DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-193/S-004

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
On behalf of: Ortho-McNeil Pharmaceutical, Inc.
Attention: Catherine Glamkowski, B.S.
Associate Director, Regulatory Affairs
1125 Trenton-Harbourton Road, Mail Stop 64
Titusville, NJ 08560-0200

Dear Ms. Glamkowski:

Please refer to your supplemental New Drug Application dated September 1, 2005, received September 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elmiron® (pentosan polysulfate sodium) capsules, 100 mg.

We acknowledge receipt of your submissions dated March 13 and 27, and August 18, 2006.

Your submission of March 27, 2006, constituted a complete response to our March 7, 2006, action letter.

This supplemental New Drug Application provides for revised product labeling based on the findings described by the National Toxicology Program in their report titled *Toxicology and Carcinogenesis Study of Elmiron® in F344/N Rats and B6C3F$_1$ Mice (May 2004)*, addition of nonsteroidal anti-inflammatory drugs to the precaution regarding therapies that may increase bleeding risk, and addition of the inactive ingredients to the list of ingredients in the DESCRIPTION section.

We 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.

We request that you submit Structured Product Labeling (SPL), identical to the enclosed labeling (text for the package insert and patient package insert), as soon as it is available. For administrative purposes, designate this submission "**SPL for approved supplement NDA 20-193/S-004**." Approval of this submission by FDA is not required before the labeling is used. For additional information and specifications on SPL, see *FDA Data Standards Council Structured Product Labeling Resources* on the Internet at http://www.fda.gov/oc/datacouncil/spl.html.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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}

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

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

/s/

Mark S. Hirsch

9/20/2006 04:12:28 PM