14 September 2006

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Clobetasol Propionate Foam, 0.05%

CITIZEN PETITION

Dear Sir or Madam:

The undersigned is submitting this petition in quadruplicate, under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) and in accordance with 21 CFR §10.20, §10.30, and §314.93 to request that the Commissioner of the Food and Drug Administration declare that the drug product Clobetasol Propionate Foam, 0.05%, is suitable for consideration in an Abbreviated New Drug Application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Clobetasol Propionate Foam, 0.05% is suitable for submission in an ANDA.

B. Statement of Grounds

The reference listed drug (RLD), upon which this petition is based, is Olux® (clobetasol propionate) Foam, 0.05%. The petitioner seeks a change in dosage form from that of the RLD. The change would be from a hydrocarbon propellant pressurized aerosol foam to a non-propellant mechanical pump-produced foam.

Under section 505(j)(2)(C) of the Act and 21 CFR §314.93(b), an ANDA suitability petition may be submitted for a change in dosage form.

The Federal Food, Drug, and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage form from that of the RLD provided the FDA has approved a petition that proposed filing such an application.

The reference listed drug, Olux® (clobetasol propionate) Foam, 0.05%, contains clobetasol propionate, USP, a synthetic corticosteroid, for topical dermatologic use. Olux® Foam is the subject of NDA 21-142, which was approved on 26 May 2000. Connetics Corporation, Palo Alto, California is the NDA holder. Each gram of Olux® Foam contains 0.5 mg clobetasol propionate, USP, in a thermolabile foam. Olux® Foam is dispensed from an aluminum can

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pressurized with a hydrocarbon propellant (propane/butane). A copy of the current Orange Book[1] listing for Olux® Foam (updated through July 2006) is provided in Attachment 1.

The proposed drug product is a clobetasol propionate foam for topical dermatologic use that is the same strength (0.05%) as the RLD referred to in this petition, but in a different dosage form as defined in Appendix C, Uniform Terms, Dosage Forms, in the Orange Book[1] and USP General Chapter ⟨1151⟩. There are also differences in some of the inactive ingredients. The proposed dosage form is a non-propellant foam and is designed to facilitate ease of topical application. Thus, the proposed drug product will provide a convenient alternative to the already available dosage forms of clobetasol propionate.

Aerosol foam formulations have achieved commercial success as innovative drug delivery vehicles. Regardless of the therapeutic indication, aerosol foams represent an effective and elegant means for delivering drug substances topically. When comparing foams with conventional dermatological formulations, such as ointments, creams, lotions, solutions, and gels, it becomes apparent that the aerosol foam has advantages.

Considering the evolution of topical drug delivery vehicles, from basic ointment and solution formulations, to technologically advanced cream, gel, and lotion formulations, the aerosol foam formulation is certainly the next step in the evolution of topical drug delivery.

The current Orange Book definition of an aerosol foam is technology limited, i.e., was created based on available technology at the time. It, therefore, restricts or limits improvements based on new technology.

A copy of the approved labeling for the RLD, Olux® Foam, is provided in Attachment 2.

A side-by-side comparison of the approved labeling for the RLD with the proposed drug product draft labeling is provided in Attachment 3. Please note that the draft labeling for the proposed product includes changes to the inactive ingredients, the Dosage and Administration section, and the How Supplied section. The specific differences will be addressed in the ANDA for the proposed drug product. The proposed labeling is otherwise the same as the approved labeling for the RLD with the exception of changes that are necessary because the manufacturer of the proposed drug product differs from that of the RLD, and those changes related to the change in dosage form proposed in this petition, i.e., non-propellant foam. There are no other differences between the conditions of use recommended or suggested in the labeling for the proposed, non-propellant foam and those approved for the RLD. Please be advised that the petitioner, as the ANDA applicant, will demonstrate that the proposed non-propellant foam is bioequivalent to the RLD.

The active ingredient of the proposed drug product is of the same pharmacological or therapeutic class as that of the RLD, in that it is the same active ingredient; see 21 CFR §314.93(d)(1).

The proposed drug product is expected to have the same therapeutic effect as the RLD when administered to patients for each condition of use in the RLD labeling for which an ANDA will be submitted, in that the proposed drug product will contain the same active ingredient at the

same concentration on a weight basis, administered under the same conditions of use as the RLD; see 21 CFR §314.93(d)(2).

The proposed drug product will be shown to be bioequivalent to the reference product in accordance with FDA usual criteria.

Investigations should not be necessary to show the safety and effectiveness of the proposed product, as the product only differs in dosage form from currently approved products; see 21 CFR §314.93(e)(1)(i).

In the petitioner's view, this ANDA suitability petition does not represent any new or novel issues.

Applicability of Pediatric Research Equity Act

The Pediatric Research Equity Act (PREA), which was signed into law on 02 December 2003, requires that applications for approval of a new active ingredient, indication, dosage form, dosing regimen, or route of administration contain a pediatric assessment unless the applicant has obtained a waiver or deferral under Section 505(B)(b) of the Act. If the pediatric assessment requires the conduct of clinical studies, the application will be ineligible for submission as an ANDA.

The petitioner hereby requests that a full waiver of the requirement to conduct pediatric studies be granted in respect to the proposed product that is the subject of this petition. The following information supports the request for a waiver:

1. The RLD labeling includes the statement in the Indications and Usage section "Use in children under 12 years of age is not recommended". This demonstrates that according to the labeling of the RLD, the product is not intended for use in pediatric patients.
2. The petitioner, by way of an ANDA submitted pursuant to this petition, after its approval, will seek approval for the same conditions of use as given in the approved labeling for the RLD. Thus, the proposed product will not represent any meaningful therapeutic benefit over the presently available dosage forms of clobetasol propionate.

Thus, because the requirements for the conduct of pediatric studies were waived for Connectics, Olux® Foam 505(b)(2)[2], there should be no need to conduct additional studies for the proposed product for which this petition is being submitted.

For the reasons cited above, the petitioner requests that the Commissioner find that a change in dosage form from a hydrocarbon propellant pressurized aerosol foam to a non-propellant mechanical pump-produced foam containing clobetasol propionate, 0.05%, raises no questions of safety or effectiveness. The petitioner requests that the Commissioner approve the petition accordingly.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR §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 RLD.

D. Economic Impact

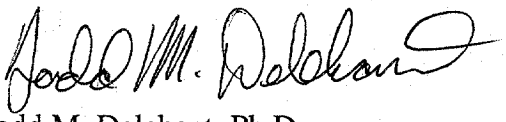
The petitioner believes that analysis of economic impact does not apply to the submission of this petition. The petitioner agrees to provide such an analysis if requested by the Agency.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information 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,

PADDOCK LABORATORIES, INC.



Todd M. Delehant, Ph.D.
Regulatory Affairs Manager

Enclosures

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[1] The listing for Olux® Foam was reviewed in the on line publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) on 11 September 2006 at the following web address: http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm

[2] Olux® (clobetasol propionate) Foam, 0.05% was approved under section 505(b)(2) of the act. Full waiver of the requirement to submit clinical assessments according to subsection 505B(a)(4)(A)(iii)(I) of the Act was requested and granted.