MEMORANDUM

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

Date:	October 13, 2010
From:	Michael Brony, Pharm.D. Regulatory Review Officer Advertising and Promotional Labeling Branch (APLB) (HFM-602) Division of Case Management
Through:	Lisa Stockbridge, Ph.D., Acting Branch Chief, APLB, HFM-602
Through:	Robert A. Sausville, DCM Director, (HFM-610)
To:	Crystal Allard, RPM, OBRR, DBA, RPM (HFM-380) Laurence Landow, M.D., Medical Officer and Committee Chair, OBBR, DH, CRB (HFM-392)
Subject:	Review of proposed proprietary name "**KEDBUMIN"** **BLA 125384/0**
Recommendation:	"**KEDBUMIN**" proprietary name be found **Acceptable**

Executive Summary:

KEDBUMIN (kîd-byú-mən) is a 25% albumin U.S.P. (human) that will only be used in inpatient/hospital setting (e.g., intended to be dispensed from a hospital pharmacy for administration by a health care professional). KEDBUMIN, which will be distributed in a 50 mL vial (25%), is to be administered intravenously. APLB recommends that the proposed proprietary name KEDBUMIN be found **Acceptable**.

Background:

On July 30, 2010, Kedrion, S.p.A., submitted a proprietary name request (PNR) for KEDBUMIN to their original BLA 125384/0 for a 25% albumin U.S.P. (human); CBER receipt date of this submission is August 3, 2010. This PNR submission also contained draft carton and container labels and proposed prescribing information (PI) to support the review of the proposed name.

The PDUFA action date for this PNR is November 1, 2010.

Discussion:

According to its proposed PI, KEDBUMIN will be indicated for the restoration and maintenance of circulating blood volume for: hypovolemia, hypoalbuminemia, prevention of central volume depletion after paracentesis due to cirrhotic ascites, ovarian hyperstimulation syndrome (OHSS), adult respiratory distress syndrome (ARDS), hemodialysis, ----------(b)(4)----------, burns, and cardiopulmonary bypass procedures.

KEDBUMIN is a 25% albumin U.S.P. (human) that will only be used in inpatient/hospital setting and will be dispensed from a hospital pharmacy for administration by a health care professional). KEDBUMIN, which will be distributed in a 50 mL vial (25%), is to be administered intravenously.

APLB consulted with the Committee Chair and Medical Officer for this product; no concerns were identified.

Evaluation Summary for KEDBUMIN:

1) **False or Misleading [21 CFR 201.6 (a)]:**

   The proposed proprietary name, KEDBUMIN, is not regarded to be false or misleading. Kedbumin is a combination of the sponsor's name KEDrion and alBUMIN. A dictionary, thesaurus and acronym search for "KEDBUMIN" was conducted by APLB. No matches were found.

2) **Fanciful [21CFR 201.10 (c)(3)]:**

   Based on APLB's review, the proposed proprietary name, KEDBUMIN, is not regarded to be fanciful and does not imply a unique composition, advanced formulation, or superiority over existing products beyond that supported by the data.

3) **Similarity in Spelling or Pronunciation [21 CFR 201.10 (c) (5)]:**

   There are minimal potential problems due to similarity in spelling and pronunciation with proprietary names for other marketed products. In the US, the following albumin products are approved:

   Octapharma: Albumin (Human), 5%, 25%
   Grifols: Albutein (Albumin (Human)), 5%, 25%
   Buminate 5%, 25% (Albumin, human)
   Flexbumin (albumin, human), 25%

   KEDBUMIN has a similar ending ("bumin"), albumin concentration (25%), and similar indications as Flexbumin. Taking into account the dissimilarity of first syllable phonetics and orthographics of these two products ("Ked" and "Flex"), APLB believes that the overall potential for confusion and risk of medication errors between these two products is expected to be low. Furthermore, inclusion of the first syllable of the sponsor's name

helps distinguish KEDBUMIN from other albumins. APLB completed a review of existing proprietary and established name products, and other than the noted approved albumin products (see table and references below), no exact or other sound-alike, look-alike matches to KEDBUMIN were identified. APLB believes that there is minimal risk for medication errors with the proprietary names for any currently marketed products when taking into account similarity in spelling, therapeutic class, indication, pronunciation, handwriting, storage, dosage form, setting of use, and route of administration.

