



NDA 20-831/S-009

Novartis Pharmaceutical Corporation  
One Health Plaza  
East Hanover, New Jersey 07936-1080

Attention: Ann Shea  
Senior Associate Director  
Drug Regulatory Affairs

Dear Ms. Shea:

Please refer to your supplemental new drug application dated December 15, 2005, received December 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Foradil Aerolizer (formoterol fumarate) Inhalation Powder.

We acknowledge receipt of your submissions dated March 29, April 12, and June 6, and 16, 2006.

This supplemental new drug application provides for changes in the Package Insert and the implementation of a Medication Guide so as to furnish adequate information for the safe and effective use of the drug.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We acknowledge receipt of your labeling in Structured Product Labeling format (SPL) dated June 16, 2006, we will comment on the SPL, as necessary, at a later date.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted June 16, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-831/S-009.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Please submit one market package of the drug product when it is available.

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 Ms. Akilah Green, Senior Regulatory Management Officer, at (301) 796-1219.

Sincerely,

*{See appended electronic signature page}*

Badrul A. Chowdhury, M.D., Ph.D.  
Director  
Division of Pulmonary Allergy Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure

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

/s/

-----  
Badrul Chowdhury  
6/19/2006 01:37:59 PM