements for contract manufacturers. As a result, FDA declines to amend § 807.20(a)(2) and (c)(1) as suggested by the comment, and the agency encourages foreign contract manufacturers to register.

(Comment 46) One comment noted that, under § 807.20(a)(2), contract manufacturers do not have to list devices, and that § 807.22(c)(1) does not require initial importers to submit a list of devices. The comment suggested that FDA move the language regarding initial importers from § 807.22(c)(1) to § 807.20(a)(2) to enhance clarity and consistency.

(Response) The comment goes beyond the scope of the rule. While FDA agrees that §§ 807.20(a)(2) and 807.22(c)(1) could be written more clearly and consistently, the agency is considering more substantial revisions to part 807. Therefore, FDA declines to amend this rule to make the changes suggested by the comment.

(Comment 47) As stated earlier, one comment suggested that FDA revise § 207.20(a) and similar language in §§ 607.20(a) and 807.20(a) to allow a foreign parent company to register and list on behalf of its foreign subsidiaries. The comment explained that the rule allows parent companies to list on behalf of their subsidiaries, but does not allow them to register their subsidiaries.

(Response) FDA agrees with the comment and has amended §§ 207.20(a), 607.20(a), and 807.20(a) to allow parent companies to register and list on behalf of their subsidiaries.

3. Information Required or Requested for Establishment Registration and Device Listing (§ 807.25)

Proposed § 807.25 would delete the word ''ZIP'' from the term, ''post office ZIP Code,'' because the term ''ZIP Code'' is not used in many foreign countries.

FDA received no comments on this provision and has finalized it without change.

4. Establishment Registration and Device Listing for United States Agents of Foreign Establishments (§ 807.40)

Proposed § 807.40 would delete the existing language in § 807.40 entirely and replace it with general descriptions of the foreign establishment's obligations and the United States agent's role. The proposal would also use the term ''foreign establishment,'' rather than ''foreign manufacturer,'' and revise the title to § 807.40 to be more consistent with section 510 of the act.

Proposed § 807.40(a) would require any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States to register and list its devices in conformance with subpart B of part 807 (''Procedures for Device Establishments''). This would have foreign establishments comply with the same procedures as domestic establishments.

The proposal would also require the official correspondent for the foreign establishment to facilitate communication between the establishment's management and FDA. This change complements the requirement for an official correspondent in § 807.25(d).

Proposed § 807.40(b) would require each registered foreign establishment to submit the name, address, and phone number of its United States agent as part of its registration information. The proposal would also require the agent to reside or maintain a place of business in the United States, but would allow (rather than require) a foreign establishment to designate its United States agent as its official correspondent. The preamble to the proposed rule explained that designating the United States agent as the official correspondent may be more efficient than having a separate United States agent and an official correspondent, but the proposed rule would give foreign establishments flexibility in deciding how to allocate their resources in this area and what the United States agent's responsibilities would be (see 64 FR 26330 at 26337). The preamble to the proposed rule also noted that electronic product manufacturers, under § 1005.25 (21 CFR 1005.25), must designate a permanent resident of the United States as the manufacturer's agent upon whom service of process may be made for and on behalf of the manufacturer as provided in section 360(d) of the Radiation Control for Health and Safety Act of 1968. The preamble to the proposed rule suggested that manufacturers of products that are both medical devices and electronic products might wish to consider whether their agents, under § 1005.25, can also serve as their United States agent under proposed § 807.40 and perform the duties expected of a United States agent (id.).

Like proposed §§ 207.40 and 607.40, proposed § 807.40(b) would require the United States agent, upon request from FDA, to assist the agency in communications with the foreign establishment, to respond to questions regarding devices imported or offered for import, and to assist FDA in scheduling inspections of the foreign establishment. Proposed § 807.40(b) would also enable FDA, when it is unable to contact the foreign manufacturer directly or expeditiously, to provide information or documents to the United States agent and for that act to be considered equivalent to providing the same information or documents to the foreign establishment, and would further require a foreign establishment to report to FDA changes in the United States agent's name, address, or phone number within 10 days of the change.

Proposed § 807.40(c), like proposed §§ 207.40(b) and 607.40(b), would prohibit the importation of devices that have not been listed or manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment.

(Comment 48) One comment noted that § 807.40(a) requires the official correspondent to facilitate communications between a firm and FDA while proposed § 807.40(b)(2) would require the United States agent to facilitate communications between a foreign establishment and FDA. The comment suggested revising § 807.40(a) to require the official correspondent to facilitate communications pertaining to registration and listing. The comment said this would help distinguish between the official correspondent and the United States agent.

