



DA 208799/S-019

SUPPLEMENT APPROVAL

Teva Pharmaceutical Industries Limited N
c/o Teva Branded Pharmaceutical Products R&D, Inc.
Attention: Stephen Dobowski
Senior Manager
145 Brandywine Parkway
West Chester, PA 19380

Dear Mr. Dobowski:

Please refer to your Supplemental New Drug Application (s DA) dated and received May 6, 2021, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AirDuo Digihaler (fluticasone propionate and salmeterol) Inhalation Powder.

This Prior Approval supplemental new drug application provides for labeling revisions to the carton for Air Duo Digihaler.

APPROVAL & LABELING

We have completed our review of this supplemental application. 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, 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 208799/S-019.**” Approval of this submission by FDA is not required before the labeling is used. N

REPORTING REQUIREMENTS N

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.8).

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 3777.

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incerely,

{See appended electronic signature page} n

Ramesh Raghavachari, Ph.D.
Branch Chief, BI
Division of Post Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research n

Enclosure(s):

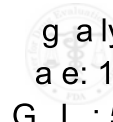
Carton and Container Labeling

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Ramesh U
Raghava ha



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