MEMORANDUM
To: File: STN 125512
From: Igor Bacik, PhD, Staff Fellow, LACBRP, DBSQC, OCBQ
Thru: Kori Francis, Team Leader, LACBRP, DBSQC, OCBQ
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Sponsor/Product: Baxter Healthcare Corp./ Recombinant Porcine Factor VIII,
                    B-Domain Deleted (OBI-1)
Subject: STN 125512: In-support testing for Licensing Action of OBI-I.
Background: A request to test 3 lots of OBI-1, Recombinant Porcine Factor VIII, was received.
Method:
Factor VIII One-Stage Clotting Assay was performed using the ---------(b)(4)-------------------------------- following the procedure described in the Document ID No. 000643, with following reagents modification:

- --(b)(4)--
- FVIII Standard: Baxter in-house standard, ----------(b)(4)------------------
- Positive Control Plasma: Baxter in-house Activity Control, ----(b)(4)------
  The manufacturer used the similar clotting assay but different clotting instrument, ------------------(b)(4)--------------------------------------.

Results:
- The results were obtained by linear regression analysis, using Baxter in-house FVIII standard, -------(b)(4)----------------. The assay was valid with R^2 = 0.9957.
- Potency of Positive Control Plasma (Baxter), -------(b)(4)---------- vial recovery was 99% and %CV from all dilutions being 0.6.
- %CV from measurement of samples dilutions were in the range 2.3 – 5.9, which is less than the assay validity criteria of ---(b)(4)-----.
- Measured potencies of 3 lots are shown in Table 1.

Table 1.
FDA/CBER Baxter FVIII One – Stage Clotting Assay results

Lot number	FVIII Potency* (Manuf.)	Specification*	FVIII Potency (CBER)	CBER/ Manuf ratio
1. ---(b)(4)--	490 IU/vial	-----(b)(4)--------	432 IU/vial	88%
2. ---(b)(4)--	470 IU/vial	-----(b)(4)--------	414 IU/vial	88%
3. ---(b)(4)--	490 IU/vial	-----(b)(4)--------	472 IU/vial	96%

*Specification and manufacturer's results were taken from OBI-1 Drug Product Specification, section 3.2.P.5.1, and from Batch Analyses, section 3.2.P.5.4 of the BLA.
Conclusion:

The results summarized in Table 1 show that FVIII potencies of all 3 lots submitted for evaluation are within specification limits.