DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20380/S-011

SUPPLEMENT APPROVAL

Galderma Laboratories, L.P.
Attention: S. Chase Edwards
Senior Manager, Regulatory Affairs
14501 North Freeway
Firth Worth, TX 76177

Dear Mr. Edwards:

Please refer to your Supplemental New Drug Application (sNDA) dated November 18, 2016, received November 18, 2016 and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Differin Gel (adapalene), 0.1%.

This Prior Approval supplemental new drug application provides for alternate secondary packaging (carton) configurations. 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 agreed-upon labeling text.

We are approving the supplemental application for secondary packaging (cartons) containing 15 and 45 gram tubes of Differin Gel (adapalene), 0.1%. We note that the 45 gram tube size is the size used in the Juno trial, your actual use study that evaluated consumer behavior. Subjects in this trial were permitted to purchase up to two 45 gram tubes at one time. We also note that usage and exposure were key review issues in our evaluation of the potential risks of nonprescription marketing.

Research has shown that increased package sizing of products leads to increased usage among consumers. [1,2] Conversely, limiting package sizes has been shown to reduce overconsumption by limiting the immediate availability of drugs to the consumer.[3,4] In the future, if you are interested in marketing immediate containers containing more than 45 grams of Differin Gel or packaging sizes greater than two 45 gram tubes, justify in your submission why larger package

[1] Wansink B, 1996, Can Package Size Accelerate Usage Volume? *J Mark*, 60(3): 1-14.

[2] Chandon P, B Wansink, 2002, When are Stockpiled Products Consumed Faster? A Convenience-salience Framework of Postpurchase Consumption Incidence and Quantity, *J Mark Re*s, 39(3): 321-335.

[3] Hawton K, H Bergen, S Simkin, S Dodd, P Pocock, W Bernal, et al., 2013, Long Term Effect of Reduced Pack Sizes of Paracetamol on Poisoning Deaths and Liver Transplant Activity in England and Wales: Interrupted Time Series Analyses, *BMJ*, 346: f403 (doi: 10.1136/bmj f403).

[4] Weiss S, 2009, Compliance Packaging for Over-the-counter Drug Products, J Public Health, 17(2): 155-164.

sizes will not adversely impact the safety of the product. Consider requesting a pre-submission meeting with us to discuss safety implications and your proposed justification to support a larger package size.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the enclosed labeling: outer container (carton) labeling for the 15 gram and 45 gram tubes submitted November 18, 2016, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submit the final printed labeling electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020380/S-011**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 Lara Akinsanya, Regulatory Project Manager, at (301) 796-9634.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton Labeling

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

/s/

THERESA M MICHELE
05/19/2017