

MEMORANDUM

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

Date: August 18, 2016

From: Alpita Papat, Pharm.D., MBA
Consumer Safety Officer
Advertising and Promotional Labeling Branch (APLB) (HFM-602)
Division of Case Management

Through: Lisa L. Stockbridge, Ph.D.
Branch Chief
Advertising and Promotional Labeling Branch (APLB) (HFM-602)
Division of Case Management

To: Laurence Landow, Medical Officer, CBER/OBRR/DH
Thomas Maruna, RPM, CBER/OBRR/DBA/RPMB

Subject: Review of proposed proprietary name **CUVITRU (Immune Globulin Subcutaneous (Human), 20% Solution**
Sponsor: Baxalta USA Inc
BLA: 125596/0

Background: The sponsor submitted:

☒ New Approval
☐ Changes Being Effectuated (CBE) supplement
☐ Prior Approval Supplement (PAS) Amendment
☐ Major Amendment

Submission contains:

☒ Prescribing Information (PI)
☐ Patient Package Insert (PPI)
☒ Carton and/or container labels
☐ Other

Submission Date: September 14, 2016

PDUFA action Date: September 13, 2016

On September 14, 2015, Baxalta US, Inc. submitted an original Biologics License Application (BLA) for CUVITRU (Immune Globulin Subcutaneous (Human), 20% Solution) indicated for the treatment of primary immune deficiency disorders associated with defects in humoral immunity.

The manufacturing process for IGSC, 20% utilizes almost the same manufacturing process steps as the currently licensed Immune Globulin Infusion, (Human), 10% [IGI, 10%, STN 125105] with the exception of the (b) (4) and formulation steps. The concentration of this product is 20% rather than 10% and the route of administration is only subcutaneous.

APLB reviewed the proposed labeling submitted on April 22, 2016 and the Medical Officer's review from June 15, 2015, and has the following additional comments from a promotional and comprehension perspective.

HIGHLIGHTS

In the **BOXED WARNING**, we recommend listing each concept under a separate bullet to make the information more visually accessible. For example:

- Thrombosis may occur with immune globulin products, including CUVITRU. Risk factors include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.
- For patients at risk of thrombosis, administer CUVITRU at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration.
- Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

FULL PRESCRIBING INFORMATION

- In the **BOXED WARNING**, we recommend listing each concept under a separate bullet to make the information more visually accessible. For example:
 - Thrombosis may occur with immune globulin products, including CUVITRU. Risk factors include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors.
 - For patients at risk of thrombosis, administer CUVITRU at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration.
 - Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

- In the **6 ADVERSE REACTIONS** and **14 CLINICAL STUDIES** sections, please avoid arbitrary categories of “mild,” “moderate,” and “severe” that to not established definitions.

CONTAINER LABEL

APLB has no objections to the container label.

PACKAGE LABEL

Please add the lot number or other lot identification and the expiration date to the package label.

CUVITRU (Immune Globulin Subcutaneous (Human), 20% Solution)
BLA: 125596/0

Firm name: Baxter Healthcare Corporation

File name: LR_Cuvitru_2016 07 19_125596_0.doc

History

Prepared:	Alpita Popat	8/18/16
Concur w/rev:	Lisa Stockbridge	8/18/16
Final:	Alpita Popat	8/18/16

Bcc:	HFM-602	Lisa Stockbridge
	HFM-602	Chron File
	HFD-602	APLB Files

Concurrence box:

MailCode or Office	Name/ Date
HFM-602	
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