DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-193/S-007

Johnson & Johnson Pharmaceutical,
Research & Development, L.L.C.
Susan Nemeth, Ph.D.
Director, Regulatory Affairs
920 U.S. Highway 202
P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Nemeth:

Please refer to your supplemental new drug application dated January 28th, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elmiron® (pentosan polysulfate sodium) capsules, 100 mg.

We also refer to your July 23, 2008, submission in which you agreed to our labeling revisions.

This supplemental new drug application provides for the update of product labeling to include pharmacokinetic and pharmacodynamic data from Studies C-2000-011-00 and C-2002-031-03.

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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-193/S-007."

If you have any questions, call Celia Hayes, MPH, RD, Regulatory Project Manager, at (301) 796-4154.

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

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
7/24/2008 01:22:46 PM