CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-909

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-909

Sanofi-aventis
200 Crossing Blvd, PO Box 6890
Bridgewater, NJ 08807-0890

Attention: Mary Beth Wigley, B.S., M.S.
Assistant Director, Regulatory Development

Dear Ms. Wigley:

Please refer to your new drug application (NDA) dated September 28, 2006, received September 29, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) Orally Disintegrating Tablets, 30mg.

We acknowledge receipt of your submissions dated November 10, 2006, and January 11, 18 and 25, February 8, April 4, May 7, June 21 and 29, and July 20 and 25, 2007.

This new drug application provides for the use of Allegra (fexofenadine hydrochloride) Orally Disintegrating Tablets, 30mg, for the relief of symptoms associated with seasonal allergic rhinitis (SAR) and for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU) in children 6 years to 11 years of age.

We have 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 and with the minor editorial revision listed below.

1. The text "Other adverse reactions have been reported" may be added to the Adverse Reactions section of the Highlights section of the labeling as submitted on July 20, 2007.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revision listed, the submitted labeling [package insert submitted July 25, 2007 (copy enclosed)]. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-909."

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on November 10, 2006, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **"Final Printed Carton and Container Labels for approved NDA 21-909."** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

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 0 to < 2 years and deferring pediatric studies for ages 2 years to < 6 years 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 these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the relief of symptoms associated with seasonal allergic rhinitis (SAR) and for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU) in pediatric patients 2 years to < 6 years of age.

   Final Report Submission: July 31, 2010

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form

FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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 LCDR Lori Garcia, Regulatory Project Manager, at (301) 796-1212.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and 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
7/26/2007 04:35:57 PM