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June 24, 2019

VIA ELECTRONIC SUBMISSION

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

CITIZEN PETITION

This Citizen's Petition is being submitted under the authority of 21 CFR § 10.30, 21 CFR §314.93, and Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the "FD& C Act"). The Petitioner is requesting that the Food and Drug Administration permit the filing of an Abbreviated New Drug Application ("ANDA") for a proposed drug product that has the same active ingredient, is of the same strength, and is expected to have the same therapeutic effect as that of a reference product in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, but differs in dosage form.

I. Action Requested

By this petition, the Commissioner of the Food and Drug Administration is being requested to declare that:

(1) Rivaroxaban Capsules, 2.5 mg, 10 mg, 15 mg, 20 mg are suitable for submission as an Abbreviated New Drug Application (ANDA), pursuant to 21 CFR §314.94; and

(2) The reference product on which the contents of this petition are based is XARELTO (rivaroxaban) Tablets 2.5 mg, 10 mg, 15 mg and 20 mg.

II. Statement of Grounds

Section 505(j)(2)(C) of the FDCA allows for the submission of an ANDA for a proposed new drug product that differs in dosage form from that of the Reference Listed Drug on which it is based, provided that the Commissioner of Food and Drugs has approved a petition, filed by or on behalf of the applicant, requesting a declaration that an application to market a drug product with such change is suitable for an ANDA submission.

The Commissioner of Food and Drugs has previously approved ANDA suitability petitions of this nature, in particular, those in which the petitioners have sought to change the dosage form in order to make an alternate dosage form available for those who have difficulty swallowing tablets or simply prefer the alternative. In support of this petition, the following information is being provided:

(1) The proposed drug product is a capsule with the same active ingredient, the same strength, and the same route of administration as that of the reference product, XARELTO (Rivaroxaban Tablets) available as 2.5 mg, 10 mg, 15 mg and 20 mg Tablets.

A copy of the most recent Orange Book listing of "Approved Drug Products with Therapeutic Equivalence Evaluations" is provided as Attachment 1.

(2) The proposed drug product will be labeled with the same conditions of use as the reference product, and is expected to have the same therapeutic effect when used as indicated in the labeling. Labeling for the proposed drug product and the reference product will differ with respect to the manufacturer identification, contact information, and the inactive ingredients.

A draft of the proposed drug product labeling is provided as Attachment 2.

A copy of the current reference product labeling also is provided as Attachment 3.

(3) All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Please note FDA has waived the pediatric study requirement for the reference product XARELTO (Rivaroxaban Tablets), since there are too few children with disease/condition to study, so pediatric studies are impossible or highly impracticable and hence the petitioner is also seeking waiver for pediatric studies.

A copy of the approval letter is provided as Attachment 4.

Conclusion

For the above stated reasons, this Citizen Petition should be granted.

III. Environmental Impact

Petitioner believes that this petition does not require an environmental impact analysis report under 21 C.F.R. § 25.1(g).

IV. Economic Impact

An economic impact report is required only when requested by the Administration and such report has not been requested under 21 C.F.R. § 10.30(b).

V. Certification

Petitioner certifies that, to the best of its knowledge and belief, this Petition includes all of the information and views on which the Petition relies and that it includes representative data and information known to the Petitioner which are unfavorable to the Petitioner.

Respectfully Submitted,

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