(Response) FDA agrees with the comment and has revised § 807.40(a) accordingly. This change would make the official correspondent's role, for foreign establishments, more consistent with that for domestic establishments, as seen in § 807.25(d) (official correspondent for a domestic establishment is the point of contact for matters relating to registration and listing).

(Comment 49) As stated earlier, one comment asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. The comment said that foreign establishments which send goods to a foreign trade zone and later re-export those goods from the United States without entering them into U. S. commerce should be exempt from registration requirements.

(Response) FDA agrees with the comment, but only as it pertains to foreign establishments who send products into foreign trade zones and

whose products are re-exported from the United States without having entered domestic commerce. FDA, therefore, has amended §§ 207.40(a), 607.40(a), and 807.40(a) accordingly.

(Comment 50) Two comments sought to exempt foreign establishments from the United States agent requirement if the foreign establishment makes class I devices. The comments asserted that these devices present little or no risk to consumers so requiring these establishments to have a United States agent would increase costs to those establishments and provide little or no benefit.

(Response) FDA declines to amend the rule as suggested by the comments. Section 510(i) of the act does not base the United States agent requirement on a product's level of risk, and FDA's interpretation of section 510(i) of the act would be more consistent and fair if it applied the United States agent requirement to all foreign establishments regardless of their device classifications.

Additionally, § 807.40 only requires the United States agent to assist in communications with the foreign establishment, to respond to questions regarding devices imported or offered for import, and to assist in scheduling inspections of the foreign establishment. These duties are not dependent on a device's classification. For example, FDA might ask the United States agent to help schedule an inspection of the foreign establishment. Such assistance could facilitate the inspection, regardless of the device classification for the foreign establishment's products.

5. Miscellaneous Device Comments

(Comment 51) One comment would revise the title for part 807 to delete the word ''distributors.'' The comment said that FDA does not require distributors to register or list devices.

(Response) The proposed rule used an incorrect title for part 807; the current title for part 807 refers to manufacturers and initial importers of devices and does not refer to distributors. Therefore, no changes are necessary.

(Comment 52) One comment offered several suggestions on how to revise the registration and listing forms for device establishments. The comment would also redesignate the forms and make corresponding changes in part 807 whenever a provision referred to a form by its designation.

(Response) FDA has or will address issues regarding its registration and listing forms as part of the process of seeking approval, under the Paperwork Reduction Act of 1995, for the revised information collection requirements in those forms.

(Comment 53) One comment said that FDA must amend § 807.65, ''Exemptions for device establishments,'' so that certain exemptions would not apply for foreign establishments. The comment said that the following exemptions should not apply to foreign establishments:

1. Section 807.65(d) for licensed practitioners;

2. Section 807.65(e) for pharmacies, surgical supply outlets, or other similar retail establishments making final deliveries or sales to the ultimate user;

3. Section 807.65(f) for persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution; and

4. Section 807.65(i) for persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer with a device or the benefits to be derived from the use of a device.

The comment explained that amending § 807.65 in this manner would be similar to the limitations on exemptions in proposed §§ 207.10 and 607.65.

(Response) FDA agrees with the comment and has amended § 807.65 accordingly. Section 510(g)(5) of the act gives FDA discretion to decide whether to exempt a class of persons from the registration requirements. Here, in the case of § 807.65(d) and (e), the exemptions are expressly or implicitly dependent on a person's compliance with Federal, State, or local laws, and so FDA has insufficient information to make a finding, under section 510(g)(5) of the act, to justify an exemption for foreign practitioners, pharmacies, surgical supply outlets, and other similar establishments.

For § 807.65(f) and (i), FDA, again, has insufficient information to make a finding, under section 510(g)(5) of the act, to justify an exemption for foreign establishments engaged in those practices. Consequently, the exemptions in § 807.65(d), (e), (f), and (i) will apply only to domestic persons or establishments.

F. Registration Schedules

The preamble to the proposed rule indicated that FDA would develop a staggered schedule for foreign establishment registration for foreign establishments subject to part 207. FDA explained that a staggered schedule might be needed because part 207 applies to human drugs, animal drugs, and biologics. The preamble to the proposed rule also stated that FDA did not intend to develop any special registration schedules for parts 607 and 807 because, compared to part 207, fewer foreign manufacturers are subject to the registration requirements in parts 607 and 807.

After the proposed rule had appeared in the **Federal Register**, FDA began efforts to create an electronic registration program for all establishments subject to part 207. Thus, for foreign human drug, animal drug, and biologics establishments subject to part 207, a staggered registration schedule is no longer necessary. Foreign establishments subject to part 207 should register by May 28, 2002.

