



NDA 21-287/S-008

sanofi-aventis U.S. LLC  
Attention: Sanjukta Bhaduri, M.B.B.S., M.F.P.M.  
Senior Manager, Regulatory Affairs  
300 Somerset Corporate Blvd.  
Bridgewater, NJ 08807

Dear Ms. Bhaduri:

Please refer to your supplemental new drug application dated October 17, 2006, received October 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Uroxatral® (alfuzosin HCl extended release tablets).

We also refer to your submission of February 21, 2007. We further refer to our March 16, 2006, letter requesting revisions to the Uroxatral® package insert based on the results of the QT interval study PKD5627.

This "Prior Approval" supplement provides for revisions to the **CLINICAL PHARMACOLOGY, Electrophysiology** subsection and **PRECAUTIONS, General** section of the alfuzosin label of the labeling as requested by the Division on December 8, 2006 via facsimile.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter.

Submit revised content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions, call Olga Salis, Regulatory Project Manager, at (301)796-0837.

Sincerely,

*{See appended electronic signature page}*

Mark Hirsch, M.D.  
Acting Deputy Director  
Division of Reproductive and Urologic  
Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mark S. Hirsch  
3/29/2007 10:27:40 AM