

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE: January 22, 2007

FROM: Patricia Holobaugh, Chief of Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Telephone: 301-827-6347 FAX: 301-827-6748

SUBJECT: Filing Meeting STN: 125251/0
Sponsor: Octapharma Pharmazeutika Produktionsges.m.b.H.
Product: Coagulation Factor VIII/von-Willebrand Factor Complex (Human)

TO: Franklin Stephenson, HFM-380

I reviewed representative study reports in Module 5 of this BLA. I was able to locate the types of information we will need to prepare bioresearch monitoring inspection assignments. I did not identify any issues that would trigger a Refusal to File.

Patricia Holobaugh

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Cc: HFM-664 BLA Summary File
HFM-664 AccessChron
HFM-664 125251/0 BLA File / Wesley