For foreign blood and blood product establishments subject to part 607, no special registration schedules are necessary. FDA has determined that the foreign establishments subject to part 607 have previously submitted information that fulfills the registration requirement (with the exception of the United States agent requirement), and CBER will contact those manufacturers to obtain information regarding the United States agent for each establishment.

For foreign device establishments, FDA will begin enforcing the requirements in part 807 beginning on April 26, 2002.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Title II of the Unfunded Mandates Reform Act requires that agencies prepare a written assessment and economic analysis before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector,

of $100 million (adjusted annually for inflation).

The final rule is consistent with the principles set out in the Executive order and in these two statutes. As explained below, FDA finds that the final rule does not require a Regulatory Flexibility Analysis. Also, because the rule does not impose any mandates on State, local, or tribal governments, or the private sector, that will result in an expenditure in any 1 year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act.

The new economic burdens imposed by the rule will involve broader requirements for foreign firms with respect to the registration of establishments and to the designation of United States agents. First, some foreign manufacturers will have to register their establishment before importing drugs, biological products, or devices into the United States. As stated earlier, before FDAMA amended section 510 of the act to require foreign establishment registration, many foreign establishments voluntarily registered their establishments, but all foreign establishments that imported or offered for import drugs, blood and blood products, and devices into the United States were required to list their products. The registration and listing activities used forms prepared by FDA.

FDA is able to estimate the rule's economic impact by using time and hourly wage estimates for registration. FDA estimates the labor costs associated with establishment registration are small, ranging from $25 per hour for device establishments, $20 per hour for blood and blood product establishments, and $100 per hour for drug establishments. These costs are based on information obtained primarily from domestic establishments, and FDA assumes that the average costs for foreign establishments will be similar. FDA also estimates that completing an establishment registration form will range from 15 minutes to 1 hour (depending on the form used). These estimates are derived from the estimated registration costs for domestic establishments and foreign establishments that voluntarily registered before FDAMA's enactment.

For devices subject to part 807, the agency's device establishment data base presently includes about 8,200 foreign establishments, of which almost 3,000 are unregistered establishments with listed products. FDA's paperwork officials estimate that registration activities would take about 15 minutes at a cost of about $6.25 per facility. Thus, the one-time cost to register these foreign device establishments would be about $18,750 (3,000 x 15 minutes x $25 per hour). For the remaining device firms, the paperwork costs would be minimal, consisting of the time required to name a United States agent.

For blood and blood products subject to part 607, FDA records suggests there are 98 foreign establishments and that all have voluntarily registered with FDA. Therefore, the cost to register these foreign establishments should be minimal and consist of the time required to name a United States agent.

For drugs and biological products subject to part 207, FDA records suggest there are 5,630 foreign establishments, but the number of foreign establishments that have already registered cannot easily be determined. Thus, even if all of these foreign establishments must register, the one-time cost to register would be about $281,500 (5,630 x 30 minutes x $100 per hour).

(Comment 54) Several comments, almost all from medical device companies, criticized the proposed rule as not estimating the economic impact of the United States agent requirement. One comment declared that the United States agent requirement would ''easily'' exceed $100 million, but did not explain how it arrived at that conclusion. Another comment stated that the Regulatory Flexibility Act requires U. S. agencies to analyze regulatory options that would minimize any significant impact on small entities and claimed that FDA failed to conduct that analysis. Other comments said FDA must consider the insurance costs for a United States agent, retainer fees, office costs, hourly rates, and/or daily rates. One comment implied that the rule was intended to lower FDA's operating costs while transferring more responsibilities and costs to foreign establishments. Another comment sought more time to determine the rule's economic impact.

(Response) FDA disagrees with the comments. The comments did not provide any evidence to support their claims that the United States agent requirement would result in costs exceeding $100 million. In response to the comments, FDA examined the costs of retaining a United States agent. Several persons have contacted FDA to express an interest in becoming a United States agent, and their fees have ranged between $750 and $2,000 annually.

FDA does not have a precise estimate of the number of foreign device firms that would need to develop an arrangement with a United States agent, but the agency's establishment data base identifies about 6,400 foreign device establishments that show only a foreign address for their ''official correspondent.'' If each of these 6,400 device establishments incurred costs of $1,000 to obtain a United States agent, the total industry annual cost would be about $6,400,000.

