ABBOTT LABORATORIES

Corporate Regulatory and Quality Science

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May 23, 2001

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

Ref: **Docket No. 01D-0056 - Draft Guidance for Industry on Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines; Availability**

Abbott Laboratories was pleased to provide comments on the "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines" Draft Guidance. The comments were sent to the Agency on May 10, 2001.

In addition to those comments, Abbott Laboratories would like to add the following comment on this draft guidance that will make a significant improvement on the 3500A form reporting system:

Line 1027 and Appendix C – FDA Form 3500A – Section G. All Manufacturers.

We recommend that Box 4 "Date Received by Manufacturer" in Section G be split into 2 boxes to contain:

4a. "Initial Date Received by Manufacturer"
4b. "Follow-up Date Received by Manufacturer"

We thank the Agency for your consideration of our comments. Should you have any question, please contact Ivone Takenaka (Corporate Regulatory Affairs – Policy & Information Coordinator) at 847-935-9011 or by FAX at 847-938-3106.

Sincerely,

RPoda for D. Sporn

Douglas L. Sporn

01D-0056

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Douglas L. Sporn

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