021279 - Original Approval - Package. PDF

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
21-279

Trade Name:	Foradil Aerolizer
Generic Name:	Formoterol fumarate inhalation powder
Sponsor:	Novartis Pharmaceutical Corporation
Approval Date:	September 25, 2001
Indications:	Provides for the use of Foradil (formoterol fumarate inhalation powder) Aerolizer for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with Chronic Obstructive Pulmonary Disease including chronic bronchitis and emphysema.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-279

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter(s)	
Final Printed Labeling	X
Medical Review(s)	X
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	X
Statistical Review(s)	X
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	X
Administrative Document(s) and Correspondence	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-279

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-279
NDA 20-831/S-002

Novartis Pharmaceutical Corporation
59 Route 10
East Hanover, New Jersey 07936-1080

Attention: Kathleen Basmadjian, Ph.D.
Associate Director, Drug Regulatory Affairs

Dear Dr. Basmadjian:

Please refer to your new drug application (NDA) dated September 22, 2000, received September 25, 2000, and your supplemental new drug application dated September 24, 2001, received September 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Foradil (formoterol fumarate inhalation powder) Aerolizer.

We acknowledge receipt of your submissions dated November 15, 2000, January 31, May 4, June 18, July 5, 23 and 26 and September 12 and 24, 2001.

This new drug application provides for the use of Foradil (formoterol fumarate inhalation powder) Aerolizer for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with Chronic Obstructive Pulmonary Disease including chronic bronchitis and emphysema.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the revisions shown in the enclosed labeling, and discussed during a telephone conversation between Dr. Craig Ostroff of this Division and yourself. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (patient instructions for use submitted September 24, 2001). These revisions are terms of the NDA and supplemental NDA approvals. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL to each NDA as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved NDA 21-279 and NDA 20-831/S-002." Approval of these submissions by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submission dated September 5, 2001 to NDA 21-279. These commitments are listed below.

1. Foradil Aerolizer: Holter Monitoring in Patients with COPD

Protocol Submission:	Within six months of the date of this letter
Study Start:	Within 12 months of the date of this letter
Final Report Submission:	Within 34 months of the date of this letter

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to NDA 20-831. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to NDA 20-831. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this indication.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA. To comply with these regulations, all 3-day and 15-day alert reports, periodic adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 20-831 for this drug product, not to NDA 21-279. This includes the quarterly periodic adverse drug experience reports required by this new NDA. In the future, no submissions should be made to NDA 21-279 except for the 20 copies of the final printed labeling, as requested above.

If you have any questions, call Dr. Craig Ostroff, Regulatory Management Officer, at 301-827-5585.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research