Similarly, FDA does not know the precise number of drug establishments that would incur costs to retain a United States agent. The agency believes, however, that the added costs for most pharmaceutical firms would be minimal, because under current rules (21 CFR 314.50(a)), all applications and supplements to approved applications must already ''contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.'' Bulk drug establishments not holding an approved application could generally rely on the primary purchaser of their product to serve as their United States agent. Thus, while many foreign drug establishments would incur some additional paperwork costs, the additional costs would be minimal.

(Comment 55) One comment said FDA failed to offer exemptions from the United States agent requirement to small- and medium-sized Canadian firms as required under the Regulatory Flexibility Act.

(Response) The agency examined, but rejected, alternatives to the proposed rule. The registration information required by FDA is minimal, consisting largely of the establishment's address, names of owners or responsible officials, and additional identifying information on the establishment (such as type of establishment, types of products at the establishment, type of ownership). Similarly, identification of the United States agent requires minimal information (name, address, phone number). An alternative that required less information from foreign establishments would not provide sufficient information to identify the foreign establishment's location, a responsible person at the foreign establishment, or the type of establishment, thereby complicating any effort to locate or contact the foreign establishment or to determine whether the foreign establishment complied with the appropriate statutory and regulatory requirements. FDA also rejected an alternative that would eliminate the United States agent requirement for small- and medium-sized firms; section 510(i) of the act expressly requires foreign establishment to have a United States agent and does not provide for

exemptions from the United States agent requirement.

Moreover, as stated earlier, FDA does not object to having multiple firms use the same United States agent. Neither the act nor these regulations require a foreign establishment to enter an exclusive arrangement with its United States agent. In other words, several foreign establishments could use the same agent or ''share'' an agent, so long as the foreign establishments and the United States agent meet their regulatory obligations. This may reduce the United States agent's cost for small- and medium-sized firms.

Finally, the agency is not required to prepare a Regulatory Impact Analysis under the Regulatory Flexibility Act, because the rule will not have a significant economic effect on a substantial number of small entities. The term ''small entity'' is defined (5 U.S.C. 601(6)) to include the term ''small business,'' which, in turn, is defined (5 U.S.C. 601(3)) to have the ''same meaning as the term small business concern.'' The term ''business concern'' is defined by the Small Business Administration (SBA), at 13 CFR 121.105(a), in relevant part, as a business entity ''with a place of business located in the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor.'' Although some foreign firms would meet the SBA definition of a ''business concern'' because of their significant contribution to the United States economy (even though they do not operate primarily in the United States), it is unlikely that a substantial number that do not already have a U. S. presence that could act as a United States agent would be significantly impacted by this rule.

The Unfunded Mandates Reform Act (Public Law 104–114) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation). Because the total expenditures under the final rule will not result in a 1-year expenditure of $100 million or more, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description for the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Foreign Establishment Registration and Listing

Description: The final rule requires foreign establishments that import or offer to import human drugs, animal drugs, biologics, blood products, and devices into the United States to register and to name a United States agent. This information is required by section 510(i)(1) of the act, as amended by section 417 of FDAMA.

Although section 510(i)(2) of the act also requires foreign establishments to list their products at FDA, the final rule does not include such a requirement because FDA's existing regulations already require foreign manufacturers to submit such lists, and the agency has already obtained OMB approval for the information collection burden associated with product listing for parts 207 and 607 (for part 207, the OMB approval number is 0910–0045 and expires on April 30, 2001; for part 607, the OMB approval number is 0910–0052 and expires on February 28, 2003). Through this notice, FDA is also seeking approval for the device listing requirements insofar as they will be applied to foreign establishments.

Description of Respondents: Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses perRespondent	Total Annual Responses	Hours per Response	Total Hours
207.21(a)	2,463	1	2,463	0.5	1,231.5
207.22(a) and 207.40	5,630	1	5,630	0.5	2,815
207.25(b)	53	4.3	228	0.5	114
607.22(a) and 607.40	98	1	98	1	98
607.26	1	1	1	0.5	0.5
607.31	1	1	1	10	10
807.22(a) and 807.40	7,200	1	7,200	0.25	1,800
807.22(b)	27,720	1	27,720	0.5	13,860
807.31(c)	7	1	7	0.5	3.5
Total					19,932.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses perRespondent	Total Annual Responses	Hours per Response	Total Hours
807.31	6,480	10	64,800	0.5	32,400

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses perRespondent	Total Annual Responses	Hours per Response	Total Hours
Total					32,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The above estimates were based on the number of foreign establishments that currently list drugs or devices (as required by existing FDA regulations), the annual average number of new foreign establishments that voluntarily registered or began importing devices, and comparable burden hour estimates for registration by domestic establishments.

