



NDA 21-098/S005

Berlex Laboratories, Inc.
Attention: Ms. Nancy Velez
Manager, Drug Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, New Jersey 07045-1000

Dear Ms. Velez:

Please refer to your supplemental new drug application dated July 11, 2002, received July 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Yasmin (drospirenone/ethinyl estradiol) Tablets.

We acknowledge receipt of your submissions dated July 23, 2002 and May 6, 2003.

This supplemental new drug application provides for changes to the Physician Package Insert and Detailed Patient Package Insert to reflect the results of the final clinical study reports for A03161, B990, and A00824.

We completed our review of this application, as amended. It is approved effective of 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 the patient package insert submitted on May 6, 2003).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement, NDA 21-098/S005." Approval of this submission by FDA is not required before the labeling is used.

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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 Karen Anderson, N.P., Regulatory Project Manager, at (301)827-4260.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Deputy Director
Division of Reproductive and Urologic Drug Products (HFD-580)
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
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/s/

Donna Griebel
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