DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852-1448

Our STN: BL 103677/5261

JUL 11 2006

Wyeth Pharmaceuticals
Attn: Joyce Schwenk
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Schwenk:

We have approved your request to supplement your biologics license application for Coagulation Factor IX (Recombinant) to revise the Clinical Pharmacology section of the package inset as follows:

> "Factor IX is the specific clotting factor deficient in patients with hemophilia B. The administration of BeneFIX®, Coagulation Factor IX (Recombinant), increases plasma levels of factor IX and can temporarily correct the coagulation defect in these patients."

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (five for circulars). All labeling submissions must be accompanied by FDA Form 2567.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Basil Golding, M.D.
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research