FERNDALE LABORATORIES INC
ETHICAL PHARMACEUTICALS SINCE 1897 TM

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June 28, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: ANDA Suitability Petition for Lidocaine Cream 5%

Dear Sir or Madam:

The undersigned submits this petition pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and 21 CFR §314.93, §10.25(a) and §10.30 of the Food and Drug Administration's regulations, to request the Commissioner of Food and Drugs to make a determination of ANDA suitability for a topical anesthetic drug product. The health care community would benefit from having an alternate choice via the availability of a topical cream which is pharmaceutically more elegant, and has greater cosmetic acceptability to the end-user than the ointment dosage form.

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 cream containing 5% lidocaine.

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 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.

01P-0291

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The reference listed drug product, which forms the basis for this petition, is a topical ointment containing 5% lidocaine (Xylocaine® 5% Ointment – NDA 08-048 – manufactured by AstraZeneca). Exhibit A contains page 3-216 from the 20th edition of the "Orange Book".

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, lidocaine, and the drug product, Xylocaine® 5% Ointment or which claim a use for the drug substance or drug product referenced to in this petition.

- The proposed drug product, Lidocaine Cream 5%, differs from the reference listed drug product, Xylocaine® 5% Ointment, in regard to the dosage form (a cream instead of an ointment). It is identical with respect to active ingredient and strength. Ferndale Laboratories, Inc. proposes only topical administration rather than topical and oral as in the innovator drug. Ferndale Laboratories, Inc. formulation is not flavored, as is one of the innovator's formulations. Labeling (package insert) for the reference listed drug is included in Exhibit C.

Other approved topical dosage forms of lidocaine are available (see Exhibit A). These include:

Product	**Strength**	**Dosage Form**	**A/NDA No.**
Alphacaine® (Carlisle)	5%	Topical Ointment	84-947
Lidocaine (Fougera)	5%	Topical Ointment	80-198
Lidocaine (Graham Chem)	5%	Topical Ointment	80-210
Lidocaine (Thames)	5%	Topical Ointment	86-724
Xylocaine® (AstraZeneca)	5%	Topical Solution	14-127
Xylocaine® (AstraZeneca)	10%	Oral Aerosol	14-394

Lidocaine (Noven)	23 mg/patch 46.1 mg/patch	Buccal Film, Extended Release	20-575
Lidoderm® (Teikoku Pharma)	700 mg/12 hours	Topical Film, Extended Release	20-612

If this petition is approved, Petitioner intends to request a waiver of bioequivalence based on the DESI status of lidocaine, as part of the ANDA submission.

The health care community would benefit from having an alternate choice via the availability of a topical cream which is pharmaceutically more elegant, and has greater cosmetic acceptability to the end-user than the ointment dosage form. The proposed product contains the same active ingredient, at the same strength and route of administration, and would be labeled with the same conditions for use as the reference listed drug, Xylocaine® 5% Ointment.

Draft labeling for Lidocaine Cream 5% is enclosed in Exhibit D and is modeled on the reference listed drug. The finished product will be packaged in an appropriate container/closure system.

Based on the above, Petitioner believes that Lidocaine Cream 5% warrants a finding of ANDA suitability and that the Commissioner should grant permission for the filing of an ANDA for Lidocaine Cream 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 §25.24(c)(1).

Economic impact

Information under this section will be submitted if 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.

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

Enclosures:

Exhibit A	Approved Drug Products with Therapeutic Equivalence Evaluations, 20th edition, p. 3-216.
Exhibit B	Side by Side Insert Comparison
Exhibit C	Labeling for Xylocaine® 5% Ointment (NDA 08-048, manufactured by AstraZeneca).
Exhibit D	Draft labeling (package insert).