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September 1, 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: ANDA Suitability Petition for Alclometasone Dipropionate Lotion, 0.05%

Dear Sir or Madam:

The undersigned submits this petition 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, requesting that the Commissioner of the Food and Drug Administration (FDA) make a determination that a new dosage form of a topical alclometasone dipropionate drug product, Alclometasone Dipropionate Lotion 0.05%, is suitable for filing under an abbreviated new drug application (ANDA).

A. Actions Requested

Petitioner requests 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) product is an alclometasone dipropionate 0.05% cream formulation. The RLD upon which this petition is based is Aclovate® (alclometasone dipropionate cream) Cream 0.05% (GlaxoSmithKline Consumer Healthcare LP, NDA 18-707). A copy of the *Approved Drug Products with Therapeutic Equivalence Evaluation* ("Orange Book") 26th edition listing for Aclovate® (alclometasone dipropionate) Cream 0.05% is provided as **Attachment 1**.

B. Statement of Grounds: Change in Dosage Form

The RLD product that is the basis of this petition is a cream formulation [Aclovate® (alclometasone dipropionate cream) Cream 0.05%; GlaxoSmithKline, NDA 18-707] containing the same concentration of active drug substance as the proposed new dosage form, Alclometasone Dipropionate Lotion 0.05%. In the Petitioner's opinion and to the best of Petitioner's knowledge, there are no applicable U.S. patents with respect to the drug substance, alclometasone dipropionate, and the drug product, Aclovate® (alclometasone dipropionate cream) Cream 0.05%, or which claim a use for the drug substance or drug product referenced to in this Petition.

Petitioner is proposing a lotion form of the RLD as it is believed that a lotion formulation of this topical corticosteroid drug product would benefit the health care community. A lotion form of the RLD would provide a pharmaceutically elegant and cosmetically acceptable dosage form to the medical professional



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and patient. Lotion dosage forms are often preferred over cream formulations due to their spreadability and ease of application, allowing for improved patient compliance.

The proposed drug product Alclometasone Dipropionate Lotion 0.05% differs from the RLD product only in regard to dosage form. The two products are identical with respect to active ingredient, potency (0.05% alclometasone dipropionate), route of administration (topical) and proposed conditions of use (corticosteroid). A one-period, randomized study was conducted to compare the relative potency of the proposed Alclometasone Dipropionate Lotion, 0.05% formulation with that of already approved formulations of alclometasone dipropionate cream and ointment, 0.05% (Aclovate[®] (alclometasone dipropionate cream) Cream 0.05%, GlaxoSmithKline), a placebo lotion, and four other comparator topical corticosteroids of known potency, in asymptomatic subjects. The study found that the proposed Alclometasone Dipropionate Lotion, 0.05% is a low potency steroid formulation relative to the included comparators. Additionally, the study showed there to be no statistically significant difference between the test product and the RLD product, Aclovate[®] (alclometasone dipropionate cream) Cream 0.05%. A copy of the Clinical Study Report is provided as **Attachment 2**.

Although a lotion dosage form of alclometasone dipropionate is not currently available, other topical corticosteroids are available in lotion formulations as follows:

Product	Sponsor	NDA No.
Clobex [®] (clobetasol propionate) Topical Lotion, 0.05%	DPT Laboratories, Ltd.	21-535
Diprolene [®] (brand of augmented betamethasone dipropionate) Lotion, 0.05%	Schering Corporation, Ltd.	19-716
Elocon [®] (brand of mometasone furoate) Lotion, 0.1%	Schering Corporation, Ltd.	19-796
Hydrocortisone Lotion USP, 1%	E. Fougera & Co.	N/A

The container, carton and package insert labeling for the proposed Alclometasone Dipropionate Lotion 0.05% product will be the same as the RLD labeling for Aclovate[®] (alclometasone dipropionate cream) Cream 0.05% with the exception of the product name, ingredient listing and How Supplied section. The finished product will be packaged in an appropriate container/closure system for a lotion drug product. An annotated comparison of the proposed package insert labeling changes for Alclometasone Dipropionate Lotion 0.05%, as compared to the RLD, Aclovate[®] (alclometasone dipropionate cream) Cream 0.05%, is listed below in Table 1.0. The FDA-approved labeling for Aclovate[®] (alclometasone



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dipropionate cream) Cream 0.05% is provided as **Attachment 3**. The proposed labeling for Alclometasone Dipropionate Lotion 0.05% is provided as **Attachment 4**.

Labeling Comparison for RLD and Proposed Alclometasone Dipropionate Lotion 0.05%

Table 13.0

Aclovene® (alclometasone dipropionate cream) Cream 0.05%	Alclometasone Dipropionate Lotion 0.05%	Differences
Product Name	Product Name	Change in dosage form
DESCRIPTION ALCLOVATE Cream and Ointment contain alclometasone dipropionate ... Each gram of ALCLOVATE Cream contains 0.5 mg of alclometasone dipropionate in a hydrophilic, emollient cream base of propylene glycol, white petrolatum, cetearyl alcohol, glyceryl stearate, PEG 100 stearate, Ceteth-20, monobasic sodium phosphate, chlorocresol, phosphoric acid, and purified water.	DESCRIPTION Alclometasone dipropionate lotion 0.05% contains alclometasone dipropionate ... Each ml contains 0.5 mg of alclometasone dipropionate in a lotion consisting of stearyl alcohol, cetyl alcohol, glyceryl monostearate, sorbitan monopalmitate, mineral oil, purified water, monobasic sodium phosphate, phosphoric acid, polysorbate 20, simethicone and propylene glycol.	Inactive ingredients list has been revised for the lotion vehicle formulation.
HOW SUPPLIED ACLOVATE Cream, 0.05% is supplied in: 15-g tubes (NDC 0173-0401-00), 45-g tubes (NDC 0173-0401-01), and 60-g tubes (NDC 0173-0401-06).	HOW SUPPLIED Alclometasone Dipropionate Lotion, 0.05% is supplied in 2oz and 4oz bottles.	Lotion formulation is supplied in appropriate container / closure presentation.



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C. Environmental Impact

A categorical exclusion is claimed as the granting of this Petition will result in an ANDA for a drug product that is consistent with the parameters for exclusion established under 21 CFR §25.31(a).

D. Economic Impact

Information under this section will be submitted if requested by the Commissioner following review of this petition.

E. Certification

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

All regulatory correspondence related to this Petition should be addressed to the following individual:

Sincerely,

A handwritten signature in black ink, appearing to read 'Gary L. Yingling'. The signature is fluid and cursive, with a large loop at the end.

Gary L. Yingling

GLY:
Attachments