

MEMORANDUM

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research**

Date: December 18, 2015

From: Alpita Popat, Pharm.D, MBA Consumer Safety Officer
OCBQ/DCM/APLB

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

Robert A. Sausville, Division Director
OCBQ/DCM

To: Christopher Hooban, RPM, OBRR/RPMB
Michael Kennedy, Team Lead, OBRR/DHCR
Laurence Landow, Medical Officer, OBRR/DHCR/CRB

Subject: Review of Proposed Proprietary Name “**CUVITRU**” [Immune Globulin
Subcutaneous (Human), 20% Solution]
BLA 125596/0
Sponsor: Baxalta US, Inc.

Recommendation: **CUVITRU – Acceptable**

Executive Summary

APLB has completed the review of the proposed proprietary name, CUVITRU, [Immune Globulin Subcutaneous (Human), 20% Solution] for the treatment of primary immune deficiency disorders associated with defects in humoral immunity in adults and pediatric patients two years of age and older. The proposed proprietary name, (b) (4), was also submitted as an alternative name. We recommend that the proposed proprietary name, **CUVITRU**, be found **Acceptable**.

According to SOPP 8001.4 Review of CBER Regulated Product Proprietary Names, the product office, Office of Blood Research and Review (OBRR), makes the final decision on the acceptability of a proposed proprietary name. To meet the PDUFA performance goal, OBRR must communicate this decision to the sponsor within 90 days of the receipt of the proprietary name review (PNR) submission. The PDUFA goal date for this PNR is February 12, 2016.

If OBRR accepts our recommendation that the proposed primary proprietary name, CUVITRU, be found unacceptable, 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, CUVITRU, is acceptable.

OBRR is responsible for communicating CBER's decision to the sponsor and should enter the communication issuance date into RMS-BLA before February 12, 2016, in order to meet the deadline and stop the performance clock. Please notify APLB when this action has been completed.

Background

On February 27, 2015, Baxter Healthcare Corporation submitted a PNR request for (b) (4) (BB-IND 14505.54) and APLB concluded that the name was unacceptable because GAMMAGARD and (b) (4) have high phonetic and orthographic similarities and have many product characteristics in common that could contribute to medication errors.

On November 13, 2015, Baxalta submitted an alternative PNR request for CUVITRU [Immune Globulin Subcutaneous (Human), 20% Solution]. The pronunciation for CUVITRU is KUE-vih-tru. If approved, CUVITRU would be the only subcutaneously administered product in the Baxalta portfolio.

CUVITRU will be available as a 0.2 g/mL solution for injection in 5 mL, 10 mL, 20 mL, and 40 mL vials. The usual dosage for this product is approximately 300 to 1000 mg/kg monthly. The dose will be divided and administered from once daily to once every two weeks to individualize the dosing interval.

Baxter plans to request storage requirements at refrigerated 2 °C to 8 °C and/or room temperature conditions not to exceed 25 °C.

The primary care environment for this product will be in the homecare setting to be self-administered. This product primarily will be dispensed in a specialty pharmacy setting.

Baxter selected a proprietary name based on a review by Addison Whitney Health. The study was conducted in September and October 2015. The research study was conducted with 75 healthcare professionals in the United States to assess potential for medication error to occur due to name confusion with **CUVITRU**. The study concluded that CUVITRU is an acceptable proprietary name. APLB reviewed the results of this study, which were included in the sponsor's submission.

Method

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

1. CBER list of Licensed Products ending November 30, 2015 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 November 24, 2015 at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda>

4. Electronic Orange Book current through October 2015 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-application-process/search-trademark-database>
8. USAN Stem List accessed May 5, 2015

Results

1. Prescreening for Objectionable Naming Practices

The proposed proprietary name, CUVITRU, 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 sponsor'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 primary proprietary name, CUVITRU, is not regarded as 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 searches using POCA, with Drugs@FDA, RxNorm, and names entered by safety evaluators as data sources, to identify names with potential similarity to the proposed name, CUVITRU. Any name with a combined match percentage score greater than 70% is considered to be “highly similar,” and between 50% and 69% is considered to be “moderately similar.”

There were no names that were considered highly similar to CUVITRU and 58 names were considered moderately similar. APLB reviewed the moderately similar names for similarity in dosage form, dose, and strength to CUVITRU. When these characteristics were considered, none of the moderately similar names was of concern.

In conclusion, APLB recommends that CUVITRU be found unacceptable.

If you have any questions regarding this review, please contact Alpita Popat, Pharm.D, MBA Consumer Safety Officer, at 240-402-9053.

Firm name: Baxalta US, Inc.

IND: 125596

Letter type: PNR Memorandum

Bcc: A. Popat
L. Stockbridge
R. Sausville
DCM Files

History:

Prepared:	A. Popat	12/17/15
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Concurrence box:

MailCode or Office	Name	Approval
APLB	A. Popat	
APLB	L. Stockbridge	
DCM	R. Sausville	