



NDA 21-225/S-018

Bayer Healthcare Pharmaceuticals, Inc.
Attention: Jo-Ann Ruane
Associate Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Ruane:

Please refer to your supplemental new drug application dated November 28, 2007, received November 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mirena[®] (levonorgestrel-intrauterine releasing system).

We also acknowledge receipt of your submissions dated March 17, May 27, and May 28, 2008.

This supplemental new drug application provides for (1) relocating information previously contained in the DIRECTIONS FOR USE section of the package insert to the DOSAGE AND ADMINISTRATION section of the package insert and (2) clarifying the instructions for insertion and removal of Mirena[®].

We have 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 enclosed agreed-upon labeling text.

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

NDA 21-225/S-018

Page 2

If you have any questions, call Charlene Williamson, Regulatory Project Manager, at (301) 796-1025.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.

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/

Scott Monroe

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