NDA 220736

NDA APPROVAL

Galderma Laboratories, L.P.
Attention: Chase Edwards
Director, Regulatory Affairs
14600 Heritage Parkway
Fort Worth, TX 76177

Dear Chase Edwards:

Please refer to your new drug application (NDA) dated and received July 24, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Differin Epiduo Acne Gel (adapalene/benzoyl peroxide) gel, 0.1%/2.5%.

This new drug application provides for the nonprescription use of Differin Epiduo Acne Gel (adapalene/benzoyl peroxide) gel, 0.1%/2.5% for the treatment of acne in adults and children 12 years and older.

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 application for immediate containers containing 2, 15, 30 and 45 grams of Differin Epiduo Acne Gel (adapalene/benzoyl peroxide) gel, 0.1%/2.5%. We note that the 45 gram tube size is the size that you market in the United States as a prescription product.

Research has shown that increased package sizing of products leads to increased usage among consumers. [1,2] Conversely, limiting pack sizes of medication has been shown to reduce episodes of overconsumption by limiting the immediate availability of the drug to the consumer. [3,4] In the future, if you are interested in marketing immediate containers containing more than 45 grams of Differin Epiduo Acne Gel (adapalene/benzoyl peroxide) gel, 0.1%/2.5% or packaging sizes greater than two 45 gram containers, justify in your submission why larger package sizes will not adversely impact the safety of the product. Consider requesting a pre-submission meeting with us

[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 Res, 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.

to discuss safety implications and your proposed justification to support a larger package size.

LABELING

Submit final printed labeling (FPL) 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, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date submitted
Outer Container	
2 g Tube Backer Card	05/08/2026
15 g Pump Carton	04/02/2026
15 g Tube Carton	04/02/2026
30 g Tube Carton	04/02/2026
45 g Pump Carton	03/05/2026
45 g Tube Carton	03/05/2026
Immediate Container	
2 g Tube	03/05/2026
15 g Pump	04/02/2026
15 g Tube	04/02/2026
30 g Tube	04/02/2026
45 g Pump	03/05/2026
45 g Tube	03/05/2026
Additional Labeling	
Consumer Information Leaflet (15, 30, 45 g SKUs)	03/05/2026
Consumer Information Leaflet (2 g SKU)	03/05/2026
2 g Tube Dispenser Tray	05/08/2026

The final printed labeling should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[5] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 220736**." Approval of this submission by FDA is not required before the labeling is used.

[5] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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 FDA.gov.[6] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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

[6] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, contact Odongerel Pount, PharmD, Regulatory Project Manager at (240) 402-7144 or Odongerel.Pount@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
05/22/2026 08:26:11 AM