

From: Hooban, Christopher
Sent: Wednesday, September 02, 2015 9:20 AM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Information Request (Diphtheria Test) - 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 and request for additional information to continue our review:

1. Please provide the following documents referenced in validation report 007VAL100 FC 851/00 for Determination of Diphtheria Antitoxin in IVIG 10% (NewGam):

a. 007VAL 100 FC 851/00.prot Analytical Method Validation Protocol for the determination of Diphtheria Antitoxin in IVIG 10% final containers using the (b) (4) test;

b. Standard operating procedure SOP/DIPH/001-7 Diphtherie (b) (4); and

c. 007VAL 100 FC 84x /00 Determination of Diphtheria Antitoxin in OctaGam 5% final containers using the (b) (4) test.

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 September 9, 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
Regulatory Project Manager
OBRR/CBER/FDA
U.S. Food & Drug Administration
White Oak Building 71, Room 4257
Office: (240)402-8376
Mobile: (240)762-2266
Email: christopher.hooban@fda.hhs.gov

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