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

CITIZEN PETITION

The undersigned submits this petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FDC Act) and 21 C.F.R. § 314.93, § 10.20, and § 10.30 to request permission from the Commissioner of Food and Drugs to submit an abbreviated new drug application (ANDA) for a proposed drug product that differs from the reference listed drug in dosage form.

A. Action Requested

We request that the Food and Drug Administration (FDA) permit an ANDA to be filed for betamethasone valerate foam (non-aerosol), 0.12%.

2006P-0438

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B. Statement of Grounds

1. ANDA Suitability

The reference listed drug for this petition is Luxiq®, betamethasone foam (aerosol), 0.12%. This petition requests permission to submit an ANDA for a generic version of that product that differs from Luxiq in dosage form, namely, a change from Luxiq's hydrocarbon propellant pressurized aerosol foam to a non-propellant foam produced by a mechanical pump.

The proposed drug product is a different dosage form of the reference listed drug. Under section 505(j)(2)(C) of the FDC Act and 21 C.F.R. § 314.93(b), an ANDA suitability petition may be submitted for a change in dosage form.[1]

The current FDA-approved labeling for Luxiq (obtained from www.luxiq.com on October 25, 2006) is Enclosure A.[2] A list of the proposed labeling changes for the proposed drug product, based on the labeling of the reference listed drug Luxiq, is Enclosure B.

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[1] At this time, FDA's Uniform Terms for dosage forms in Appendix C of the Orange Book only includes "aerosol, foam"; there is no defined term for non-aerosol foam. We request that FDA establish, at the appropriate time, a uniform term for the proposed dosage form, such as "foam." This would be consistent with existing practice, which includes the Uniform Terms "aerosol" and "aerosol, metered" and their non-aerosol counterparts "spray" and "spray, metered."

[2] FDA's website indicates that revised labeling for Luxiq was approved on July 11, 2006. That labeling is not available either on FDA's website or on www.luxiq.com. Based on FDA's approval letter, the labeling approved on July 11, 2006 only provides for format changes to be consistent across the sponsor's product line. It does not appear that any substantive labeling changes were approved.

The active ingredient of the proposed drug product is of the same pharmacological or therapeutic class as that of the reference listed drug, in that it is the same active ingredient. *See* 21 C.F.R. § 314.93(d)(1).

The proposed drug product is expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the reference listed drug's labeling for which an ANDA will be submitted, in that the proposed drug product will contain the same active ingredient at the same concentration, administered under the same conditions of use as the reference listed drug. *See* 21 C.F.R. § 314.93(d)(2). The proposed product will be shown to be bioequivalent to the reference product in accordance with FDA's usual criteria.

Investigations should not be necessary to show the safety and effectiveness of the proposed product, as the product only differs in dosage form from the currently approved product. *See* 21 C.F.R. § 314.93(e)(1)(i).

In petitioner's view, this ANDA suitability petition does not present any new or novel issues.

2. Request For Waiver Under Pediatric Research Equity Act

Under the Pediatric Research Equity Act, any person that submits an NDA or ANDA for, in relevant part, a new dosage form is required to conduct pediatric studies. 21 U.S.C. § 355c(a)(1)(A). However, FDA can grant a full waiver of this requirement if the applicant certifies, and FDA finds, that, in relevant part:

> (iii) the drug … product—
>
> (I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

21 U.S.C. § 355c(a)(4)(A)(iii).

FDA should grant a full waiver under this provision because both criteria have been satisfied. With regard to the first criterion, assuming this petition is approved, any proposed drug product that is the subject of an ANDA submitted pursuant to the approved petition would have the same conditions of use as Luxiq. Thus, the proposed drug product would not "represent a meaningful therapeutic benefit over existing therapies for pediatric patients."[3] With regard to the second criterion, in approving NDA 20-934 for Luxiq, FDA concluded that pediatric studies are not needed, specifically because "[d]iagnosis is rare in pediatric patients." Enclosure C (Pediatric Page for Luxiq, obtained from www.fda.gov/cder). Thus, like Luxiq, the proposed product "is not likely to be used in a substantial number of pediatric patients."

C. Environmental Impact

This petition is eligible for a categorical exclusion under 21 C.F.R. § 25.31(a) because approval of this petition will not increase the use of the active moiety. The proposed drug product will not be administered at higher dosage levels, for longer duration, or for different indications than the reference listed drug.

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[3] The "new" dosage form would not by itself provide any therapeutic benefit to pediatric patients. From a clinical perspective, the resulting drug product is foam, regardless of whether the foam is produced by an aerosol propellant or by a mechanical pump.

D. Economic Impact

Information on economic impact will be submitted upon request.

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 are unfavorable to the petition.

Respectfully submitted,

Arthur Y. Tsien

AYT:cr
Enclosures

A – Luxiq labeling
B – Labeling changes for proposed product, based on Luxiq labeling
C – Pediatric Page for Luxiq