



**ABBOTT LABORATORIES**  
**Corporate Regulatory and Quality Science**

Douglas L. Sporn  
Divisional Vice President  
Corporate Regulatory Affairs  
D-387, AP6C-1  
Telephone: (847) 937-7986

6468 '00 NOV 28 10:28  
Abbott Park Road  
Abbott Park, Illinois 60064-6091  
Facsimile: (847) 938-3106  
E-mail: doug.sporn@abbott.com

November 27, 2000

Docket Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: Proposed Rules, Postmarket Surveillance (Docket 00N-1367)

Dear Sir:

Abbott Laboratories is pleased to have the opportunity to provide comments on the Proposed Rule on Postmarket Surveillance for devices as published on August 29, 2000, in the *Federal Register*. We propose the attached comments and suggestions to help strengthen the utility of the proposed rule.

On behalf of the 57,000 Abbott employees who help produce healthcare products marketed in more than 130 countries, we thank you for your consideration of these comments.

Sincerely,

Douglas L. Sporn

cc: Jill Sackett, HPD

00N-1367

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**COMMENTS TO FDA  
PROPOSED RULES, POSTMARKET SURVEILLANCE  
(Docket 00N-1367)**

***General Comment***

While Abbott recognizes the need to provide safety and efficacy information about devices to the FDA, we feel the proposed rule goes beyond what is necessary. We feel that current systems, such as the MDR, are adequate in providing safety and efficacy information to the agency.

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***Specific Comments***

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Preamble  
II. Contents of Proposed Rule  
C. Notification

***Comment: Provisions already exist for postmarket surveillance of IVD Biologics and such devices should not be included in Part 822.***

FDA states, "This provision applies to...in vitro diagnostic products that we review under licensing provisions of section 351 of the Public Health Service Act." Such IVD biologics are already under postmarket surveillance through 21CFR 610.2 Lot Release, 21CFR 01.12 Changes to be Reported, and 21CFR 600.14 Reporting of Errors. There would be little or no public health benefit to institute additional or redundant measures as indicated in the proposed rule for this class of medical devices.

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Preamble  
II. Contents of Proposed Rule  
D. Postmarket Surveillance Plan

***Comment: Exported devices should be exempt from postmarket surveillance***

FDA states: "Domestic manufacturers marketing a device for export only are also subject to the provisions of section 522(a) of the act because they are introducing the device into interstate commerce under the terms of the act" (65 FR 52379).

Abbott questions the value in requiring postmarket surveillance for device products that are only exported.

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Proposed Rule  
Part 822.1

***Comment: Clarify language used in Part 822.1***

To make the scope of the regulation clearer, we recommend FDA elucidate the statutory criteria in 822.1, such that it might read: "This part implements section 522 of the Federal Food, Drug and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of devices that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) The device is implanted in the human body for more than one year; or (c) The device is used to support or sustain life and is used outside a user facility."

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