

MEMORANDUM FOR RECORD

04 March, 2014

To STN # 125512/0

From Dr. Hyesuk Kong,
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Through Dr. James L. Kenney, Chief
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Cc Thomas Maruna, RPM OBRR/DBA
Natalya Ananyeva, Chair, BLA Review Committee

Subject CBER In-support Bacterial Endotoxin Test Results on Antihemophilic Factor (Recombinant), Porcine Sequence (OBI-1)

The Division of Biological Standards and Quality Control's Laboratory of Microbiology, *In-vivo* Testing and Standards tested three lots of Antihemophilic Factor (Recombinant), Porcine Sequence (OBI-1) for bacterial endotoxin using the -----(b)(4)----- test method, as Baxter Healthcare Corporation (Baxter) is requesting the approval of this method in their license application. The bacterial endotoxin results are listed below:

-----**(b)(4)**----- **Assay Results**

Lot Number	Dosage per mL	Endotoxin Test Results	Proposed Specification
-(b)(4)-	500 U/mL	< 0.06 IU/mL	---(b)(4)---
-(b)(4)-	500 U/mL	< 0.06 IU/mL	---(b)(4)---
-(b)(4)-	500 U/mL	< 0.06 IU/mL	---(b)(4)---

CBER performed licensing support testing for the above lots at multiple test dilutions. Baxter's testing dilution is (b)(4), which CBER tested; however, all of CBER's test dilutions were negative for endotoxin and allowed valid recovery of endotoxin spike. CBER therefore presents the results as calculated at the lowest sample dilution (i.e., (b)(4),). CBER's (b)(4) sensitivity is 0.06 IU/mL, where Baxter's is ---(b)(4)-----; since Baxter tested at a (b)(4), dilution, the maximum sensitivity of their release test is ---(b)(4)----- vs. CBER's maximum test sensitivity of 0.06 IU/mL. All tests were negative for endotoxin.