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)

.

(b) (4)

(b) (4)

4 Page(s) has been Withheld in Full as B4 (CCI/TS) immediately following this page

Signatures/Distribution List

Primary Statistical Reviewer: Kathleen Fritsch, PhD
Date: 9/3/2010

Statistical Team Leader: Mohamed Alosh, PhD

cc:
DDDP/Walker
DDDP/Kettl
DDDP/Woitach
DDDP/Phillips
OBIO/Patrician
DBIII/Wilson
DBIII/Alosh
DBIII/Fritsch

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KATHLEEN S FRITSCH
09/03/2010

MOHAMED A ALOSH
09/03/2010