



Corporate Regulatory Affairs

Abbott Laboratories

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August 3, 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 this second set of remarks in response to the Agency's request for comments on the above-named subject and docket.

The liability of a US agent, whether this is an individual or an importing domestic firm, should be limited to a fulfillment of the agent's responsibility as defined in proposed 207.40(c), 607.40(d), and 807.40(b) on behalf of the foreign firm. The US agent should only be viewed as a conduit for facilitating communications between the FDA and the foreign firm. The US agent should not be held accountable for any violation of the Food, Drug and Cosmetic Act committed by the foreign firm. While FDA considers delivery of documents or other information to the US agent equivalent to providing the same documents or other information to the foreign firm, the US agent should not be held legally responsible, after having made reasonable attempts to provide the documents or other information to the foreign firm, if the foreign firm fails to respond appropriately to those documents or other information. Since FDAMA does not prohibit limiting the legal liability of the US agent, it is appropriate for FDA to do so by regulation. Therefore, proposed Sections 207.40(c)(2), 607.40(d)(2), and 807.40(b)(2) should be revised by adding the following sentences to the end of each paragraph:

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"The liability of the US agent shall be limited to a fulfillment of the agent's responsibility as defined in this section on behalf of the foreign firm. The US agent shall be viewed only as a conduit for facilitating communications between the FDA and the foreign firm, and shall not be held legally liable for any violation of the Act committed by the foreign firm."

Yours truly,



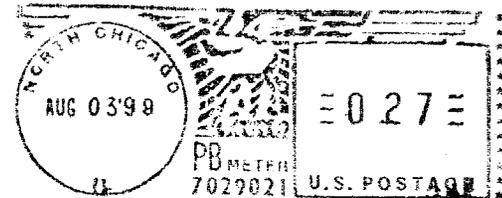
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