

From: Alicea, Candido  
Sent: Monday, November 19, 2018 12:26 PM  
To: 'Robertson, Joan'  
Subject: STN 125683/0 -Request for proposed suffixes

Product: Immune Globulin Subcutaneous (Human) (b) (4)  
Applicant: Grifols Therapeutics LLC

Dear Ms. Robertson:

Your application falls within the scope of the Guidance to Industry entitled Nonproprietary Naming of Biological Products (Nonproprietary Naming Guidance). This guidance describes FDA's current thinking on the need for biological products licensed under the Public Health Service Act (PHS Act) to bear a nonproprietary name that includes an FDA-designated suffix. You may submit up to 10 proposed suffixes in the order of your preference. The final determination on the acceptability of a proposed suffix is based on FDA's review of the information you submit using the criteria set forth in the Nonproprietary Naming Guidance. Alternatively, if you choose not to submit suffixes for review, FDA will assign a randomly generated, pre-screened suffix for inclusion in the proper name designated in the license at the time FDA approves the application.

Please submit your proposed suffixes as an amendment to the file within 10 days of this request or let us know if you prefer that FDA assign a suffix. Please acknowledge receipt of the email.

Sincerely,

Candido

Cándido Alicea Ph.D.

CDR, USPHS

Regulatory Project Manager

Center for Biologics Evaluation and Research

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