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\*PRACTICE WITHIN THE DISTRICT OF COLUMBIA  
IS LIMITED TO MATTERS AND PROCEEDINGS  
BEFORE FEDERAL COURTS AND AGENCIES.

March 28, 2007

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

**CITIZEN PETITION**

The undersigned submits this petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FDC Act) and 21 C.F.R. § 314.93, § 10.20, and § 10.30 to request permission from the Commissioner of Food and Drugs to submit an abbreviated new drug application (ANDA) for a proposed drug product that differs from the reference listed drug in dosage form.

**A. Action Requested**

We request that the Food and Drug Administration (FDA) permit an ANDA to be filed for clindamycin phosphate foam (non-aerosol), 1%.

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CPI

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## **B. Statement of Grounds**

### **1. ANDA Suitability**

The reference listed drug for this petition is Evoclin®, clindamycin phosphate foam, 1%. This petition requests permission to submit an ANDA for a generic version of that product that differs from Evoclin in dosage form, namely, a change from Evoclin's hydrocarbon propellant pressurized aerosol foam to a non-propellant foam produced by a mechanical pump.

The proposed drug product is a different dosage form of the reference listed drug. Under section 505(j)(2)(C) of the FDC Act and 21 C.F.R. § 314.93(b), an ANDA suitability petition may be submitted for a change in dosage form.<sup>1</sup>

The current FDA-approved labeling for Evoclin (obtained from <http://www.fda.gov/cder/foi/label/2006/050801s006lbl.pdf> on March 28, 2007) is Enclosure A. A list of the proposed labeling changes for the proposed drug product, based on the labeling of the reference listed drug Evoclin, is Enclosure B.

The active ingredient of the proposed drug product is of the same pharmacological or therapeutic class as that of the reference listed drug, in that it is the same active ingredient. *See* 21 C.F.R. § 314.93(d)(1).

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<sup>1</sup> At this time, FDA's Uniform Terms for dosage forms in Appendix C of the Orange Book only includes "aerosol, foam"; there is no defined term for non-aerosol foam. We request that FDA establish, at the appropriate time, a uniform term for the proposed dosage form, such as "foam." This would be consistent with existing practice, which includes the Uniform Terms "aerosol" and "aerosol, metered" and their non-aerosol counterparts "spray" and "spray, metered."

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The proposed drug product is expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the reference listed drug's labeling for which an ANDA will be submitted, in that the proposed drug product will contain the same active ingredient at the same concentration, administered under the same conditions of use as the reference listed drug. *See* 21 C.F.R. § 314.93(d)(2). The proposed product will be shown to be bioequivalent to the reference product in accordance with the appropriate 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 the currently approved product. *See* 21 C.F.R. § 314.93(e)(1)(i).

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

## **2. Request For Waiver Under Pediatric Research Equity Act**

Under the Pediatric Research Equity Act (PREA), any person that submits an NDA or ANDA for, in relevant part, a new dosage form is required to conduct pediatric studies. 21 U.S.C. § 355c(a)(1)(A). However, FDA can grant a waiver of this requirement if the applicant certifies, and FDA finds, that the drug, in relevant part:

- (I) does not represent a meaningful 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)(I)-(II).

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FDA should grant a full waiver under this provision. First, the proposed product is not intended to represent a meaningful benefit over Evoclin, as both are clindamycin phosphate foams for the same conditions of use.<sup>2</sup> Second, the reference listed drug product is not recommended for use in pediatric patients under 12 years of age, as the FDA-approved labeling for Evoclin indicates that “[s]afety and effectiveness of Evoclin in children under the age of 12 have not been established.” *See* Enclosure A.<sup>3</sup> Connetics Corporation (Connetics), the sponsor of NDA 50-801 for Evoclin, conducted studies to address the safety and effectiveness of its product in adolescents. *See* Medical Review for Evoclin at p. 7, available at [http://www.fda.gov/cder/foi/nda/2004/050801s000\\_Evoclin\\_MedR.pdf](http://www.fda.gov/cder/foi/nda/2004/050801s000_Evoclin_MedR.pdf).<sup>4</sup> Therefore, requiring additional pediatric studies would not advance the goals of PREA or any other public health purpose. As a result, a full waiver of the requirement for pediatric studies should be granted.

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<sup>2</sup> The fact that aerosol foam and non-aerosol foam are regarded as different dosage forms for ANDA purposes arguably is an artifact of FDA’s Uniform Terms in Appendix C of the Orange Book. If FDA regarded all “foam” products as a single dosage form regardless of the mechanism used to produce the foam – just as all “patch” products are considered a single dosage form irrespective of their drug release mechanism – this entire petition would be unnecessary.

<sup>3</sup> FDA did not require any studies in children under 12 years of age to support the approval of Evoclin. *See* Evoclin pediatric page, available at [http://www.fda.gov/cder/foi/nda/2004/050801s000\\_Evoclin\\_AdminCorres.pdf](http://www.fda.gov/cder/foi/nda/2004/050801s000_Evoclin_AdminCorres.pdf).

<sup>4</sup> We note that the NDA is referred to as 50-801 and as 21-709. The NDA evidently was renumbered by FDA on or before November 9, 2004. *See* [http://www.fda.gov/cder/foi/appletter/2004/21709to50801\\_Num\\_Change\\_ltr.pdf](http://www.fda.gov/cder/foi/appletter/2004/21709to50801_Num_Change_ltr.pdf).

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The situation presented by this ANDA suitability petition is, in relevant part, indistinguishable from the agency's July 5, 2005 decision to grant a full waiver of the requirement for pediatric studies in connection with an ANDA suitability petition for a change in dosage form, from chewable tablets to orally-dissolving strips, based on the reference listed drug Pepsid AC® (famotidine) chewable tablets, 10 mg. There, as here, the reference listed drug was not recommended for use in patients younger than 12 years of age. Merck, the sponsor of the NDA for Pepsid AC chewable tablets, had conducted pediatric studies to address the safety and effectiveness of its products in pediatric patients for whom the drug is indicated. As noted, Connetics has done so here. FDA granted a full waiver of requirements under PREA, stating that "the FDA has determined that your proposed change in dosage form is subject to PREA, but has concluded that the requirements for PREA have already been met." *See* Letter from Gary J. Buehler, Director, Office of Generic Drugs, Center for Drug Evaluation and Research, to Lachman Consultant Services, Inc. (July 5, 2005; Docket No. 2004P-0353 (FDA letter and ANDA suitability petition are Enclosure C)).

#### **C. Environmental Impact**

This petition is eligible for a categorical exclusion under 21 C.F.R. § 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 reference listed drug.

#### **D. Economic Impact**

Information on economic impact will be submitted upon request.

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**E. 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,



Arthur Y. Tsien  
Valerie B. Solomon

OFW:jdc  
Enclosures

- A – Evoclin labeling
- B – Labeling changes for proposed product, based on Evoclin labeling
- C – Docket No. 2004P-0353 (FDA letter and ANDA suitability petition)