NDA 208798/S-016

SUPPLEMENT APPROVAL

Teva Pharmaceutical Industries Ltd.
Attention: Lisa Carle
Director, Regulatory Affairs
145 Brandywine Parkway Building 300
West Chester, PA 19380

Dear Ms. Carle:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 25, 2023, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ARMONAIR DIGIHALER (fluticasone propionate) inhalation powder.

This Prior Approval supplemental new drug application provides for revision of carton labeling for ArmonAir Digihaler to improve understanding and to increase awareness around connecting to the Digihaler app.

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 LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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 Labeling for approved NDA 208798/S-016**." Approval of this submission by FDA is not required before the labeling is used.

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 Emma Gimose, PharmD, BCPS, Regulatory Business Process Manager, at (240) 402 - 1681.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, Branch II
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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