DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA18-680/S-060

FEI Women's Health LLC
Attention: Thomas E. Mehs
825 Wurlitzer Drive
North Tonawanda, NY 14120-2029

Dear Mr. Mehs:

Please refer to your supplemental new drug application dated October 19, 2004, received November 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ParaGard® Copper T 380 A (intrauterine device).

We acknowledge receipt of your submissions dated November 3, and December 6, 2004, January 17, 2005, February 10, 17, March 4, 15, April 13, 27, July 19, August 19, and September 1, 2005.

This supplemental drug application provides for less restrictive language in the indication and usage section of the product labeling as well as numerous changes to update other labeling sections.

We completed our review of this application as amended, and it 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 for the package insert and patient package insert).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 18-680/S-060.**" 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
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Charlene Williamson, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Donna Griebel, 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/

Donna Griebel

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