



Memorandum

Date: December 18, 2018

From: Lisa L. Stockbridge, Ph.D.
Branch Chief
OCBQ/DCM/APLB

To: Patrick Riggins, RPM, OMPT/CBER/OTAT/DRPM
Candido Alicea, RPM, OMPT/CBER/OTAT/RMS

Subject: PROPER NAME SUFFIX RECOMMENDATION
STN 125683/0
Sponsor: Grifols Therapeutics LLC

Background

On December 3, 2018, Grifols Therapeutics LLC (Grifols) submitted proposed proper name suffixes for (b) (4) (immune globulin subcutaneous, human) 20% solution (BLA125683). The proposed indication is treatment of primary immunodeficiency (PI) in adults, including, but not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

The proposed proper name suffixes for review, listed in their order of preference: - grfs, - scgf, - scgr, - gfsc, -grsc

Assessment of the proper name with suffix

The proposed suffixes were evaluated using the criteria set forth in *Guidance for Industry – Nonproprietary Naming of Biological Products*. A suffix should be unique, devoid of meaning, composed of four lowercase letters of which at least three are distinct, nonproprietary, and free of legal barriers that would restrict its usage. A suffix should not include numbers or symbols, be false or misleading with respect to safety or efficacy of the product, include abbreviations commonly used in clinical practice in a manner that may lead it to be misinterpreted as another element on the prescription or order, contain or suggest a drug substance name or core name, look similar to or have the potential to be mistaken for the name of a currently marketed product, connote the name of the license holder, or be too similar to another FDA-designated suffix.

Using the above criteria, Grifols' proposed proper name suffixes are not devoid of meaning and are all unacceptable for the following reasons:

- Directly referencing the applicant's name, Grifols: (e.g., - **grfs**, - **scgf**, - **scgr**, - **gfsc**, - **grsc**)
- Connoting the product's route of subcutaneous administration (e.g- **scgf**, - **scgr**, - **gfsc**, - **grsc**)

Recommendation

Grifols' proposed proper name suffixes were reviewed and all were found unacceptable. Thus, we offer the following letter-ready language to convey to the applicant:

We find that each one of your proposed suffixes is unacceptable in one or both of the following ways:

- *Suffix connotes your name, GRIFOLS (e.g., - grfs, - scgf, - scgr, - gfsc, - grsc)*
- *Suffix connotes your product's route of administration, subcutaneous (e.g., scgf, - scgr, - gfsc, - grsc).*

Because your proposed suffixes were found unacceptable, you may provide us with additional proposed suffixes for consideration. Please be informed that, in the absence of acceptable alternative proposals, we intend to assign a randomly generated, pre-screened suffix for inclusion in the proper name if your product is licensed within this review cycle.