DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Our STN: BL 103332/6409

Bayer HealthCare LLC
Attention: Xiao (Michelle) Meng, PhD
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981-0915

Dear Dr. Meng:

We have approved your request to supplement your biologics license application for Antihemophilic Factor (Recombinant) [Kogenate FS] to expand the indication of Kogenate FS to include adult prophylaxis.

The review of this product was associated with the following National Clinical Trial (NCT) number: NCT00623480.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h and FDA Form 2567 as appropriate.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled, "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. You must submit copies of your final advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 [21 CFR 601.12(f)(4)].

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 or substantial clinical experience to support such claims [21 CFR 202.1(e)(6)].

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

PEDIATRIC REQUIREMENTS:

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

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

Sincerely yours,

Paul Mintz, MD
Acting Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Enclosure: Package Inserts