



NDA 21-225/S-009

Berlex Laboratories, Inc.
Attention: Jo-Ann Ruane
Manager, Drug Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Ruane:

Please refer to your supplemental new drug application dated July 8, 2003, received July 9, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mirena® (levonorgestrel- releasing intrauterine system).

We acknowledge receipt of your submission dated July 8, 2003.

These "Changes Being Effected in 30 days" supplemental new drug application provide for changes in the blister pack labels, secondary carton, hologram label, description of manufacturing process, master packaging record, description and suitability of container closure system and stability commitment, physician insert and patient information.

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 July 8, 2003.

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

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

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Division Deputy Director
Division of Reproductive and Urologic Drug
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Donna Griebel
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