

From: Hooban, Christopher
Sent: Monday, 05 October, 2015 11.44
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Information Request (OCT 5): STN 125587/0

Our Reference: BL 125587/0
Original BLA

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 are providing the following comments for your lot release protocol submitted on June 15, 2015:

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1. For the Chemical Assays, please add another column for the test date, for each test.
2. For Clarity, (b) (4) please state the results of the test and not “passed test”
3. Please state the (b) (4) titer limit as (b) (4)”

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4. Please add a test date for the (b) (4)
5. In the sterility template, please include (b) (4) in the method used.

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6. In the general safety template, please use “complies with 21CFR 610.11” in the specification
7. In the endotoxin test template, please use “(b) (4)” in the test method.
8. In the endotoxin test template, please ensure the correct STD Endotoxin Concentrations are listed in the (b) (4) for each assay, as different endotoxin concentrations have been approved for OSA and OPG. In addition, the (b) (4) in the standard curve and product test summary should be changed to (b) (4). Please use the CBER (b) (4) template or include the data suggested by the template, below.

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9. In the endotoxin test template: the (b) (4) template states the testing dilution is (b) (4); however, in both qualification reports the testing dilution of (b) (4) was selected. Please ensure this is corrected.
10. Please provide (b) (4) on the template.

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 October 30, 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.

Chris Hooban

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