DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-287/S-013

sanofi-aventis U.S. LLC
Attention: Kentan Patel
US Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Patel:

Please refer to your supplemental new drug application dated March 23, 2008, received March 24, 2008, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Uroxatral® (alfuzosin HCl extended release tablets).

We also refer to your amendments dated April 14, April 16 and May 12, 2009.

This Prior Approval supplemental new drug application provides for new labeling content and format to comply with the requirements of the Physician's Labeling Rule (PLR), revisions to Pharmacokinetics section, Drug-Drug Interactions subsection, and minor editorial changes.

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.

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 Olga Salis, Regulatory Project Manager, at (301) 796-0837.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (PI & PPI)

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

/s/

George Benson
5/20/2009 03:55:12 PM