CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 076298

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 076298

Impax Laboratories, Inc.
Attention: Michelle Wong, Ph.D.
Senior Director, Regulatory Affairs
30831 Huntwood Avenue
Hayward, CA 94544

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 12, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets, 60 mg/120 mg (12-Hour Formulation).

Reference is also made to the tentative approval letter issued by this office on February 27, 2004, and to your amendments dated January 10, and March 23, 2006; August 23, and November 15, 2007; April 8, 2008; March 19, 2009; and February 26, March 3, July 8, July 19, July 23, July 27, and September 3, 2010.

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 and Pseudoephedrine Hydrochloride Extended-release Tablets, 60 mg/120 mg, (12-Hour Formulation) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Allegra-D Extended-release Tablets, 60 mg/120 mg (12-Hour) of Sanofi Aventis US, LLC. (Aventis).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The “interim” dissolution specifications are as follows:

Dissolution testing should be conducted in 900 mL of 0.001 M HCl, at 37°C using USP Apparatus II (Paddle) at 50 rpm. The test product should meet the following "interim" specifications:

Fexofenadine: Not less than (b) (4) of the labeled amount in the dosage form is dissolved in 45 minutes.

Pseudoephedrine:

Time (Hours)	Percent Dissolved
1	(b) (4)
4	
12	

These "interim" dissolution tests and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Aventis' Allegra-D (12-Hour) Extended-release Tablets, is subject to periods of patent protection. The following patents and 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)	May 26, 2014*
5,855,912 (the '912 patent)	August 28, 2015*
6,037,353 (the '353 patent)	September 14, 2017*
6,039,974 (the '974 patent)	July 31, 2018
6,113,942 (the '942 patent)	August 28, 2015*
6,187,791 (the '791 patent)	November 11, 2012*
6,399,632 (the '632 patent)	November 11, 2012*
7,135,571 (the '571 patent)	November 18, 2014*
7,138,524 (the '524 patent)	November 18, 2014*
7,662,835 (the '835 patent)	November 18, 2014*
7,666,881 (the '881 patent)	November 18, 2014*

*with pediatric exclusivity added

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets, 60 mg/120 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Impax Laboratories, Inc. (Impax) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that Impax complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '912, '353, '974, '942, '791, and '632 patents was brought against Impax within the statutory 45-day period in the United States District Court for the District of New Jersey [Aventis Pharmaceuticals Inc., Merrell Pharmaceuticals Inc., and Carderm Capital L.P. v. IMPAX Laboratories, Inc., Civil Action No. 02-1322 (JAG)]. You have also notified the agency that the court determined that the '912 and '942 patents were not infringed and that litigation remains ongoing for the '353, '974, '791, and '632 patents.

With respect to 180-day generic drug exclusivity, we note that Impax (a) was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the '632, '571 and '524 patents, and (b) was one of the first ANDA applicants to submit a substantially complete ANDA with paragraph IV certifications to the '835 and '881 patents. Therefore, with this approval, Impax is eligible for 180 days of generic drug exclusivity for Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets, 60 mg/120 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[1] 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.

[1] Because your ANDA and others were filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications 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/U CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

11/12/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.