FERNDALE LABORATORIES INC
ETHICAL PHARMACEUTICALS SINCE 1897 ™

August 10, 2001

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

Re: ANDA Suitability Petition for Hydrocortisone Acetate Lotion USP, 2.5%

Dear Sir or Madam:

The undersigned respectfully submits this citizen petition pursuant to 21 U.S.C. § 355(j)(2)(C) and 21 CFR §§10.30 and 314.93, to request that the Commissioner of Food and Drugs make a determination of ANDA suitability for a 2.5% topical preparation of a dermatological drug product, Hydrocortisone Acetate Lotion USP, where the reference listed drug is a 0.5% lotion. The proposed 2.5% strength would give physicians greater flexibility in prescribing than is available in the current dosage form, cream. The health care community would benefit from the alternative choice provided by the availability of a 2.5% topical lotion, which is pharmaceutically elegant, and cosmetically acceptable to the end-user. The higher water content of lotions promotes drying of the skin through evaporation. This makes lotions useful for treating weeping or blistered lesions where additional hydration is not desired. In addition, lotions are more easily applied to hair-covered skin.

Action Requested

Petitioner requests that the Commissioner of Food and Drugs make a determination that an abbreviated new drug application (ANDA) is suitable for a topical solution containing 2.5% hydrocortisone acetate.

01P-0355

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780 West Eight Mile Road • Ferndale, Michigan 48220 • 248.548.0900 • 800.621.6003

Statement Of Grounds

The Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch - Waxman Act") extends eligibility for the submission of ANDAs to certain drug products identical to those approved via new drug applications, as identified in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") issued by the Food and Drug Administration. Where the proposed drug product differs from the "reference listed drug" in one or more respects, a person may petition the Agency, under section 505(j)(2)(c) of the Act, for a determination of ANDA suitability as a similar or related drug product.

The reference listed drug product, which forms the basis for this petition, is a topical lotion containing 0.5% of the active pharmaceutical ingredient, hydrocortisone acetate (Dricort® Lotion 2.5% – A/NDA 86-207 – application held by Ingram Pharma. Exhibit A contains page 3-189 from the 21st edition of the "Orange Book", showing the Reference Listed Drug designation as determined by the FDA.

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, hydrocortisone acetate, and the drug product, Dricort®, have expired or which claim a use for the drug substance or drug product referenced to in this petition.

The proposed drug product, Hydrocortisone Acetate Lotion USP, 2.5%, differs from the reference listed drug product, Dricort® Lotion 0.5%, only in regard to strength (2.5% vs 0.5%). It is identical with respect to active ingredient, dosage form, route of administration and conditions of use.

Other approved topical dosage forms and strengths of hydrocortisone acetate are available. These include:

Product	**Strength**	**Dosage Form**	**ANDA No**
Hydrocortisone Acetate Cream	2.5%	Topical Cream	40-259
Micort-HC	2.5%	Topical Cream	40-396

For hydrocortisone acetate products, the relevant pages from the 21st edition of the *Orange Book* ADA-3-189 and 3-190 and page 1-18 from the Cumulative Supplement 4 are enclosed as Exhibit B.

In addition to those approved hydrocortisone acetate products, numerous dosage forms and strengths of hydrocortisone are available. These include:

Product	**Strength**	**Dosage Form**	**A/NDA No**
Hytone	1%	Topical Lotion	80-473
Hytone	2.5%	Topical Lotion	80-473
Hytone	1%	Topical Cream	80-472
Hytone	2.5%	Topical Cream	80-472
Cortril	1%	Topical Ointment	09-176
Cortril	2.5%	Topical Ointment	09-176

For hydrocortisone products, the relevant pages from the 21st edition of the *Orange Book* ADA-3-187 and 3-188 and page 1-18 from the Cumulative Supplement 4 are enclosed as Exhibit C.

Hydrocortisone and hydrocortisone acetate are generally regarded as equipotent and have been used interchangeably for many years. In the tentative final monograph for "External Analgesic Drug Product for Over-the-Counter Human Use", published in the Federal Register, February 8, 1983; hydrocortisone and hydrocortisone acetate were grouped together as *hydrocortisone preparations.* Moreover, in the preamble to the proposed rules for "External Analgesic Drug Product for Over-the-Counter Human Use," published in the Federal Register, December 4, 1979 states "...that FDA recognizes that topical hydrocortisone in concentrations of 0.5 to 2.0 percent is safe and effective for steroid-responsive dermatoses when the drug is used as directed as a prescription drug."

The health care community would benefit from the alternative choice provided by the availability of a hydrocortisone acetate 2.5% topical lotion, which is pharmaceutically

elegant, and cosmetically acceptable to the end-user. The higher water content of lotions promotes drying of the skin through evaporation. This makes lotions useful for treating weeping or blistered lesions where additional hydration is not desired. In addition, lotions are more easily applied to hair-covered skin.

The proposed drug product contains the same active ingredient, in the same dosage form and route of administration as the reference listed drug, Dricort® Lotion 0.5%. Draft labeling (insert) for the proposed drug product, which is modeled after the Class Labeling for Topical Corticosteroids, is enclosed. (See Appendix D.) Requests have been made to obtain copies of the labeling for the reference listed drug through both the Office of Labeling Support and the Freedom of Information office in early 2001. However, to date, copies of the labeling have not been provided. The Petitioner would expect any labeling received for Dricort® Lotion 0.5%, if received, would not be different from the proposed labeling.

The finished product will be packaged in a container/closure system that is appropriate for and compatible with the dosage form.

Based on the above, Petitioner believes that Hydrocortisone Acetate Lotion USP, 2.5% warrants a finding of ANDA suitability, and that the Commissioner should grant permission for the filing of an ANDA for Hydrocortisone Acetate Lotion USP, 2.5%.

Environmental Impact

Petitioner hereby claims a categorical exclusion from the requirement of an Environmental Assessment (EA) statement. The approval of this petition will result in an abbreviated new drug application (ANDA) for a drug product that will be excluded from the requirement of an Environmental Assessment statement, pursuant to 21 CFR §25.31(a).

Economic Impact

In accordance with 21 CFR §10.30(b), information on economic impact will be submitted only when requested by the Commissioner following review of this petition.

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,

Deborah L. Theres
Manager, Regulatory Affairs
Ferndale Laboratories, Inc.

Enclosures:

Exhibit A	Approved Drug Products with Therapeutic Equivalence Evaluations, 21st edition, p. 3-189
Exhibit B	Approved Drug Products with Therapeutic Equivalence Evaluations, 21st edition, pp. 3-189 and 3-190 Cumulative Supplement 4, p. 1-18
Exhibit C	Approved Drug Products with Therapeutic Equivalence Evaluations, 21st edition, pp. 3-187 and 3-188 Cumulative Supplement 4, p. 1-18
Exhibit D	Draft labeling for the proposed drug product