



Memorandum

Date: April 04, 2018

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Through: Lisa L. Stockbridge, Ph.D.
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To: Jean Gildner, RPM, OMPT/CBER/OTAT/DRPM, RPMBII
Mikhail Ovanesov, Committee Chair, OMPT/CBER/OTAT/ DPPT/HB

Subject: PROPER NAME SUFFIX RECOMMENDATION
STN 125586/0
Sponsor: Portola Pharmaceuticals, Inc.

Background

On December 18, 2015, Portola Pharmaceuticals submitted a biologics license application (STN 12586) for ANDEXXA (coagulation factor Xa, inactivated) under the accelerated approval pathway. On August 17, 2016, Portola received a complete response letter for their application. On August 04, 2017, Portola resubmitted their application for review.

The proposed indication is reversal of anticoagulation for patients treated with indirect factor Xa inhibitors, rivaroxaban and apixaban, in situations such as, life-threatening or uncontrolled bleeding. The product will be available as a reconstitutable powder for intravenous injection. It will be supplied as 100mg of reconstitutable powder per vial. The intended care environment is for use in hospital and inpatient emergency rooms as a one-time intravenous bolus followed by an infusion.

On March 30, 2018 (CBER Receipt Date: April 2, 2018), Portola provided eight proposed proper name suffixes for review, listed in their order of preference: -andx, -anex, -annx, -anxx, -anxa, -axxn, -adxx, -pxxa.

Assessment of the proper name with suffix

The proposed suffixes were evaluated using the criteria set forth 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, Portola's proposed proper name suffixes are not devoid of meaning and are all unacceptable for the following reasons:

- Connoting the product's proprietary name, ANDEXXA (e.g., *andx, anex, annx, anxx, anxa, axxn, adxx*)
- Connoting the product's drug substance (factor Xa) or core name (e.g., *andx, anex, annx, anxx, anxa, axxn, adxx*)
- Directly referencing Portola and their product (e.g., *pxxa*)

Recommendation

Portola's proposed proper name suffixes were reviewed and were all found unacceptable. Thus, we offer the following letter-ready language to convey to the applicant:

*FDA has determined that each of your proposed proper name suffixes are not devoid of meaning because each suffix either connotes the proprietary name, ANDEXXA, for this product (e.g., *andx, anex, annx, anxx, anxa, axxn, adxx*), connotes the product's drug substance, factor Xa, (e.g., *andx, anex, annx, anxx, anxa, axxn, adxx*), or directly references Portola and your product (e.g., *pxxa*). Thus, these proposed suffixes are each inconsistent with the principles described in our final guidance and unacceptable for inclusion in the proper name of this proposed product.*

Because the proposed suffixes were found unacceptable, and given the time constraints, we recommend that you use one of FDA's randomly-generated, pre-screened suffixes for inclusion in the proper name of your product.

Please choose one of the following FDA-generated suffixes: zhzo, sjbg, knkq