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APPLICATION NUMBER:

21-544

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-544

Barr Laboratories
Attention: Christine Mundkur
Senior Vice President, Quality and Regulatory Counsel
One Bala Plaza
Suite 324
Bala Cynwyd, PA 19004-1401

Dear Ms. Mundkur:

Please refer to your new drug application (NDA) dated August 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seasonale® (levonorgestrel / ethinyl estradiol) Tablets.

We acknowledge receipt of your submissions dated September 26, October 31, November 22, and December 12, 2002; February 7, 13 and 14 (2), March 6 and 26, April 3,9, 10 (2), 11(2), 14 and 23, May 1(2), 5 (2), 6, 7, 9, 12, 14, 15 (2), 16 (2), 23, 29 (2), and 30, June 5 and 6, July 1and 17, August 1, 12, 25, 27, and 29(2), September 4 and 5, 2003.

This new drug application provides for the use of for Seasonale® (levonorgestrel / ethinyl estradiol) Tablets for oral contraception.

We completed our review of this application, as amended. 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 both the brief and detailed patient package inserts, and the agreed upon immediate container and carton labels. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-544.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in the telephone conference on September 2, 2003. This commitment is listed below.

1. To continue the SEA 301-A extension study until it is completed.

Protocol Submission:	ongoing
Study Start:	ongoing
Final Report Submission:	by February, 2005

Under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and number of patients entered into the study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled **"Postmarketing Study Final Report" or "Postmarketing Study Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Reproductive and Urologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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