For device listing by foreign establishments, the above estimates are based on the number of foreign establishments that currently list devices and comparable burden hour estimates and annual frequency per response estimates for domestic firms. FDA has also made a correction to the total hour figure for § 807.31(e) to change 4 hours to 3.5 hours; the correction represents the accurate figure resulting from the mathematical calculation of 7 annual responses multiplied by 0.5 hours per response.

The estimated recordkeeping burden for § 807.31 is based on FDA's experience with foreign device establishments. FDA's experience suggests that, for foreign device establishments, there are approximately 9 owners or operators for every 10 foreign device establishments. Therefore, because FDA records indicate that there are 7,200 foreign device establishments, the estimated number of recordkeepers required to maintain the initial historical files is 6,480 (7,200 x 0.90 = 6,480).

The information collection provisions of this final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 607

Blood.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, Title 21 of the Code of Federal Regulations is amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for part 207 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

2. Section 207.3 is amended by revising paragraph (a)(5) and by adding paragraph (a)(11) to read as follows:

§ 207.3 Definitions.

(a) * * *

(5) *Commercial distribution* means any distribution of a human drug except for investigational use under part 312 of this chapter, and any distribution of an animal drug or animal feed bearing or containing an animal drug for noninvestigational uses, but the term does not include internal or interplant transfer of a bulk drug substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term ''commercial distribution'' shall have the same meaning except that the term shall not include distribution of any drug that is neither imported nor offered for import into the United States.

* * * * *

(11) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

* * * * *

3. Section 207.7 is amended by revising paragraph (a) to read as follows:

§ 207.7 Establishment registration and product listing for human blood and blood products and for medical devices.

(a) Owners and operators of human blood and blood product establishments shall register and list their products with the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, on Form FDA–2830 (Blood Establishment Registration and Product Listing), in accordance with part 607 of this chapter. Such owners and operators who also manufacture or process other drug products at the same establishment shall, in addition, register and list all such other drug products with the Drug Listing Branch in accordance with this part.

* * * * *

4. Section 207.10 is amended by revising the section heading and the introductory text to read as follows:

§ 207.10 Exemptions for establishments.

The following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g)(1), (g)(2), and (g)(3) of the act, or because FDA has found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. The exemptions in paragraphs (a) and (b) of this section are limited to pharmacies, hospitals, clinics, and public health agencies located in any State as defined in section 201(a)(1) of the act.

* * * * *

5. Section 207.20 is amended by revising paragraphs (a) and (c) to read as follows:

§ 207.20 Who must register and submit a drug list.

(a) Owners or operators of all drug establishments, not exempt under section 510(g) of the act or subpart B of this part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register and submit a list of every drug in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Drug listing is not required for the manufacturing, preparation, propagation, compounding, or processing of an animal feed bearing or containing an animal drug (i.e., a Type B or Type C medicated feed), nor is drug listing required for establishments engaged in drug product salvaging. Drug products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such establishments or any particular drug so listed enters interstate commerce. No owner or operator may register an establishment if any part of the establishment is registered by any other owner or operator.

* * * * *

(c) Before beginning manufacture or processing of a drug subject to one of the following applications, an owner or operator of an establishment is required to register before the agency approves it: A new drug application, an abbreviated new drug application, a new animal drug application, an abbreviated new animal drug application, a medicated feed mill license application, or a biologics license application.

* * * * *

6. Section 207.21 is amended by revising paragraph (a) to read as follows:

§ 207.21 Times for registration and drug listing.

(a) The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall submit a list of every drug in commercial distribution at that time. If the owner or operator of the establishment has not previously entered into such an operation, the owner or operator shall register within 5 days after submitting a new drug application, abbreviated new drug application, new animal drug application, abbreviated new animal drug application, medicated feed mill license application, or a biologics license application. Owners or operators shall renew their registration information annually.

* * * * *

§ 207.25 [Amended]

7. Section 207.25 *Information required in registration and drug listing* is amended in paragraph (b)(2) by removing ''or new animal drug application number'' and by adding in its place the phrase ''new animal drug application number, or abbreviated new animal drug application number''.

8. Section 207.37 is amended by revising the introductory text of paragraph (a) and by revising paragraph (b) to read as follows:

§ 207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA–2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Division of Labeling and Non-Prescription Drug Compliance (HFD–310), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. In addition, copies of these forms for establishments located within a particular geographic area are available for inspection at FDA district offices responsible for that geographical area. Copies of forms submitted by foreign drug establishments are available for inspection at the Foreign Inspection Team (HFD–322), Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Pl., Rockville, MD 20855. Upon request and receipt of a stamped, self-addressed envelope, the Division of Labeling and Non-Prescription Drug Compliance, the Foreign Inspection Team, or the appropriate FDA district office will verify registration numbers or provide the location of a registered establishment.

