



NDA 21-225/S-019

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 30, 2007, received December 3, 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 18 and June 24, 2008.

This supplemental new drug application provides for changes to the WARNINGS section, Intrauterine Pregnancy, Embedment, Perforation, Expulsion, and Ovarian Cysts subsections, and PRECAUTIONS section, Patient Evaluation and Clinical Considerations, Insertion Precautions, and Continuation and Removal subsections of the Physician Package Insert. The Patient Package Inset was updated to be consistent with the Physician Package Insert.

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

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  
7/21/2008 02:27:36 PM