

From: Thompson, Edward
Sent: Friday, February 23, 2018 11:58 AM
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:

In your original submission and the response to the FDA information request, you did provide the datasets in SAS format (files *. xpt) . However, you did not provide the SAS programs used in you study (files *.sas). Particular you did not provide the SAS programs used to calculate the number person-year exposure, the point estimates and 95% Confidence intervals in Table 9 or statistics in Table 2. Please provide ALL SAS programs and specify the datasets used in each particular program/SAS PROCs.

Please submit your response to this information request as an amendment to this file by March 9, 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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