* * * * *

(b) Requests for information about registrations and drug listings of an establishment should be directed to the Information Management Team (HFD–095), Office of Information Technology, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or, with respect to the information described in paragraph (a) of this section, to the FDA district office responsible for the geographic area in which the establishment is located.

9. Section 207.40 is revised to read as follows:

§ 207.40 Establishment registration and drug listing requirements for foreign establishments.

(a) Foreign drug establishments whose drugs are imported or offered for import into the United States shall comply with the establishment registration and drug listing requirements in subpart C of this part, unless exempt under subpart B of this part or unless the drugs enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U. S. commerce.

(b) No drug may be imported or offered for import into the United States unless it is listed as required in subpart C of this part and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment; however, this restriction does not apply to a drug imported or offered for import under the investigational use provisions in part 312 of this chapter, or the investigational new animal drug use provisions in part 511 of this chapter, or to a component of a drug imported under section 801(d)(3) of the act. Foreign drug establishments shall submit all listing information, including labels and labeling, and registration information in the English language.

(c) Each foreign drug establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart C of this part. Each foreign drug establishment shall designate only one United States agent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. If the agency is unable to contact the foreign drug establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign drug establishment.

(3) The foreign drug establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

10. The authority citation for part 607 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

11. Section 607.3 is amended by revising paragraphs (b) and (e) and by adding paragraph (j) to read as follows:

§ 607.3 Definitions.

* * * * *

(b) *Blood and blood product* means a drug which consists of human whole blood, plasma, or serum or any product derived from human whole blood, plasma, or serum, hereinafter referred to as ''blood product.'' For the purposes of this part only, blood and blood product also means those products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health Service Act.

* * * * *

(e) *Commercial distribution* means any distribution of a blood product except under the investigational use provisions of part 312 of this chapter, but does not include internal or interplant transfer of a bulk product substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term ''commercial distribution'' shall have the same meaning except that the term shall not include distribution of any blood or blood product that is neither imported nor offered for import into the United States.

* * * * *

(j) *United States* agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

12. Section 607.7 is amended by revising paragraphs (b) and (c) to read as follows:

§ 607.7 Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products.

* * * * *

(b) Forms for registration of an establishment are obtainable on request from the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or at any of the Food and Drug Administration district offices.

(c) The completed form should be mailed to the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

13. Section 607.20 is amended by revising paragraph (a) to read as follows:

§ 607.20 Who must register and submit a blood product list.

(a) Owners or operators of all establishments, not exempt under section 510(g) of the act or subpart D of this part, that engage in the manufacture of blood products shall register and submit a list of every blood product in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Blood products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such blood product establishment or any particular blood product so listed enters interstate commerce.

* * * * *

14. Section 607.22 is revised to read as follows:

§ 607.22 How and where to register establishments and list blood products.

(a) The first registration of an establishment shall be on Form FD–2830 (Blood Establishment Registration and Product Listing) obtainable on request from the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or from Food and Drug Administration district offices. Subsequent annual registration shall also be accomplished on Form FD–2830, which will be furnished by the Food and Drug Administration before November 15 of each year to establishments whose product registration for that year was validated under § 607.35. The completed form shall be mailed to the preceding address before December 31 of that year.

(b) The first list of blood products and subsequent June and December updatings shall be on Form FD–2830, obtainable upon request as described in paragraph (a) of this section.

15. Section 607.25 is amended in the second sentence in paragraph (a) by removing the word ''ZIP'', and by revising paragraph (b)(3) to read as follows:

§ 607.25 Information required for establishment registration and blood product listing.

* * * * *

(b) * * *

(3) For each blood product listed, the registration number of the parent establishment. An establishment not owned, operated, or controlled by another firm or establishment is its own parent establishment.

16. Section 607.26 is amended by revising the first sentence to read as follows:

§ 607.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, location, or blood-product handling activity shall be submitted on Form FDA–2830 (Blood Establishment Registration and Product Listing) as an amendment to registration within 5 days of such changes. * * *

17. Section 607.31 is revised to read as follows:

§ 607.31 Additional blood product listing information.

(a) In addition to the information routinely required by §§ 607.25 and 607.30, the Director of the Center for Biologics Evaluation and Research may require submission of the following information by letter or by **Federal Register** notice:

(1) For a particular blood product so listed, upon request made by the Director of the Center for Biologics Evaluation and Research for good cause, a copy of all advertisements.

