



Our Reference: BLA 125668/o

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

July 25, 2018

Sent by email

Dear Mr. Ammons:

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

1. Please apply the changes found in the attached package insert label.
2. Please include your updated revisions that you submitted for the package insert label on June 18, 2018 [eCTD 0014] and on July 18, 2018 [eCTD 0018].
3. Please (on a volunteer basis) present your charts and figures to comply with Section 508 Amendment to the Rehabilitation Act of 1973 for web posting on the FDA.gov site. If the charts and figures are not in compliance, then these items will not be presented on the site after the issuance of the final action letter for this application. For resource purposes please access this link:
<https://www.section508.gov/>.

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

Please submit your suffixes as an amendment to this file by August 8, 2018, referencing the date of this request.

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
FDA/CBER/OBRR/RPMS