DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852-1448

Our STN: BL 125260/0

FEB - 6 2008

GlaxoSmithKline Biologicals
Attention: Ms. Donna Boyce
2301 Renaissance Boulevard
P.O. Box 61540
King of Prussia, PA 19406-2772

Dear Ms. Boyce:

We have completed the review of your submissions to your biologics license application (BLA) for Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine (KINRIX) for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis as the fifth dose in the DTaP series and the fourth dose in the inactivated poliovirus vaccine (IPV) series submitted under section section 351 of the Public Health Service Act.

The deficiency is as follows:

> You propose to manufacture KINRIX using Diphtheria and Tetanus Toxoids Adsorbed Combined Bulk (For Further Manufacturing Use) supplied by Novartis Vaccines and Diagnostics GmbH & Co. (U.S. License 1754) in a shared manufacturing arrangement. A Warning Letter was issued to Novartis Vaccines and Diagnostics GmbH & Co. on January 24th, 2008 as a result of an inspection performed by FDA September 20 – 27th, 2007. Outstanding compliance issues as noted in the Warning Letter must be resolved before final approval action may be taken.

We acknowledge our correspondence regarding the label, including the revision of the package insert that you sent by E-mail January 31, 2008 and our comments on the revised package insert that were conveyed on February 5, 2008. While we cannot take final action on this supplement until the compliance issue listed above has been resolved, you may submit revised labeling for our review. We reserve final comment on the labeling until the application is otherwise acceptable.

Within 10 days after the date of this letter you should notify us of your intent to file an amendment.

We stopped the review clock with the issuance of this letter. We will reset and start the review clock when we receive your complete response.

If you have any questions, please contact the Regulatory Project Manager, Dr. Joseph Temenak, at (301) 827-3070.

Sincerely yours,

Milan S. Blake, Ph.D.
Acting Director
Division of Bacterial, Parasitic
and Allergenic Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research