DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-680/S-057

Johnson and Johnson Pharmaceutical Research and Development, L.L.C.
Attention: Susan J. Merchant
Manager, Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, New Jersey 08560-0200

Dear Ms. Merchant:

Please refer to your supplemental new drug application dated June 4, 2002, received June 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ParaGard®T380A (Intrauterine Copper Contraceptive).

This "Changes Being Effected" supplemental new drug application provides for revision of the package insert and the patient package insert as recommended in the October 11, 2001 supplement request letter.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 4, 2002.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Karen Anderson, Regulatory Project Manager, at (301) 827-4259.

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

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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