NDA 022518/S-033

SUPPLEMENT APPROVAL

Organon LLC
Attention: Prachi Haldankar
Associate Principal Scientist, Global Regulatory Affairs - CMC
30 Hudson Street, 33rd Floor
Jersey City, NJ 07302

Dear Prachi Haldankar:

Please refer to your supplemental New Drug Application (sNDA) dated February 19, 2025, received February 19, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DULERA® (mometasone furoate and formoterol fumarate dihydrate) inhalation aerosol.

We also refer to our approval letter dated June 5, 2025, which contained the following error: The initial approval letter did not have the USPPI attachment.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain June 5, 2025, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for:

- (b) (4)
- Labeling changes to the 120-actuation pack, proposing to store the inhaler with the mouthpiece down or in a horizontal position.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and text for the patient package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also, within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 022518/S-033.**" 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, please contact Janell Artis, PharmD., Regulatory Business Process Manager at email: Janell.Artis@fda.hhs.gov, or (301) 796 – 6309.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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