MEMORANDUM

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

Date: March 28, 2011

From: Alpita Popat, PharmD, MBA, Consumer Safety Officer
CBER/OCBQ/DCM/APLB, HFM-602

Through: Lisa L. Stockbridge, Ph.D., Branch Chief
CBER/OCBQ/DCM/APLB, HFM-602

To: Crystal Allard, RPM, OBRR, DBA, RPM (HFM-380)
Laurence Landow, M.D., Medical Officer and Committee Chair,
OBBR, DH, CRB (HFM-392)

Subject: Re-evaluation of proposed proprietary name **KEDBUMIN**
BLA 125384/0

Recommendation: **KEDBUMIN** proprietary name found **Acceptable**

Executive Summary:

APLB performed a re-evaluation of the proposed proprietary name **KEDBUMIN**, 25% albumin USP (human), to determine if any new products were approved since our previous review on October 13, 2010. APLB found that no new products were approved that would change our previous recommendation. APLB recommends that the proposed proprietary name KEDBUMIN be found **Acceptable.**

Background:

APLB re-reviewed the proprietary name to ensure that our review is within 90 days of approval. The PDUFA goal date for this product is March 5, 2011. There are no newly marked products whose names resembled Kedbumin.

Recommendation:

APLB recommends that the proposed proprietary name, **KEDBUMIN,** be found acceptable**.**

If you have any questions with regards to this review please contact Alpita Popat, PharmD, MBA, Consumer Safety Officer at 301-827-6329.

References:

http://www.uspto.gov/
http://www.thomsonhc.com
http://www.labeldataplus.com/