DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

MAY 3 1 2000

Dear Biologic Product Manufacturer:

The Center for Biologics Evaluation and Research (CBER) has completed its evaluation of the use of thimerosal in vaccines under the Food and Drug Administration Modernization Act (FDAMA) of 1997, Section 413, "FDA Study of Mercury Compounds in Drugs and Food." Our review concluded that reducing or eliminating thimerosal from vaccines is merited.

On July 1, 1999, CBER issued a letter to Biologic Product Manufacturers in which information was requested regarding plans for removing or reducing thimerosal in U.S. licensed vaccines. We are now requesting an update on progress toward this goal, particularly for vaccines administered to infants and children. For each product listed in your reply, we request the following information:

1. Actions taken to date to develop thimerosal-free or thimerosal-reduced vaccine.

2. Time lines for implementing proposed changes to reduce or eliminate thimerosal from your product(s).

3. Please identify in which products, if any, you intend to continue using thimerosal and explain why reduction or removal of thimerosal is not feasible.

Please note that the joint statement by the American Academy of Pediatrics and the United States Public Health Service of July 7, 1999, called for the removal of thimerosal from vaccines as soon as possible. As mentioned in our July 1, 1999, letter, CBER encourages discussions with us to develop strategies for the reduction and elimination of thimerosal in vaccines and to discuss the data requirements to support effecting these changes.

We request that you submit specific information requested above within 45 days to the attention of Valerie Vashio, HFM-475. Please contact me or Dr. Norman Baylor at 301-827-0655 if you have questions, or would like to schedule a meeting with CBER regarding the above request.

Sincerely yours,

William M. Egan

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