WYETH-AYERST RESEARCH

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Division of American Home Products Corporation

WORLDWIDE REGULATORY AFFAIRS



November 13, 2001

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

**RE: Comments on Docket No. 01D-0221**
**Draft Guidance for Industry on Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components**

Dear Sir or Madam:

Wyeth-Ayerst Laboratories, a Division of American Home Products Corporation, hereby submits comments to Docket No. 01D-0221, pertaining to the Draft Guidance for Industry on "Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components".

Wyeth-Ayerst is a major research-oriented pharmaceutical company with leading products in the areas of women's health care, cardiovascular disease therapies, central nervous system drugs, anti-inflammatory agents, anti-infective agents, vaccines, and biopharmaceuticals. American Home Products Corporation is one of the world's leading research-based pharmaceutical and healthcare products companies, and is a leading developer, manufacturer, and marketer of prescription drugs and over-the-counter medications.

We would like to propose a clarification to one aspect of the draft guidance. We note that page 3 (second paragraph) states that, "Some common manufacturing steps performed under contract include testing, filling, storage and distribution". The guidance further indicates that if the manufacturer contracts out any of these steps, the product remains under the manufacturer's control. This wording might be interpreted to mean that the manufacturer is responsible for reporting a deviation that occurs during any stage of distribution of the product.

We believe that clarification is needed to clearly indicate that the manufacturer must only report a deviation that occurs during distribution while the product is still under the manufacturer's control. This point is clearly illustrated in the example provided at the top of page 4 of the draft guidance (example no. 2). Nevertheless, it would help to avoid misinterpretation if the text on page 3 pertaining to contract manufacturing is revised to clarify that downstream distribution by wholesalers, third party distributors, pharmacy chains, etc are outside of the manufacturer's control.

01D-0221 C1

Wyeth-Ayerst appreciates the opportunity to provide this constructive input to the draft guidance. This letter is submitted in duplicate. Please contact the undersigned at (484) 865-3794 if there are any questions regarding the submitted comments.

Sincerely,

Roy J. Baranello, Jr.
Assistant Vice President
Worldwide Regulatory Affairs

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