



Memorandum

Date: May 31, 2018

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

To: Lorraine Wood, RPM, OMPT/CBER/OBRR/RPMS
Charles Maplethorpe, MD, PhD CBER/OBRR/DBCD/CRS

Subject: PROPER NAME SUFFIX RECOMMENDATION
ALBUMINEX (human albumin solution)
STN 125644
Sponsor: Bio Products Laboratory

Background

On December 8, 2016, Bio Products Laboratory (BPL) submitted a Biologics License Application (STN 125644) for ALBUMINEX (human albumin solution). ALBUMINEX will be supplied as 5% and 25% solutions. The proposed indication is the treatment of hypovolemia, ascites, burns, nephrotic syndrome, acute respiratory distress syndrome, and cardiopulmonary bypass. The care environment is likely to be an inpatient hospital setting.

On August 25, 2017, BPL received a Complete Response (CR) due to CMC and facility deficiencies. On December 18, 2017, BPL resubmitted the application with responses to the CR letter and, on May 23, 2018, BPL provided ten proposed proper name suffixes for review.

Listed in order of preference, the proposed suffixes are: *-kjda*; *-mvst*; *-cvmw*; *-wmbv*; *-usuk*; *-elst*; *-mbje*; *-msmd*; *-ewdb*; *-cmsj*.

Assessment of the proper name with suffix

Proposed suffixes are evaluated using the criteria set for in *Guidance for Industry – Nonproprietary Naming of Biological Products*. A suffix should be unique, devoid of meaning, composed of four lowercase letters of which at least three are distinct, nonproprietary, and free of legal barriers that would restrict its usage. A suffix should not include numbers or symbols, be false or misleading with respect to safety or efficacy of the product, include abbreviations commonly used in clinical practice in a manner that may lead it to be misinterpreted as another element on the prescription or order, contain or suggest a drug substance name or core name, look similar to or have the potential to be mistaken for the name of a currently marketed

product, connote the name of the license holder, or be too similar to another FDA-designated suffix.

Using the above criteria, BPL's first proposed suffix, *-kjda*, is considered acceptable.

This finding was shared with CDER/DMEPA and members of the review committee. There were no identified concerns that would render the suffix unacceptable.

Recommendation

BPL's first proposed suffix, *-kjda*, was reviewed and found acceptable. Thus, we offer the following letter-ready language to convey to the applicant:

We find the proper name, human albumin solution-kjda, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, human albumin solution-kjda, will be the proper name designated in the license, and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your proposed proper name unacceptable upon our re-evaluation at that time, we will inform you of our finding.