

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-320

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-320

NDA APPROVAL

Galderma Laboratories, L.P.
ATTENTION: Paul Clark
Director, Regulatory Affairs
14501 North Freeway
Fort Worth, Texas 76177

Dear Mr. Clark:

Please refer to your new drug application (NDA) dated and received, February 8, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Epiduo (adapalene and benzoyl peroxide) Gel 0.1%/2.5%.

We acknowledge receipt of your submissions dated March 11, April 25, June 6, September 10, November 12, December 5, and December 8, 2008.

This new drug application provides for the use of Epiduo (adapalene and benzoyl peroxide) Gel 0.1%/2.5% for the treatment of acne vulgaris.

We have completed our review of this application as amended. It is approved effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text. We note that this approval only includes the 45g tube size.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 22-320."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format- Human Pharmaceuticals Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on

heavy-weight paper or similar material. For administrative purposes, designate this submission **“Final Printed Carton and Container Labels for approved NDA 22-320.”** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for up to 9 years of age, because necessary studies are impossible or highly impractical in that age group.

We are deferring submission of your pediatric studies for ages 9 to 11 years for this application because this product is ready for approval for use in patients 12 years and older.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

A multi-center, randomized, placebo-controlled double blind study to evaluate the safety and efficacy of Epiduo Gel administered once daily for the treatment of subjects 9 to 11 years of age with acne vulgaris.

Final Report Submission: July 1, 2011

Submit final study reports to this NDA. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated **“Required Pediatric Assessments”**.

We note that you have fulfilled the pediatric study requirement for ages 12 to 18 years for this application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane

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REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Dawn Williams, Regulatory Project Manager, at (301) 796-0155.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, M.D., F.A.A.D.
Director
Division of Dermatology and Dental
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research