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*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEEDINGS BEFORE FEDERAL COURTS AND AGENCIES.

February 9, 2006

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 strength.

A. Action Requested

We request that the Food and Drug Administration (FDA) permit an ANDA to be filed for prednisolone sodium phosphate, USP, oral solution, 10mg prednisolone base/5mL.

B. Statement of Grounds

The reference listed drug for this petition is Pediapred, prednisolone sodium phosphate, USP, oral solution, 5mg prednisolone base/5mL. This petition requests permission to submit an ANDA for a generic version of that product at a strength of 10mg prednisolone base/5mL.

2006P-0072

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The proposed drug product is a different strength 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 strength.

Pediapred is approved for use for, in relevant part, the following indications and conditions of use: allergic states, dermatologic diseases, edematous states, endocrine disorders, gastrointestinal diseases, hematologic disorders, neoplastic diseases, nervous system disorders, ophthalmic diseases, respiratory diseases, and miscellaneous uses. According to Pediapred's labeling, the approved initial dose of prednisolone sodium phosphate, USP, oral solution, "may vary from 5mL to 60mL (5mg to 60mg prednisolone base) per day depending on the specific disease entity being treated." In addition to Pediapred, FDA has approved Orapred (prednisolone sodium phosphate, USP, oral solution) at a strength of 15mg prednisolone base/5mL. As the proposed 10mg/5mL strength would be between the currently available 15mg/5mL and 5mg/5mL strengths, the proposed 10mg/5mL strength would provide greater flexibility in dosing and administration. In many cases, it may allow fewer dosage calculations to be performed (*e.g.*, dose of 10mg/5mL).

The current FDA-approved labeling for Pediapred (obtained from www.fda.gov/cder/ on February 9, 2006) is Enclosure A. A list of the proposed labeling changes for the proposed drug product, based on the labeling of the reference listed drug Pediapred, is Enclosure B.

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 conditions 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. If appropriate, the sponsor of the proposed product will seek a waiver of a demonstration of in vivo bioequivalence under 21 C.F.R. § 320.22(b)(3).

Investigations should not be necessary to show the safety and effectiveness of the proposed product, as the product only differs in strength from currently approved products that are, respectively, at lower and greater strengths. *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. In fact, the reference listed drug Orapred is itself the subject of an ANDA that was approved pursuant to an approved ANDA suitability petition for a different strength of Pediapred. *See* Exhibit C (December 14, 2000 approval letter for Orapred; citizen petition (Docket No. 87P-0235); November 4, 1987 letter approving citizen petition).

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.

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 – Pediapred labeling
B – Labeling changes for proposed product, based on Pediapred labeling
C – Approval letter for Orapred, related ANDA suitability petition, and approval letter for petition