



NDA 217242/S-002

APPROVAL LETTER

Arcutis Biotherapeutics, Inc.
Attention: Jennifer Mahilo
Executive Director, Regulatory CMC
3027 Townsgate Road, Suite 300
Westlake Village, CA 91361

Dear Jennifer Mahilo:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 21, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ZORYVE (roflumilast) aerosol, Foam.

This “Changes Being Effected in 30 days” supplemental new drug application provides for addition of a 25 g physician sample can for ZORYVE (roflumilast) topical foam.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on February 28, 2024, 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 *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 217242/S-002.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, email Rajani Ranga, Regulatory Business Process Manager, at Rajani.Ranga@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Supervisor
Division of Product Quality Assessment XI
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



David
Lewis

Digitally signed by David Lewis

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