ABBOTT

Corporate Regulatory Affairs

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July 27, 1999

The Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: Foreign Establishment Registration and Listing Comments on Proposed Rule [Docket No. 98N-1215]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

I. GENERAL REMARKS

A. Consistency. Overall Abbott finds that the proposed rule brings a desired level of consistency in requirements for both domestic and international manufacturing activities. By following the provisions of FDAMA, the FDA will be able to identify and locate plants and products which have been manufactured in offshore locations while utilizing a US agent. We feel that this enhances the public health and safety.

B. Agency Coordination. As mentioned in prior letters from Abbott on the many recent activities covering import and export activities, we believe that if these initiatives and rulemaking activities do proceed, then it will be incumbent on the FDA and US Customs Service to communicate properly to prevent any unnecessary interruption of the otherwise normal flow of goods into and out of this country. For reference purposes, those docket numbers covering the aforementioned import and export activities are listed below.

98D-0307

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C. United States (US) Agent. The new requirement for a US agent should receive some additional support and detail from the FDA on an ongoing basis. While this provision is a sound requirement, the ability to locate and contact qualified personnel for this task should be facilitated by the Agency through Internet postings and peer-reviewed directories. Enforcement of this provision needs to be considered with respect to the required office location, personnel qualifications, and the necessary communications capabilities.

II. SPECIFIC COMMENTS

A. We are requesting that, during the first six months following the effectivity of the proposed rule, there be a transition period during which FDA allows 30 days, instead of five days, for the foreign establishment to submit the name of a US agent, for the following reasons:

- There may not be an adequate number of established businesses with the expertise to act as US agents; and, if there are, they may not be well known to the US pharmaceutical industry and may be even less well known to the international pharmaceutical industry.
- During the transition period, foreign establishments will be required to register and list. FDA will therefore have the name and address of the foreign firm, the name and address of the owner/operator, and the product listing information.

B. Although the drug registration and listing regulations, as published in previous editions of the CFR, have stated that "every foreign drug establishment . . . shall comply with the drug listing requirements in subpart C," FDA has allowed the foreign drug establishment to authorize (in writing on their letterhead) a US representative (not the same as US agent), to register and list on its behalf. Even though foreign firms will be required to designate a US agent, the responsibilities of the US agent do not include registration and listing. Therefore, we are requesting that FDA clarify, in the preamble to the final regulations, that the foreign establishment may continue to authorize, in writing on its letterhead, a US representative to register and list on its behalf. This provision is outlined on Page 3 of FDA's Drug Registration and Listing Instruction Booklet.

C. Likewise, we are requesting that FDA clarify in the preamble to the final regulations that, as in the past, a foreign firm may continue to authorize, in writing on its letterhead, a US initial importer to device list on its behalf if the

foreign firm certifies in the letter that it does not ship that product to anyone else in the US. The Official Correspondent will continue to "serve as a point of contact between the FDA and the (foreign) establishment for matters relating to the registration and listing" (807.25(d). In the definition of Official correspondent at 807.3(e), the official correspondent is responsible for annual registration, but serves as a contact with FDA for device listing.)

D. 807.20(a)(2), following the sentence, "The registration and listing requirements shall pertain to any person who," reads, in part, "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." This implies that the contract manufacturer is required to register. We believe this may conflict with 807.20(c), which reads, "Registration and listing requirements shall not pertain to any person who: (1) manufactures devices for another party who both initiated the specifications and commercially distributes the device." Therefore, we are requesting that FDA clarify if there is a conflict or advise us why these two regulations do not conflict.

E. Also, regarding 807.20(c)(1), we are requesting that FDA confirm that this "exemption" applies to both domestic and foreign contract manufacturers.

F. Regarding US agent, FDA is going to depend on the US agent to assist in communication between FDA and the foreign establishment in regard to inspections, recalls, and other important matters. Therefore, we believe the US agent should be allowed to advise FDA of a change in their address or phone number. In fact, it may be to everyone's benefit if FDA allows the US agent to notify FDA if they are no longer the US agent for a foreign establishment.

G. 807.40(a) reads, in part, "the official correspondent for the foreign establishment shall facilitate communication between the foreign establishment and representatives of the FDA." 807.40(b)(2) reads, in part, "the US agent shall assist FDA in communications with the foreign establishment . . . " We believe these two statements are confusing and that 807.40(a) would be clearer if it were revised to indicate that "the official correspondent shall facilitate communication between the foreign establishment and representatives of the FDA in matters pertaining to registration and listing." This would more clearly distinguish between the official correspondent and the US agent.

H. The listing obligations of a contract manufacturer are explained and clarified in 807.20(a)(2), under "Who must register and submit a device list," following the phrase, "The registration and listing requirements shall pertain to any person who." The listing obligations of the initial importer are explained and clarified in the recently revised 807.22(c)(1), under the heading, "How and where to register establishments and list devices." We believe clarity and consistency would be enhanced by moving the explanation regarding initial importers from 807.22(c)(1) to 807.20(a)(4), under "Who must register and submit a device list."

I. If FDA is going to issue a new device registration form 2891b that will be for use specifically by foreign firms and provide a place for US agent, we are suggesting that FDA include the new form designation 2891b in sections 807.21(a), 807.22(a), 807.22(b), 807.22(c)(1), 807.25(a), 807.26, 807.35(a), and 807.37(a).

J. Also, regarding form designations, we are inquiring if this would be a good time for FDA to revise the form designations in the device regulations to FORM FDA 2891, Form FDA 2891a, and FORM FDA 2892, as they are currently designated.

K. Regarding the heading of Part 807, should the word "DISTRIBUTORS" be removed now that distributors are not required to register and list, and reference to "distributors" has been removed from 807.20(a)(4) under "Who must register and submit a device list."

III. CLOSING COMMENTS

The final rule should be implemented through a "phasing in" of the regulation in order to:

- Minimize the impact on commerce
- Facilitate communication between Federal Agencies and the many ports of entry
- Allow for the identification, development, and training of competent US agents

The final promulgation and implementation of the proposed rule should be undertaken in conjunction with an industry-wide educational effort for the following reasons:

A. General educational purposes. Due to the cost and broad scope of this proposal, any seminars on the final rule will help everyone concerned. These seminars should be carried out in conjunction with the US Customs Service, which is a party to these new regulations. The proposed seminars could be carried out with the support of FDLI, AFDO, HIMA, or other scientifically-oriented trade associations. The Agency should also consider a telecast similar in format to the FDLI's presentation on latex which was held on May 5, 1998. The agenda for this broadcast was developed through a consensus-based approach and drew upon the collective expertise of the FDA, industry, and particularly the other Federal Agencies which may be involved.

B. Publicity. The impact of this proposed rule will affect regulatory practices and expectations of manufacturers. By carrying out these seminars, the Agency can publicize and prepare all concerned for the new requirements.

C. Clarity. Finally, public seminars will serve to clarify regulatory expectations and interpretations.

Yours truly,

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cc: Philip L. Chao, FDA, Office of Policy (HFA-23)
[Docket 98D-0307]
[Docket 987N-0496]

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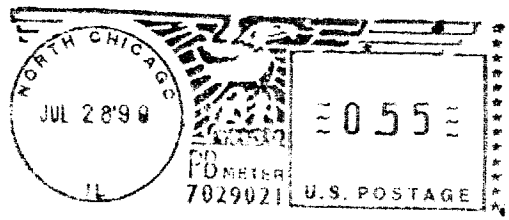

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