DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-170

TEVA Pharmaceuticals USA
Attention: Patricia Jaworski
Senior Director, Regulatory Affairs
2 University Plaza, Suite 220
Hackensack, NJ 07601

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 1, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 5 mg/120 mg.

Reference is also made to your amendments dated May 16, July 14, September 7, and November 18, 2005; September 4, December 13, and December 20, 2007 (2 submissions); and January 22, 2008.

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 Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 5 mg/120 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zyrtec-D Extended-Release Tablets, 5 mg/120 mg of Pfizer Pharmaceuticals, Inc. (Pfizer).

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:

The dissolution testing should be conducted in 500 ml of 0.1N HCl using USP Apparatus I (Basket) at 100 rpm. The test product should meet the following specifications:

Cetirizine HCl: Not less than [redacted] (Q) of the labeled amount of the drug in the dosage form is dissolved in 30 minutes.
Pseudoephedrine HCl: *1 hr* [redacted]
2 hr
4 hr
8 hr

The "interim" dissolution tests and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when 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, Pfizer's Zyrtec-D 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"):

U.S. Patent Number	Expiration Date
6,469,009 (the '009 patent)	July 13, 2019
6,489,329 (the '329 patent)	April 8, 2016
7,014,867 (the '867 patent)	June 10, 2022
7,226,614 (the '614 patent)	June 10, 2022

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 5 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 TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against TEVA within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

FDA has determined that TEVA was the first applicant to submit a substantially complete ANDA for Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 5 mg/120 mg, that contained a paragraph IV certification and therefore was eligible for 180-day generic-drug exclusivity under section 505(j)(5)(B)(iv) of the Act. However, due to the following set of circumstances, your eligibility for 180-day exclusivity was forfeited under section 505(j)(5)(D)(i)(IV).

Your ANDA was received by the agency on June 2, 2004. The ANDA filing date plus 30 months was December 2, 2006. This ANDA was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). We also have determined that the requirements for approval of this ANDA were not changed or reviewed after your ANDA was filed, nor was a related citizen petition submitted that would extend the 30-month period as described in section 505(q)(1)(G) of the Act. We therefore conclude that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act for Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 5 mg/120 mg, was forfeited by TEVA.

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.

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(s) 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.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
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/

Gary Buehler

2/25/2008 04:33:38 PM