DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22383/S-004
NDA 22383/S-005

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGEMENT

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

Attention: Bhavini Patel, PharmD
Senior Global Program Regulatory Manager

Dear Dr. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated December 7, 2012, (NDA 22-383/S-005) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Arcapta Neohaler (indacaterol maleate inhalation powder) 75 mcg.

We also acknowledge your risk evaluation and mitigation strategy (REMS) assessment dated June 29, 2012 (NDA 22-383/S-004). 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 (NDA 22-383/S-005) proposes to eliminate the requirement for the approved Arcapta Neohaler (indacaterol maleate 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 Arcapta Neohaler (indacaterol maleate inhalation powder) was originally approved on July 1, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Arcapta Neohaler (indacaterol maleate inhalation powder).

Because the assessment demonstrates that communication plan has been completed and has met its goals, 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 Arcapta Neohaler (indacaterol maleate 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SALLY M SEYMOUR
12/18/2012