



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-963/S-002

NDA 20-872/S-018

sanofi-aventis U.S. LLC  
55 Corporate Drive  
P.O. Box 5925  
Bridgewater, NJ 08807-5925

Attention: Emmanuel Hamon  
sanofi-aventis U.S. Inc on behalf of sanofi-aventis U.S. LLC  
Regulatory Manager  
US Regulatory Affairs Marketed Products

Dear Mr. Hamon:

Please refer to your supplemental new drug applications dated April 22, 2008, received April 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) Oral Suspension, 30 mg/5mL, and Allegra (fexofenadine hydrochloride) Tablets, 30 mg, 60 mg, and 180 mg.

These supplemental applications provide for revisions to the package insert, to include the combining of the tablets, oral suspension, and orally disintegrating tablet dosage forms into one package insert as approved under NDA 21-909 [Allegra (fexofenadine hydrochloride) ODT] on July 26, 2007.

We have completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the submitted labeling dated April 22, 2008 (copy enclosed).

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  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 Miranda Raggio, Regulatory Project Manager, at (301) 796-2109.

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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

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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  
6/25/2008 10:47:30 AM