(2) For a particular blood product so listed, upon a finding by the Director of the Center for Biologics Evaluation and Research that it is necessary to carry out the purposes of the act, a quantitative listing of all ingredients.

(3) For each registrant, upon a finding by the Director of the Center for Biologics Evaluation and Research that it is necessary to carry out the purposes of the act, a list of each listed blood product containing a particular ingredient.

(b) [Reserved]

18. Section 607.35 is amended by revising paragraph (a) to read as follows:

§ 607.35 Notification of registrant; blood product establishment registration number and NDC Labeler Code.

(a) The Director of the Center for Biologics Evaluation and Research will provide to the registrant a validated copy of Form FD–2830 (Blood Establishment Registration and Product Listing) as evidence of registration. This validated copy will be sent to the location shown for the registering establishment, and a copy will be sent to the reporting official if at another address. A permanent registration number will be assigned to each blood product establishment registered in accordance with these regulations.

* * * * *

19. Section 607.37 is amended by revising the introductory text of paragraph (a) and by revising paragraph (b) to read as follows:

§ 607.37 Inspection of establishment registrations and blood product listings.

(a) A copy of the Form FD–2830 (Blood Establishment Registration and Product Listing) filed by the registrant will be available for inspection under section 510(f) of the act, at the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers' Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. In addition, for domestic firms, the same information will be available for inspection at each of the Food and Drug Administration district offices for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of registration number, or location of registered establishment will be provided. The following information submitted under the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

* * * * *

(b) Requests for information regarding blood establishment registrations and blood product listings should be directed to the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers' Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

20. Section 607.40 is revised to read as follows:

§ 607.40 Establishment registration and blood product listing requirements for foreign blood product establishments.

(a) Every foreign establishment shall comply with the establishment registration and blood product listing requirements contained in subpart B of this part, unless exempt under subpart D of this part or unless the blood product enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce.

(b) No blood product may be imported or offered for import into the United States unless it is the subject of a blood product listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to a blood product imported or offered for import under the investigational use provisions of part 312 of this chapter or to a blood product imported under section 801(d)(4) of the act. The establishment registration and blood product listing information shall be in the English language.

(c) Each foreign establishment required to register under paragraph (a) of this section shall, as part of the establishment registration and blood product listing, submit the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating establishment registration information in § 607.26 and blood product listing information in § 607.30(a).

(d) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

21. Section 607.65 is amended by revising the introductory text to read as follows:

§ 607.65 Exemptions for blood product establishments.

The following classes of persons are exempt from registration and blood product listing in accordance with this part 607 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5), that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (a), (b), (f), and (g) of this section are limited to those classes of persons located in any State as defined in section 201(a)(1) of the act.

* * * * *

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

22. The authority citation for part 807 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

23. Section 807.3 is amended by revising paragraphs (b) and (r) to read as follows:

§ 807.3 Definitions.

* * * * *

(b) *Commercial distribution* means any distribution of a device intended for human use which is held or offered for sale but does not include the following:

(1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company;

(2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use under section 520(g) of the act and part 812 of this chapter;

(3) Any distribution of a device, before the effective date of part 812 of this chapter, that was not introduced or delivered for introduction into interstate

commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the act: *Provided*, That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not required to have an approved premarket approval application as provided in section 515 of the act; or

(4) For foreign establishments, the distribution of any device that is neither imported nor offered for import into the United States.

* * * * *

(r) *United States* agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

* * * * *

Subpart B [Amended]

24. The heading for subpart B of this part is revised to read as follows:

Subpart B—Procedures for Device Establishments

25. Section 807.20 is amended by revising paragraph (a) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term ''device'' includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;

(2) Manufactures for commercial distribution a device either for itself or for another person. However, a person who only manufactures devices according to another person's specifications, for commercial distribution by the person initiating specifications, is not required to list those devices.

(3) Repackages or relabels a device;

(4) Acts as an initial importer; or

(5) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

* * * * *

§ 807.25 [Amended]

26. Section 807.25 *Information required or requested for establishment registration and device listing* is amended in the last sentence of paragraph (a) by removing the word ''ZIP''.

27. Section 807.40 is revised to read as follows:

§ 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

(a) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register and list such devices in conformance with the requirements in subpart B of this part unless the device enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of the Food and Drug Administration for matters relating to the registration of device establishments and the listing of device products.

(b) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent and may designate the United States agent to act as its official correspondent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

(c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter or to a component, part, or accessory of a device or other article of a device imported under section 801(d)(3) of the act. The establishment registration and device listing information shall be in the English language.

