



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852-1448

January 31, 2007

Octapharma Pharmazeutika Produktionsges.m.b.H
Attention: Barbara Rangtiner, Ph.D.
Oberlaaer Strasse 235
A-1100 Vienna, Austria

Dear Dr. Rangtiner:

We have received your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

Our Submission Tracking Number (STN): BL 125251/0

Name of Biological Product: Coagulation Factor VIII/von Willebrand Factor Complex (Human)

Indication: For the treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease (vWD), and in mild and moderate vWD where use of DDAVP treatment is ineffective or contra-indicated.

Date of Application: 12-December-2006

Date of Receipt: 14-December-2006

Action Due Date: 14-October-2007

US License Number and Manufacturing Site: 1646; OCTAPHARMA Pharmazeutika Produktionsges.m.b.H., Oberlaaer Strasse 235, A-1100 Vienna, Austria.

We request that you submit all future correspondence, supporting data, or labeling relating to this supplement in triplicate, citing the above STN number. Send all correspondence to the following address:

Alan E. Williams, Ph.D.
Director Division of Blood Applications, HFM-370
Center for Biologics Evaluation and Research
Food and Drug Administration
Suite 200N
1401 Rockville Pike
Rockville, MD 20852-1448

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We will notify you within 60 days of the receipt date if the application is sufficiently complete to permit a substantive review.

If you have any questions, please contact the Regulatory Project Manager, Mr. Franklin T. Stephenson, at (301) 827-6165

Sincerely yours,

A handwritten signature in black ink, appearing to read "Franklin T. Stephenson".

Franklin T. Stephenson, M.S.
Regulatory Project Manager
Regulatory Project Management Branch
Division of Blood Applications
Office of Blood Research and Review
Center for Biologics Evaluation and Research