NDA 207921/S-003

SUPPLEMENT APPROVAL

Norton (Waterford) Limited
c/o Teva Branded Pharmaceutical Products R and D Inc
Attention: Daniel Larkins
Director, Regulatory Affairs
145 Brandywine Parkway
West Chester, PA 19380

Dear Mr. Larkins:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 19, 2018, and your amendments, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for QVAR REDIHALER (beclomethasone dipropionate HFA) inhalation aerosol.

This Prior Approval supplemental new drug application provides for revisions to the carton labeling to incorporate revisions to the company logo and branding elements on the cartons.

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, 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 207921/S-003.**" 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 Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

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

Enclosure(s):
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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