DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-287/S-005

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 Dr. Bhaduri:

Please refer to your supplemental new drug application dated November 22, 2005, received November 23, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Uroxatral® (alfuzosin HCl) extended release tablets.

We acknowledge receipt of your submissions dated December 13, 2005, and February 17, 2006.

This supplemental new drug application provides for the inclusion of information concerning Intraoperative Floppy Iris Syndrome (IFIS) in the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the label.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-287/S-005**." Approval of this submission by FDA is not required before the labeling is used.

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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Martin Kaufman, D.P.M., M.B.A., Regulatory Health Project Manager, at (301) 796-0928.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
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