

From: Hooban, Christopher
Sent: Tuesday, June 02, 2015 1:06 PM
To: stanley.ammons@octapharma.com
Cc: Cagungun, Nannette
Subject: Information Request - BL 125587/0; Original BLA; Octapharma; ADD 14-APR-2016

Our Reference: BL 125587/0

Octapharma Pharmazeutika Produktionsges.m.b.H.

Dear Mr. Ammons:

We are reviewing your April 15, 2015 biologics license application (BLA) for Immune Globulin Intravenous, Human 10%. We determined that the following information is necessary to continue our review:

Bioburden for (b) (4)

(b) (4)

Sterility testing for Drug Product (DP)

4. Please provide missing Appendix 1 for results of sterility test validation report (report no. 702VAL120 FC 82x/01.rep) at OSA site.
5. Please provide (b) (4) results for microorganism inoculums used in the sterility test validation report at OSA site (report no. 702VAL120 FC 82x/01.rep) and OPG site (report no. 001VAL106 FC 82x/00).

Endotoxin testing for DP at OPA Site

6. (b) (4) in endotoxin validation report (report no. 000VAL162 FC 851/00) is calculated using a release specification of (b) (4), however, the batch analysis data (section 3.2.P.5.4) for lots manufactured and tested at OPG site states their release specification is (b) (4). Please clarify the specification for endotoxin test performed at OPG site.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by June 16, 2015 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is April 14, 2016.

If you have any questions, please contact me at (240) 402-8376 or christopher.hooban@fda.hhs.gov.

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