CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20750

Trade Name: TILADE NEBULIZER SOLUTION

Generic Name: NEDOCROMIL SODIUM INHALATION SOLUTION

Sponsor: RHONE-POULENC RORER

Approval Date: OCTOBER 1, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20750

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter			X	
Approvable Letter			X	
Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
Administrative Document(s)	X			
Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20750

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-750

OCT 1 1997

Rhone-Poulenc Rorer
500 Arcola Road
Mailstop H14
Collegeville, PA 19426-0800

Attention: Steven J. Miller
Associate Director
Regulatory Affairs

Dear Dr. Miller:

Please refer to your new drug application dated September 30, 1996, received October 1, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tilade Nebulizer Solution (nedocromil sodium inhalation solution).

We acknowledge receipt of your submissions dated October 11, 1996, and January 27, February 6, 10, and 11, March 3 and 21, May 12 and 28, June 2, 10, 23, 24 and 25, July 25 and 29, August 25, and September 4, 5, 17, 18, 22, 25, and 30, 1997. The user fee goal date for this application is October 1, 1997.

We have completed the review of this application, as amended, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for maintenance therapy in the management of mild-to-moderate asthma in patients two years of age and older. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft physician labeling and draft carton and container labeling, submitted August 25, 1997, and amended September 25, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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, this submission should be designated "FPL for approved NDA 20-750." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

We remind you of your Phase 4 commitments specified in your submissions dated September 4 and 22, 1997. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to this NDA. In addition, we request under 21 CFR 314.81(b)(vii) that you include in your annual report to this application a status summary of each commitment. The status summary should include expected completion dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing,
Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

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.

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ms. Beverly Gallauresi, Project Manager, at (301) 827-1057.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE