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November 30, 2006

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Via First Class Mail

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

Re: Docket No. 2006P-0369: Amendment / ANDA Suitability Petition for Alclometasone Dipropionate Lotion, 0.05%

Dear Sir or Madam:

The undersigned submits this Amendment on behalf of an unnamed client, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and in accordance with 21 CFR §§ 10.30 and 314.93. We seek to amend a previously filed ANDA Suitability Petition for Alclometasone Dipropionate Lotion, 0.05% to include a request for a waiver from the pediatric assessment requirements of the Pediatric Research Equity Act ("PREA").

Originally filed on September 1, 2006, the aforementioned Petition (Docket No. 2006P-0369) requested that FDA make a determination that a new dosage form of a topical alclometasone dipropionate drug product, Alclometasone Dipropionate Lotion 0.05%, is suitable for submission as an ANDA where the reference listed drug (RLD) is an alclometasone dipropionate 0.05% cream formulation. A copy of the filed ANDA Suitability Petition is attached to this Amendment as **Exhibit 1**.

A. Actions Requested

The Petitioner seeks to amend the previously filed Petition and requests a waiver from the applicable pediatric assessment requirements of the PREA. Under the PREA, all applications (or supplements to an application) filed under Section 505 of the Federal Food, Drug, and Cosmetic Act for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration, are required to contain information assessing the safety and efficacy of the proposed product for pediatric use. 21 U.S.C. § 355c(a)(1)(A). The required pediatric assessment must include information pertaining to the safety and effectiveness of the drug product for the claimed indications, and supporting the dosing and administration of each pediatric age group for which the proposed drug is intended. 21 U.S.C. § 355c(a)(2). There are a number of limited exceptions to the pediatric assessment requirements. The PREA gives FDA

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AMD 1



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the authority to grant a full waiver from these requirements where the applicant certifies, and the 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).

B. Discussion

Our client's proposed product satisfies the established criteria for a full waiver under the PREA. First, assuming our client's proposed ANDA for Alclometasone Dipropionate Lotion 0.05% is approved, the proposed product will have the same conditions of use as the RLD, Aclovate[®] (alclometasone dipropionate cream) Cream 0.05%. Therefore, as a generic drug, our client's product will not "represent a meaningful therapeutic benefit over existing therapies for pediatric patients." Second, considering the finite number of pediatric patients that use Aclovate[®] Cream 0.05% to treat the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, the proposed Alclometasone Dipropionate Lotion, 0.05% is not likely to be used in a substantial number of pediatric patients.

C. Certification

The undersigned certifies that, to the best of our knowledge and belief, this Amendment includes all information and views upon which the Amendment and related Petition rely, and that it includes representative data and information known to the Petitioner which are unfavorable to the Amendment and related Petition.

Sincerely,

Gary L. Yingling

GLY: