DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 201311

Actavis Mid Atlantic LLC
Attention: Elizabeth Trowbridge
Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 23, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fexofenadine Hydrochloride Oral Suspension, 30 mg/5 mL.

Reference is also made to your amendments dated March 31, April 1, April 14, and June 22, 2010; July 6, July 15, and September 27, 2011; March 12, April 5, May 21, June 1, June 14, and July 24, 2012.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Fexofenadine Hydrochloride Oral Suspension, 30 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Allegra Oral Suspension, 30 mg/5 mL, of Sanofi Aventis U.S., LLC. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, Allegra Oral Suspension, 30 mg/5 mL, of Sanofi Aventis U.S., LLC (Sanofi), is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,578,610 (the '610 patent)	November 26, 2013
6,037,353 (the '353 patent)	March 14, 2017
6,187,791 (the '791 patent)	May 11, 2012
6,399,632 (the '632 patent)	May 11, 2012
7,138,524 (the '524 patent)	November 18, 2014*

(*with pediatric exclusivity added)

With respect to each of these patents, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fexofenadine Hydrochloride Oral Suspension, 30 mg/5 mL, under this ANDA. You have notified the agency that Actavis Mid Atlantic LLC (Actavis) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Actavis for infringement of the '353, '791, and '632 patents within the statutory 45-day period in the United States District Court for the District of New Jersey [Sanofi-Aventis U.S. LLC, Aventisub II Inc., and Carderm Capital L.P., v. Actavis Inc. and Actavis Mid Atlantic LLC, Civil Action No. 2:10-02795]. You have also notified the agency that this has action has been dismissed.

With respect to 180-day generic drug exclusivity, we note that Actavis was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the listed patents. Therefore, with this approval, Actavis is eligible for 180-days of generic drug exclusivity for Fexofenadine Hydrochloride Oral Suspension, 30 mg/5 mL. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

07/25/2012

Deputy Director, Office of Generic Drugs
for Gregory Geba, M.D., M.P.H.