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Subject: Test Results for (1) Residual Moisture, (2) Protein Content, -----
-----(b)(4)-----, (5) Appearance and (6) Reconstitution Time for
Baxter Antihemophilic Factor (Recombinant), Porcine Sequence rpFVIII (OBI-1).

STN: 125512/0

Process Validation Drug Product Lots

(b)(4)--

(b)(4)--

(b)(4)--

Through: Lokesh Bhattacharyya, Ph.D. HFM-682 Lab Chief LACBRP, DBSQC
William McCormick, Ph.D. HFM-680, Director DBSQC

Summary of Testing: Test results by DBSQC are in compliance with the drug product specifications for commercial lot release as proposed by Baxter in Section 3.2.P.5.1 of this BLA submission.

1) Residual Moisture (CBER TMID 000476)

Determination of residual moisture content was performed by CBER using Karl Fischer coulometric titration with methanol extraction of the lyophilized sample (DBSQC Test Method Doc. ID 000476). CBER analyst was Ritu Agarwal. Each lot result represents the average of three titrations from the extracted contents of two individual vials that were tested separately. Test results are as follows:

CBER			Baxter
Lot#	% w/w Moisture	Test Date	% w/w Moisture
(b)(4)--	1.0	03/05/14	0.2
(b)(4)--	0.9	03/05/14	0.2
(b)(4)--	0.8	03/05/14	0.3

Baxter has specified a release limit for residual moisture of -----(b)(4)----- . Baxter determines residual moisture using -----(b)(4)----- . CBER test results for these lots meet this criterion along with the results submitted by the manufacturer.

2) -----(b)(4)-----

CBER

Reconstitution time was evaluated concurrently with reconstitution for the determination of pH. CBER analyst was A. Del Grosso.

CBER		Baxter	
Lot#	Reconstitution Time	Test Date	Reconstitution Time
(b)(4)--	15 sec.	04/29/14	8 sec.
(b)(4)--	15sec.	04/29/14	6 sec.
(b)(4)--	15 sec.	04/29/14	5 sec.

The specification for Reconstitution Time is -----(b)(4)------. Results obtained by CBER meet this specification along with those of the manufacturer.