



ANDA 079057

Sun Pharmaceutical Industries Ltd.
U.S. Agent for: Sun Pharma Global FZE
Attention: Robert Kurkiewicz
Regulatory Affairs
1150 Elijah McCoy Drive
Detroit, MI 48202

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 12, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Alfuzosin Hydrochloride Extended-release Tablets, 10 mg.

Reference is made to the tentative approval letter issued by this office on May 6, 2009, and to your amendments dated August 23, and September 15, 2010, and May 3, May 10, July 1, and July 13, 2011.

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 Alfuzosin Hydrochloride Extended-release Tablets, 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Uroxatral Extended-release Tablets, 10 mg, of Sanofi-Aventis U.S. LLC (Sanofi).

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:

Medium: 0.01 N HCl
Volume: 900 mL
USP Apparatus: II (Paddle)
Rotational Speed: 100 rpm

The test product should meet the following "interim" specifications:

1 hr: NMT (b)(4) 6 hrs: (b)(4) 12 hrs: (b)(4) 20 hrs: NLT (b)(4) of the labeled amount of the drug in the dosage form is dissolved.

These "interim" dissolution test 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, Sanofi's Uroxatral Extended-release Tablets, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,149,940 (the '940 patent) is scheduled to expire (with pediatric exclusivity added) on February 22, 2018.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '940 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Alfuzosin Hydrochloride Extended-release Tablets, 10 mg, under this ANDA. You notified the agency that Sun Pharma Global FZE (Sun) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Sun for infringement of the '940 patent within the statutory 45-day period in the United States District Court for the District of Delaware [Sanofi-Aventis U.S. LLC v. Sun Pharma Global LLC, Civil Action No. 08-1941]. You notified us that this case was dismissed on June 24, 2009.

With respect to 180-day generic drug exclusivity, we note that Sun was a first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification to the '940 patent. Therefore, with this approval, Sun is eligible for 180 days of generic drug exclusivity for Alfuzosin Hydrochloride Extended-release Tablets, 10 mg. 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
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/UCM072392.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

07/18/2011

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