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*APPLICATION NUMBER:*

**20-784**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-784

Aventis Pharmaceuticals  
200 Crossing Boulevard  
P.O. Box 6890  
Bridgewater, NJ 08807-0890

Attention: Dr. Eric Floyd  
Senior Director, US Regulatory Affairs

Dear Dr. Floyd:

Please refer to your new drug application (NDA) dated December 16, 1996, received December 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nasacort HFA (triamcinolone acetonide) Nasal Aerosol.

We acknowledge receipt of your submissions dated February 28, March 4, 14 and 21, April 4 and 7, May 1 and 22, August 13, September 5, October 1 and 24, and November 21, 1997, March 27, and April 16, 1998, July 30, and December 9 and 20, 1999, November 20 and 21, 2000, November 30, 2001, February 28, April 30, May 28, June 10, October 3, November 15, and December 3, 2002, January 14, March 13, 14, and 21, April 30, May 5, June 9 and 30, August 7, September 2, October 3, 6, and 8, and December 9, 16, 17, 18, and 19, 2003, and January 7, 9, 14 (3), and 30, February 11, and 23, and April 1, 6 (2), and 7, 2004. Your submission of October 6, 2003, constituted a complete response to our September 23, 2003, action letter.

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

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 7, 2004, and immediate container and carton labels submitted January 9, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 20-784.**" Approval of this submission by FDA is not required before the labeling is used.

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. We are waiving the pediatric study requirement for ages zero to less than 2 years for this application and

deferring pediatric studies for ages greater than or equal to 2 years to less than 6 years for this application. We note that you have fulfilled the pediatric study requirement for ages 6 years to adults for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the treatment of seasonal allergic rhinitis in pediatric patients ages greater than or equal to 2 years to less than 6 years.

Final Report Submission: April 1, 2007

2. Deferred pediatric study under PREA for the treatment of perennial allergic rhinitis in pediatric patients ages greater than or equal to 2 years to less than 6 years.

Final Report Submission: April 1, 2007

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments.**"

We remind you of your postmarketing study commitment in your submission dated April 6, 2004. This commitment is listed below.

1. Description of Commitment - Aventis agrees to conduct a one-year pediatric growth study with Nasacort HFA Nasal Aerosol

Pediatric Growth Study

Protocol Submission: by 12/2004

Study Start: by 09/2005

Final Report Submission: by 03/2009

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. 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 this NDA. 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.**"

We remind you of your agreement to our January 13, 2004, facsimile stated in your January 14, 2004, submission to address Chemistry, Manufacturing, and Control issues related to aerodynamic particle size distribution (APSD) controls, APSD methodology, APSD mass balance, extractables testing, and dimensional tolerance control of the actuator orifice.

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:

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Colette Jackson, Project Manager, at (301) 827-9388.

Sincerely,

*{See appended electronic signature page}*

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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Badrul Chowdhury  
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