DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-236

APR 14 2005

Barr Laboratories, Inc.
Attention: Christine Mundkur
2 Quaker Road
P.O. Box 2900
Pomona, NY 10970

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 11, 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.

Reference is also made to the Tentative Approval issued by this office on July 1, 2004, and to your amendments dated April 1, 2002; and April 11, and April 12, 2005. We also acknowledge receipt of your correspondence dated April 8, 2005, addressing the patent issues noted below.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets, 60 mg/120 mg to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Allegra-D Extended-release Tablets, of Aventis Pharmaceuticals, Inc. (Aventis). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

The dissolution testing should be conducted in [redacted] of (b)(4)

The test product should meet the following interim specifications:

Fexofenadine HCl:	(b)(4)	at 45 minutes
Pseudoephedrine HCl:		at 30 minutes
		at 2 hours
		at 4 hours
		at 12 hours

The listed drug product (RLD) referenced in your application, Allegra-D Extended-release Tablets of Aventis Pharmaceuticals, Inc. (Aventis), is subject to multiple periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

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

Your ANDA contains paragraph IV patent certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that patents '610, '912, '353, '974, '942, and '791 are 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 is brought against Barr Laboratories, Inc. (Barr) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. This action must be brought against Barr prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B) was received by the NDA/patent holder(s). You have notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act and litigation was brought against Barr in the (b)(4) (b)(4) involving a challenge to the '912, '353, '974, '942, and '791 patents (b)(4) (b)(4) With respect to this litigation, the Agency recognizes that the 30-

month period identified in section 505(j)(5)(B)(iii) of the Act,[1] during which time FDA was precluded from approving your application, has expired.

The '632 patent was not listed with the Agency by the NDA holder prior to the filing of your ANDA by the Office of Generic Drugs on September 14, 2001, and the '632 patent was submitted to FDA on October 4, 2002, more than 30 days after it was issued by the Patent and Trademark Office on June 4, 2002. Because the '632 patent was "late-listed," you were not required to amend your then-pending ANDA to contain a certification to that patent. 21 CFR 314.94(a)(12)(vi). Nevertheless, Barr voluntarily submitted a paragraph IV certification to the '632 patent. An applicant that has voluntarily submitted a patent certification to a late-listed patent may withdraw that certification, and will thereafter no longer be considered to contain the prior certification. 21 CFR 314.94(a)(12)(viii). Your April 12, 2005 amendment provided for the withdrawal of your paragraph IV certification to the '632 patent.

With regard to 180-day generic drug exclusivity and Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets, 60 mg/120 mg, Barr was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the '610, '912, '353, '974, '942, and '791 patents. Therefore, with this approval, Barr is eligible for 180 days of market exclusivity. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[2] will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to this application 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 abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The

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[1] Because information on the patents was submitted before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

[2] Because your ANDA was filed before the date of enactment of the MMA 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).

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(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research