March 10, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Request for Therapeutic Equivalence Ratings
Submission Type: Citizen Petition

Dear Sir/Madam:

The following Citizen Petition is being submitted by B. Braun Medical Inc. (B. Braun) under 21 CFR l0.25(a) and 21 CFR 10.30.

A. Action Requested

The petitioner (B. Braun Medical Inc.) requests that the FDA add therapeutic equivalence ratings for various B. Braun drug products in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book). Currently, the products do not have any TE code listed in the Orange Book. B. Braun requests that the FDA add the code "AP" for all the products listed in Appendix 1.

B. Statement of Grounds

As stated in the preface of the Orange Book[1], section 1.10, Change of the Therapeutic Equivalence Evaluation for a Single Product:

> We recognize that certain drug products approved in 505(b)(2) applications may not have therapeutic equivalence codes, and that FDA may undertake therapeutic equivalence evaluations with respect to such drug products. A person seeking to have a therapeutic equivalence rating for a drug product approved in a 505(b)(2) application may petition the Agency through the citizen petition procedure (see 21 CFR 10.25(a) and 21 CFR 10.30).

Therefore, a Citizen Petition is the correct pathway to request that the FDA add therapeutic equivalence ratings for our products listed in Appendix 1.

[1] FDA. CDER. *Approved Drug Products with Therapeutic Equivalence Evaluations*. 40th edition. 31 Dec 2019.

All of the products listed in Appendix 1 are considered NDA 505(b)(2) products. At the time of the original submissions, the products relied upon literature or reference listed drugs (RLDs) to support their approval. None of the products were submitted as New Molecular Entities. The exact regulatory pathways for each application are described in the Appendix 1 notations.

As stated in the preface of the Orange Book1, section 1.7, Therapeutic Equivalence Evaluations Codes:

> **A Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which:**
>
> (1) there are no known or suspected bioequivalence problems. These are designated **AA**, **AN**, **AO**, **AP**, or **AT**, depending on the dosage form; ...
>
> **AP Injectable aqueous solutions and, in certain instances, intravenous non-aqueous solutions**

The products listed in Appendix 1 are all powder for solution (or solution) injectable products for which there are no known or suspected bioequivalence problems; therefore, we believe "AP" TE codes should be added to the Orange Book.

Accordingly, the petitioner requests that the FDA add "AP" therapeutic equivalence ratings for the listed B. Braun drug products in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book).

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 CFR 25.31.

D. Economic Impact

In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. B. Braun hereby commits to promptly provide this information, if so requested.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Sincerely,

Cindy.Katsempris@bbraunusa.com
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