



NDA 20-380/S-004

Galderma Laboratories, L.P.  
Attention: Christine Shank  
Senior Director, Regulatory Submissions  
14501 N. Freeway  
Fort Worth, Texas 76177

Dear Ms. Shank:

Please refer to your supplemental new drug application dated May 7, 2007, received May 8, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DIFFERIN<sup>®</sup> (adapalene) Gel, 0.1%.

We acknowledge receipt of your submission dated June 28, 2007.

This supplemental new drug application provides for changes to add new package sizes for the commercial drug product. The new size include -----, 75-gram, ----- tube. The 75-gram tube size will be the ---- new tube size reflected in the attached label. -----  
----- The 36-month expiration dating period is granted for the ----- 75-gram ----- package sizes.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

### 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(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical in content to the enclosed labeling text (text for the package insert and text for the immediate container and carton labels). 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 supplement NDA 20-380/S-004."

### LETTERS TO HEALTH CARE PROFESSIONALS

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

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

**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 Catherine Carr, Regulatory Project Manager, at (301) 796-2311.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Susan Walker

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