STATISTICAL REVIEW AND EVALUATION

NEW DRUG APPLICATION

LABELING REVIEW

NDA/Serial Number: 21152 / S-004
Drug Name: Cutivate (fluticasone propionate) Lotion 0.05%
Indication(s): Atopic dermatitis
Applicant: Nycomed
Dates: Submitted: 4/22/2010
        PDUFA: 10/22/2010
Review Priority: Standard review

Biometrics Division: Division of Biometrics III
Statistics Reviewer: Kathleen Fritsch, PhD
Concurring Reviewer: Mohamed Alosh, PhD

Medical Division: Division of Dermatology and Dental Products
Clinical Team: Amy Woitach, MD / David Kettl, MD
Project Manager: J. Paul Phillips

Keywords: PLR Conversion
1 Regulatory Background

NDA 21152 for Cutivate (fluticasone propionate) Lotion 0.05% was approved on 3/31/2005. The approved indication for Cutivate Lotion is for the relief of the inflammatory and pruritic manifestations of atopic dermatitis in patients 1 year of age or older. The approval letter included a postmarketing commitment to conduct a deferred pediatric study under PREA in subjects aged 3 months to 1 year. The study was to evaluate the safety (both local and systemic, to include laboratory tests) and systemic exposure. The applicant conducted a HPA axis suppression study in 56 subjects aged 3 months to 1 year.

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Signatures/Distribution List

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Date: 9/3/2010

Statistical Team Leader: Mohamed Alosh, PhD

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<th>Submission Type/Number</th>
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<th>Product Name</th>
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<td>SUPPL-4</td>
<td>NYCOMED US INC</td>
<td>CUTIVATE LOTION 0.05%</td>
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/s/

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09/03/2010

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