



# ABBOTT LABORATORIES

## Corporate Regulatory and Quality Science

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

Ref: **Docket No. 01D-0221 - "Guidance for Industry : Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components"**

To Whom it may Concern:

Abbott Laboratories is very pleased to have the opportunity to provide comments on the "Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components" published on August 13, 2001 in the *Federal Register*.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,



Richard M. Johnson

01D-0221

C7



**COMMENTS TO FDA ON**

**DOCKET No. 01D-0221**

**COMMENTS**

1) Biologic Product Deviation Reporting Flow Chart

We recommend the following changes to be more consistent with the text and to improve understanding of the diagram.

a) Reword the first diamond shaped box to read: “(1) Was there a deviation or event associated with the manufacturing of the product?”

b) If YES to the first question, include an additional rectangle box before proceeding to question (2a). The new rectangle box should indicate that a preliminary investigation is required in order to determine if the deviation or event had the potential to affect the safety, purity or potency of the product. Also note that the 45-day reporting clock starts after this determination (per item III. C. WHEN DO I REPORT? [Section 600.14 ( c )]).

c) The diamond shaped box for question (4) should include “or unexpected event”. Reword as follows: “Did you have control over the product when the deviation or unexpected event occurred?”

2) To insure the pharmaceutical manufacturing facilities provided the appropriate information, including an acceptable corrective and preventative action plan in the biologic deviation report, we request that FDA include a feedback requirement in the Draft Guidance. Clarification is also needed as to the FDA’s expectations for the manufacturer to follow up on their progress after reporting a particular Biologic Product Deviation Report.

3) To reiterate a concern stated during the comment period for the rewrite of 21 CFR 600.14, reporting deviations from cGMP and established specifications to CBER is a duplicative and burdensome effort on industry as these deviations are already required to be documented and are subject to evaluation during FDA inspections. This requirement is not keeping with the least burdensome provisions of FDAMA.

 **ABBOTT**

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