



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE: September 30- 07

TO: STN 125251/0 – Octapharma plasma derived vWF/FVIII factor

SPONSOR: Octapharma Ltd.

PRODUCT: vWF/FVIII factor

MEDICAL REVIEWERS: Hon Sum Ko
Kaushik Shastri

FROM: Nisha Jain, M.D., Clinical Review Branch, HFM-392

TO: Franklin Stephenson, Regulatory Project Manager, HFM-380

THROUGH: Toby Silverman, M.D., Chief, Clinical Review Branch, HFM-392

APPROVED
By Nisha Jain at 7:37 PM, Nov 14, 2007

Nisha Jain, M.D.

APPROVED
By Toby A. Silverman at 4:27 PM, Nov 13, 2007



Page 2 redacted for the following reason:

(b)(4)

Pages 4 through 8 redacted for the following reasons:

(b)(4)