



Our Reference: BLA 125668/0

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

June 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 information is necessary to continue our review:

Prospective Naming of Biological Products Submitted Under Section 351(a) of the PHS Act

An applicant should propose a suffix composed of four lowercase letters for use as the distinguishing identifier included in the proper name designated by FDA at the time of licensure (see section VI of the guidance).

An applicant should submit up to 10 proposed suffixes. We recommend including any supporting analyses of the proposed suffixes for FDA's consideration based on the factors described in the guidance.

Link to guidance

<https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>

The proposed suffix should:

- Be unique
- Be devoid of meaning
- Be four lowercase letters of which at least three are distinct
- Be nonproprietary
- Be attached to the core name with a hyphen
- Be free of legal barriers that would restrict its usage

The proposed suffix should NOT:

- Be false or misleading, such as by making misrepresentations with respect to safety or efficacy
- Include numerals and other symbols aside from the hyphen attaching the suffix to the core name
- Include abbreviations commonly used in clinical practice in a manner that may lead the suffix to be misinterpreted as another element on the prescription or order
- Contain or suggest any drug substance name or core name
- Look similar to or be capable of being mistaken for the name of a currently marketed product (e.g., should not increase the risk of confusion or medical errors with the product and/or other products in the clinical setting)
- Look similar to or otherwise connote the name of the license holder
- Be too similar to any other FDA-designated nonproprietary name suffix

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 July 10, 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

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Thank you