28. Section 807.65 is amended by revising the introductory text to read as follows:

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5) of the act, that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (d), (e), (f), and (i) of this section are limited to those classes of persons located in any

State as defined in section 201(a)(1) of the act.

* * * * *

Dated: November 15, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–29393 Filed 11–26–01; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[FRL–7107–4]

RIN 2060–AJ60

Change to Definition of Major Source

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates a proposed change to the definition of ''major source''. The change would no longer require States to provide that sources in categories subject to standards under section 111 or 112 promulgated after August 7, 1980 must include fugitive emissions in determining major source status under section 302 or part D of title I of the Act. The EPA is making this change to address a petition by the American Mining Congress (now known as the National Mining Association) challenging the requirement in the current regulation that sources in all section 111 or 112 categories must count fugitive emissions, regardless of when the section 111 or 112 standards were promulgated, in determining major source status under section 302 or part D of title I. By making this change, we will also allow full approval in several State programs that contain the August 7, 1980 date.

EFFECTIVE DATE: November 27, 2001.

ADDRESSES: Docket No. A–93–50 contains information considered by EPA in developing the promulgated rule and is available for public inspection between 8:00 a.m. and 5:30 p.m., Monday through Friday, excluding Federal holidays, at the following address: U.S. EPA, Air and Radiation Docket and Information Center (6102), 401 M Street SW, Washington, DC 20460, telephone (202) 260–7548. The docket is located at the above address in room M–1500, Waterside Mall (ground floor). A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: For further information, contact Mr. Raymond H. Vogel, Jr., Operating Permits Group, Information Transfer and Program Implementation Division (MD–12), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–3153, facsimile number (919) 541–5509, electronic mail address: *vogel.ray@epa.gov.*

SUPPLEMENTARY INFORMATION:

Regulated Entities

Categories and entities potentially affected by this action include facilities currently required to obtain title V permits by State programs because of having been required to count fugitive emissions for sources in categories subject to section 111 or 112 standards promulgated *after* August 7, 1980.

World Wide Web (WWW)

After signature, the final rule will be posted on the policy and guidance page for newly proposed or final rules of EPA's Technology Transfer Network at *http://www.epa.gov/ttn/oarpg/t5.html.* For more information, call the TTN HELP line at (919) 541–5384.

Table of Contents

I. Background and Public Participation

Title V of the Clean Air Act (the Act) requires EPA to promulgate regulations governing the establishment of operating permits programs. The current regulations were promulgated on July 21, 1992 and codified at 40 CFR part 70. All major sources are required to obtain Title V operating permits. Major sources include those sources subject to prevention of significant deterioration (PSD) and nonattainment new source review (NSR), and any other sources with the potential to emit 100 tons per year of an air pollutant. To determine major source status under section 302 or part D of title I, the current rules require you to count fugitive emissions if you are subject to a standard under section 111 or 112, regardless of when the standard was promulgated. The EPA proposed to revise the definition of ''major source'' for section 302 and part D of title I in August, 1994 to limit the requirement to count fugitive emissions to source categories regulated by section 111 or 112 standards promulgated as of August 7, 1980. (See 59 FR 44460, August 29, 1994.) We proposed this revision in response to a petitioner who asserted that EPA could not require that fugitive emissions be counted for determining major source status until EPA conducted rulemaking as required under section 302(j) of the Act. The EPA has not performed such rulemaking; therefore, we are today revising the rule to add the August 7, 1980 date. In the future, EPA will consider doing rulemaking under section 302(j) for individual source categories.

Subsequently, in August 1995, EPA proposed to revise the same part of the ''major source'' definition that it had proposed to change in 1994, this time to limit the requirement to count fugitive emissions for section 111 or 112 standards to those standards for which EPA had performed the rulemaking required under section 302(j). (See 60 FR 45530, August 31, 1995.) This change was proposed simply for administrative reasons, to allow EPA to avoid revising part 70 each time it performed a section 302(j) rulemaking. Today's rule does not adopt this language because some commenters expressed concern about knowing whether EPA had performed the latest section 302(j) rulemaking and which source categories they must as a result consider in determining major source status. Nevertheless, EPA will approve a State program that adopts the language we proposed in August, 1995 in lieu of the language promulgated in today's rule because the 1995 language effectively covers the same source categories.

The EPA also proposed in the same 1995 notice to delete the phrase ''but only with respect to those air pollutants that have been regulated for that category.'' The EPA proposed to delete this phrase to make the regulatory definitions of part 70 consistent with the corresponding provisions of the PSD and NSR nonattainment programs (hereafter, the term ''NSR'' is used to refer collectively to both programs). As