

From: Thompson, Edward
Sent: Wednesday, February 14, 2018 3:32 PM
To: 'stanley.ammons@octapharma.com'
Subject: Information Request for BLA 125668/0

Contacts: Stanley Ammons - Octapharma

Dear Mr. Ammons:

We are reviewing your December 28, 2017, biologics license application (BLA), for Immune Globulin Subcutaneous (Human). We determined that the following information is necessary to continue our review:

Sterility Test

1. Please provide back titration results for positive controls used in sterility test qualification of drug product (document number 001VAL106 FC 81x/100);

Endotoxin Test

2. Please clarify if (b) (4) used in endotoxin qualification test of drug product (section 6.6) were reconstituted in (b) (4) to overcome influence of (b) (4) (document number 000VAL162 FC 81x/00); and

Diphtheria Test

3. Please provide results in Unit/mL (using formula presented in section 4.8.2) instead of titer step for data/results obtained during qualification of Diphtheria test by (b) (4) test (document number 007VAL100 FC 81x/0.1.rep).

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

Please submit your response to this information request as an amendment to this file by February 28, 2018, 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.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is December 29, 2018.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me.

Sincerely,

Edward Thompson

Regulatory Project Manager

Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

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