



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

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. (b) (4) the applicant conducted a HPA axis suppression study in 56 subjects aged 3 months to 1 year. (b) (4)

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Signatures/Distribution List

Primary Statistical Reviewer: Kathleen Fritsch, PhD

Date: 9/3/2010

Statistical Team Leader: Mohamed Alesh, PhD

cc:

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DBIII/Wilson

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DBIII/Fritsch

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21152	SUPPL-4	NYCOMED US INC	CUTIVATE LOTION 0.05%

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/s/

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09/03/2010

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09/03/2010