DEPARTMENT OF HEALTH& HUMAN SERVICES

Food and Drug Administration

1401 Rockville Pike
Rockville MD 20852-1448

JUL 01 1999

Dear Vaccine Manufacturer:

The Center for Biologics Evaluation and Research (CBER) is evaluating the continued use of thimerosal in biologic products under the Food and Drug Administration Modernization Act (FDAMA) of 1997, Section 413, "FDA Study of Mercury Compounds in Drugs and Food."

As part of this evaluation, we are now requesting that all manufacturers of thimerosal-containing vaccines provide information to CBER regarding their plans for thimerosal as a preservative in U.S. licensed vaccines, addressing each product separately.

1. If you intend to remove thimerosal from your product(s), please discuss the following:

   a) proposed studies to assess the effect of removing thimerosal on sterility, potency, stability, and immunogenicity of the product;

   b) feasibility of eliminating or reducing the amount of thimerosal, using alternative preservatives, or reformulating the product solely for single dose containers;

   c) anticipated manufacturing changes as a result of removing thimerosal, if any;

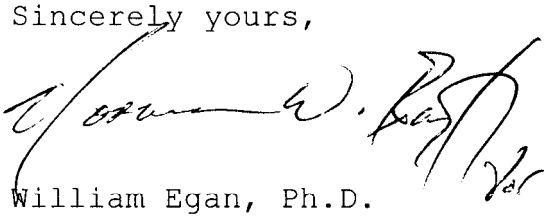
   d) approximate 'time-line necessary to evaluate and implement removal.

2. If you intend to continue using thimerosal in your product(s), please provide an explanation as to why you have made this decision.

Please note that FDA regulations do not require use of preservatives in biological products formulated for single-dose containers. CBER encourages discussions with manufacturers as to what additional data, if any, would be required to effect such a change.

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

Sincerely yours,



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