



13 November 2001

Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane (HFA-305)
Room 1061
Rockville, MD 20852-1448

2706 '01 NOV 14 P2:18

**Re: Docket No. 01D-0220
(Draft) Guidance for Industry:
Biological Product Deviation Reporting for Blood and Plasma
Establishments**

On 13 August 2001, the Food and Drug Administration (FDA) posted a notice in the Federal Register for public comment on the Draft Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments. Baxter Healthcare Corporation, Baxter Bioscience (Baxter) is a leading developer of plasma-derived biopharmaceutical products including coagulation factors, immune-globulin and albumin. Baxter is committed to providing high-quality, safe and effective therapeutics for improved patient care worldwide and is pleased to provide the following comments to the FDA.

Specific Comments:

Section III, A. WHO MUST REPORT?

This guidance document provides blood establishments with the Agency's current thinking related to the biological product deviation reporting requirements and includes licensed manufacturers of blood and blood components, including Source Plasma. We would like to **see** more **Source Plasma** applicable examples **included** in the guidance document.

Section III, B. WHAT DO I REPORT?

We would like to see a clearer definition of the terms "contract" and "contract supplier" (definition on page 3). For example, if a source plasma center is under contract to supply plasma to a fractionator, but is having samples tested by a laboratory that they have contracted, who is responsible for reporting when plasma is distributed?

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We appreciate the opportunity to provide these comments to the agency on this topic and would be happy to answer any questions regarding this issue. If there are any questions, please contact Daphne C. King, Project Manager, Regulatory Affairs, North America at 8 18-507-5546 or me at 8 18-507-5523.

Sincerely,

Arlene Vidor
Vice President, Regulatory Affairs
North America

AV/DK:dls

cc: Daphne King

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