



NDA 20831/S-029
NDA 20831/S-032

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGEMENT**

Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Attention: Yifeng Jia, PhD
Drug Regulatory Manager

Dear Dr. Jia:

Please refer to your Supplemental New Drug Application (sNDA) dated February 25, 2013, received February 22, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Foradil Aerolizer (formoterol fumarate inhalation powder).

We also acknowledge your risk evaluation and mitigation strategy (REMS) assessment dated August 8, 2012. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we have found the REMS assessment to be complete.

This supplemental new drug application proposes to eliminate the requirement for the approved Foradil Aerolizer (formoterol fumarate inhalation powder) REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Foradil Aerolizer (formoterol fumarate inhalation powder) was originally approved on May 18, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA eliminate the REMS requirement for Foradil Aerolizer (formoterol fumarate inhalation powder).

The REMS assessment received on August 8, 2012 demonstrates that the communication plan, and therefore the REMS, has met its goals. Therefore, we have determined that it is no longer

necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, we agree with your proposal, and a REMS for Foradil Aerolizer (formoterol fumarate inhalation powder) is no longer required.

OTHER

We encourage you to maintain your educational materials on your product website to provide a resource for patients and practitioners about the risks and benefits of your product.

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 Wayne Amchin, Senior Regulatory Health Project Manager for Safety, at (301) 796-0421.

Sincerely,

{See appended electronic signature page}

Sally M. Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

SALLY M SEYMOUR
03/29/2013