



Memorandum

Date: September 27, 2018

From: Oluchi Elekwachi, PharmD, MPH, Regulatory Review Officer
OCBQ/DCM/APLB

Through: Lisa Stockbridge, PhD, Branch Chief
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Agnes Lim, Medical Officer, OMPT/CBER/OTAT/DCEPT/GMBI

Subject: Review of Proposed Proprietary Name “(b) (4)” (immune globulin
subcutaneous, human), 20% Solution for Injection
BLA 125683
Applicant: Grifols Therapeutics

Recommendation: (b) (4) – **Acceptable**

Executive Summary

The Advertising and Promotional Labeling Branch (APLB) has completed the review of the proposed proprietary name, (b) (4), a human immunoglobulin. We recommend that the proposed proprietary name, (b) (4), be found **Acceptable**.

According to SOPP 8001.4 Review of CBER Regulated Product Proprietary Names, the product office, Office of Tissues and Advanced Therapies (OTAT), makes the final decision on the acceptability of a proposed proprietary name. To meet the PDUFA performance goal, OTAT must communicate this decision to the applicant within 90 days of the receipt of the proprietary name review (PNR) submission. The PDUFA goal date for this PNR is February 25, 2019.

If OTAT accepts our recommendation that the proposed primary proprietary name, (b) (4), be found **Acceptable**, we offer the following communication-ready language:

In consultation with CBER’s Advertising and Promotional Labeling Branch, we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed

proprietary name, (b) (4), is Acceptable.

OTAT is responsible for communicating CBER's decision to the Applicant and should enter the communication issuance date into RMS-BLA before February 25, 2019, in order to meet the deadline and stop the performance clock. Please notify APLB when this action has been completed.

Background

On August 29, 2018, Grifols Therapeutics (Grifols) submitted the proposed proprietary name, (b) (4), for its subcutaneous immune globulin product. According to the applicant, the name (b) (4) (pronounced (b) (4)) was not derived from a particular source. The indication is for treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

(b) (4) will be provided as a 0.2 g per mL (200 mg/mL; 20%) protein solution for subcutaneous infusion, supplied as single dose preparations in 5 ml, 10 ml, 20 ml or 50 ml glass vials in individual packaging. It should be stored at 2° to 8°C (35° to 46°F).

(b) (4) will be dispensed from specialty pharmacies or directly by the patient physician. The product can be infused subcutaneously at home by a patient or caregiver or in a healthcare facility by a clinician.

Method

APLB utilized the FDA Phonetic and Orthographic Computer Analysis (POCA) and the following databases:

1. CBER list of Licensed Products ending September 25, 2018, at <http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM149970.pdf>
2. DailyMed at <http://dailymed.nlm.nih.gov/dailymed/about.cfm>
3. Drugs@FDA current through September 25, 2018, at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda>
4. Electronic Orange Book current through September 25, 2018, at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>
5. Google Internet search at <http://www.google.com>
6. Micromedex at <http://www.micromedexsolutions.com/micromedex2/librarian>
7. United States Patent and Trademark Office (USPTO) at <http://www.uspto.gov/trademarks/index.jsp>
8. USAN Stem at <http://www.ama-assn.org/ama1/pub/upload/mm/365/stem-list-cumulative.pdf>

APLB also consulted the review team on the proprietary name and incorporated their recommendations into this review.

Results

1. Prescreening for Objectionable Naming Practices

The proposed proprietary name, (b) (4), was screened against the following:

- Obvious similarities in spelling and pronunciation
- Manufacturing characteristics
- Medical and/or coined abbreviations
- Inert or inactive ingredients
- Combination of active ingredients
- United States Adopted Name (USAN) stems
- Same proprietary name for products containing different active ingredients
- Reuse of proprietary names
- Dosage form or route of administration
- Dosing interval
- Established or proper name
- Modifiers as components of a proprietary name
 - Use of numerals as modifiers
 - Device-related modifiers
 - Descriptive modifiers
- Brand name extensions (Umbrella branding)
- Dual proprietary names
- Foreign drug proprietary name
- Prescription-to-OTC switch
- Use of symbols
- Incorporation of the Applicant's name

2. Evaluating for Promotional and Safety Concerns

a. Promotional Review [21 CFR 201.10 (c)(3), 202.1 (e)(5)(i), and (e)(6)(i)]

The proposed proprietary name, (b) (4), is not regarded to be false, misleading or fanciful.

b. Look-alike Sound-alike Safety Review [21 CFR 201.10 (c)(5)]

Since drug products are prescribed through written, verbal, and/or electronic orders, such forms of communication may lead to medication errors, particularly if proprietary or established names sound or look alike. APLB conducted a search using POCA, with DPRF, Drugs@FDA, Cerner US Legend and OTC, CBER Biologic, Orange Book, and RxNorm as data sources, to identify existing names of concern with potential combined orthographic and phonetic similarity to (b) (4) and found 190 other moderately similar names. However, different dosage form and strength mitigate the concern over confusion of these products with (b) (4).

APLB recommends that (b) (4) be found **Acceptable**.

If you have any questions regarding this review please contact Oluchi Elekwachi, PharmD, MPH Regulatory Review Officer, at 240-402-8930.