Proprietary name (established name)	***Dosage Form***	***Dosing Regimen***	***Strength***	***Rx/OTC***	***Indication***	***Potential for medication error***
KEDBUMIN (Albumin (human)), 25%	Intravenous use only.	Varies by indication	12.5 g/50 mL vial	Rx	Restoration and maintenance of circulating blood volume for hypovolemia, hypoalbuminemia, and the prevention of central volume depletion after paracentesis due to cirrhotic ascites, OHSS, ARDS, hemodialysis, HDN, burns, and cardiopulmonary bypass procedures.	N/A
Flexbumin (Albumin (human)), 25%	Intravenous use only.	Varies by indication	12.5 g in 50 mL infusion bottle 25 g in 100 mL infusion bottle	Rx	Restoration and maintenance of circulating blood volume for hypovolemia, hypoalbuminemia, and the prevention of central volume depletion after paracentesis due to cirrhotic ascites, OHSS, ARDS, acute nephrosis, and HDN.	Low-moderate

Proprietary name (established name)	***Dosage Form***	***Dosing Regimen***	***Strength***	***Rx/OTC***	***Indication***	***Potential for medication error***
Buminate 5%, 25% (Albumin, human)	Intravenous use only.	Varies by indication	BUMINATE 5% is supplied in 250 mL and 500 mL bottles BUMINATE 25% is supplied in 20 mL, 50 mL and 100 mL Bottle	Rx	**5% Solution:** -Hypovolemia -Hypoalbuminemia due to general causes and burns, and use during or prior to cardiopulmonary bypass surgery. **25% Solution:** -Hypovolemia, -Hypoalbuminemia due to general causes, burns, ARDS, and nephrosis, for use during or prior to cardiopulmonary bypass surgery, and HDN.	Low-moderate
Albumin (Human), 5%, 25%	Intravenous use only.	Varies by indication	5%: 5% is supplied in 5.0 g/100mL, 12.5 g/250 mL or 25.0 g/500 mL single use bottles 25%: 12.5 g/ 50 mL infusion bottle 25 g/100 mL infusion bottle	Rx	**5% Solution:** The restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. **25% Solution:** The restoration and maintenance of circulating blood volume for hypovolemia, hypoalbuminemia, and the prevention of central volume depletion after paracentesis due to cirrhotic ascites, OHSS, ARDS, acute nephrosis, HDN.	Low-moderate

Proprietary name (established name)	***Dosage Form***	***Dosing Regimen***	***Strength***	***Rx/OTC***	***Indication***	***Potential for medication error***
Albutein (Albumin (Human)), 5%, 25%	Intravenous use only.	Varies by indication	5%: 250 mL and 500 mL vials 25%: 50 mL and 100 mL vials	Rx	**5% Solution** The treatment of hypovolemic shock, severe hypoalbuminemia, and an adjunct in hemodialysis and in cardiopulmonary bypass procedures. **25% Solution** The treatment of hypovolemic shock, an adjunct in hemodialysis, cardiopulmonary bypass procedures, ARDS, major injury or surgery resulting in increased albumin loss or inadequate synthesis, acute nephrosis not responding to cyclophosphamide or steroid therapy, and acute liver failure or ascites.	Low-moderate

Final Recommendation:

APLB recommends that the proposed proprietary name KEDBUMIN be found A**cceptable**. There appears to be a minimal risk for medications errors with the proprietary names for other marketed products taking into account similarity in spelling, therapeutic class, indication, pronunciation, handwriting, storage, dosage form, route of administration, and setting of use (see discussion and comparison table above).

If OBRR accepts our recommendation that the proposed proprietary name KEDBUMIN be found acceptable, please include the following text in your letter to the manufacturer:

> *In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, KEDBUMIN, is acceptable at this time.*
>
> *We will perform another proprietary name review of KEDBUMIN closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.*

References:

1. http://www.accessdata.fda.gov/scripts/cder/drugsatfda (CDER New and Generic Drug Approvals); searched 9/17/10
2. CBER New BLA, NDA and ANDA approvals lists; http://www.accessdata.fda.gov/scripys/cder/ndc/gettradename.cfm; (searched 9/17/10)
3. LabelDataPlus (labeldataplus.com); searched 9/17/10