

From: Levi, Mark  
Sent: Tuesday, 10 July, 2018 08.01  
To: 'Wittig, Anja'  
Cc: Rangetiner, Barbara; Ammons, Stanley  
Subject: RE: BLA125587 Nonproprietary Naming of Biological Products

Sensitivity: Confidential

Given the action due date for this file of Aug. 2, 2018, we need time to review them. There is no deadline per se but I would think by next week would be fine.

Regards, Mark Levi  
Mark Levi, PhD  
Regulatory Project Management Staff  
Center for Biologics Evaluation and Research  
Office of Tissues and Advanced Therapies  
U.S. Food and Drug Administration  
Tel: 240-402-9662 Work iPhone 301-908-5787  
mark.levi@fda.hhs.gov

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From: Wittig, Anja [mailto:anja.wittig@octapharma.com]  
Sent: Tuesday, 10 July, 2018 07:51  
To: Levi, Mark <Mark.Levi@fda.hhs.gov>  
Cc: Rangetiner, Barbara <barbara.rangetiner@octapharma.com>; Ammons, Stanley <stanley.ammons@octapharma.com>  
Subject: RE: BLA125587 Nonproprietary Naming of Biological Products  
Sensitivity: Confidential

Dear Mr. Levi,  
We hereby confirm receipt of this e-mail.

Octapharma would like to propose potential suffixes.  
Could you please let us know if there is a deadline for submission of such a proposal for Panzyga?

Thank you for your kind support.  
Best regards,  
Rita Gorsche

On behalf of  
Anja Wittig  
Manager

International Regulatory Affairs Department

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Anfang der weitergeleiteten Nachricht:

Von: "Levi, Mark" <Mark.Levi@fda.hhs.gov>

Datum: 10. Juli 2018 um 02:27:46 MESZ

An: "'barbara.rangetiner@octapharma.com'" <barbara.rangetiner@octapharma.com>

Kopie: "Ammons, Stanley" <stanley.ammons@octapharma.com>, "Renner, Iris" <iris.renner@octapharma.com>

Betreff: BLA125587 Nonproprietary Naming of Biological Products

Dear Dr. Rangetiner,

Your application falls within the scope of the guidance entitled Nonproprietary Naming of Biological Products, which states that, for certain biological products, the FDA intends to designate a four-letter distinguishing suffix that is devoid of meaning. Certain provisions of the guidance, relating to the collection of information, are still under review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. However, provisions that do not describe the collection of information should be considered final, including the description of the naming convention and the considerations that support the convention, which reflects FDA's current thinking on the nonproprietary naming convention.

We are informing you of the designated proper name for your product and that FDA intends to assign a four-letter suffix for inclusion in the proper name designated in the license, if your product is approved. If you so choose, you are welcome to submit proposed suffixes for FDA's consideration. Please see attached guidance for additional information on the naming convention and guidelines for proposed for suffixes.

The suffix will be added to the designated proper name of your product, in the format shown below.

immune globulin intravenous (human)-????

You may submit up to 10 proposed suffixes.

If you have any questions, please feel free to contact me. Please acknowledge receipt of this email.

Regards, Mark Levi  
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Center for Biologics Evaluation and Research  
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