DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-193/S-003

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
On behalf of: Ortho-McNeil Pharmaceutical, Inc.
Attention: Kathleen Dusek, R.Ph., RAC
Manager, Global Regulatory Affairs
1125 Trenton-Harbourton Road, Mail Stop 64
Titusville, NJ 08560-0200

Dear Ms. Dusek:

Please refer to your supplemental new drug application dated September 9, 2002, received September 10, 2002, 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 October 10, 2003, February 23, and August 18, 2004. Your submission of February 23, 2004, constituted a complete response to our October 1, 2003, action letter.

This supplemental new drug application provides for changes to the text of the package insert and the patient package insert.

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 and with the minor editorial revision listed below:

> In the **CLINICAL PHARMACOLOGY** section, the words “radio labeled” should be changed to “radiolabeled” in the first sentence under the heading Pharmacokinetics.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the enclosed labeling (text for the package insert, and text for the patient package insert). This revision is a term of the approval of this application.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-193/S-003.” 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Project Manager, at (301) 827-4234.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic
Drug 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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