Memorandum

Date: March 16, 2018

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

APPROVED
By Lisa Stockbridge at 2:43 pm, Mar 19, 2018

To: Candice Jarvis, RPM, OMPT/CBER/OTAT/DRPM, RPMBII
Zuben Sauna, Committee Chair, OMPT/CBER/OTAT/ DPPT/HB

Subject: PROPER NAME SUFFIX RECOMMENDATION
STN 125661
Sponsor: Bayer Healthcare Pharmaceuticals, Inc.

Background

On August 30, 2017, Bayer Healthcare Pharmaceuticals, Inc. (Bayer), submitted a biologics license application (STN 125661) for their antihemophilic factor (recombinant), PEGylated. The proposed indication is for on-demand treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes, in children and adults with hemophilia A. The product will be supplied in (b) (4) 500, 1000, 2000, and 3000 IU powder for reconstitution for intravenous injection. The care environment is likely to be home, doctor's office, clinic, hemophilia treatment center, or hospital.

With the submission, Bayer included ten proposed proper name suffixes for review, listed in order of preference: -aucl, -auce, -aucb, -aucp, -sspg,-ehlp, -behl, -ayte, -bwpg, and -byhe. They also included an analysis report, conducted on the suffixes by the Drug Safety Institute.

Assessment of the proper name with suffix

The proposed suffixes were 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, Bayer's first proposed suffix, -aucl, is considered acceptable.

This finding was shared with CDER/DMEPA and with Dr. Tejashri Purohit-Sheth (OTAT). There were no identified concerns that would render the suffix unacceptable.

Recommendation

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

> *We find the proper name, antihemophilic factor (recombinant), PEGylated-aucl, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, antihemophilic factor (recombinant), PEGylated-aucl, 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.*