NDA 210361/S-003

APPROVAL LETTER

Dermira, Inc.
Attention: Drew Badger, PhD, DABT
Vice President, Regulatory Affairs & Toxicology
275 Middlefield Road, Suite 150
Menlo Park, CA 94025

Dear Dr. Badger:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 30, 2020, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Qbrexza (glycopyrronium) Cloth, 2.4%.

This Prior Approval supplemental new drug application provides for the addition of (b) (4) as an alternate drug product manufacturing, packaging and testing site, with the following additional changes:

- scale-up (b) (4) of the drug product manufacturing process
- extension of the shelf-life from 36 months to 48 months
- changes to the carton label artwork for drug product manufactured at (b) (4)

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 text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to 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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 210361/S-003.**" 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.

If you have any questions, call Yajun Jason Tu, Regulatory Business Process Manager, at (240) 402 - 4202.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton Labeling

David Lewis

Digitally signed by David Lewis
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