CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75803

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT.
LABELING REVIEW BRANCH

ANDA Number: 75-803

Date of Submission: February 15, 2000 (Original draft labeling)

Applicant's Name: Barr Laboratories, Inc.

Established Name: Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.1 mg/0.02 mg (21 and 28 day regimens)

Labeling Deficiencies:

1. **GENERAL COMMENT:**

   Your proposed proprietary name "Levia™" is under review. We defer comment on the proposed name at this time.

2. **CONTAINER** (Fold-over dose card – 21 and 28 Day):

   Revise "(levonorgestrel and ethinyl estradiol tablets, USP)" to read:
   "(levonorgestrel and ethinyl estradiol tablets, USP 0.1 mg/0.02 mg)"

3. **DAY STICKER** (To be affixed to the Fold-over dose card – 21 and 28 Day):

   Satisfactory in final print.

4. **SLEEVE** (To contain the fold-over dose card– 21 and 28 Day):

   a. 21- Day:

      Satisfactory in draft.

   b. 28- Day:

      Revise the "Each tablet contains..." statement to read: "Twenty-one pink tablets, each containing 0.1 mg levonorgestrel with 0.02 mg ethinyl estradiol and seven white inert tablets."

5. **CARTON** (3 x 21 and 3 x 28 Day):

   a. 21- Day:

      Satisfactory in draft.

   b. 28- Day:

      Revise "21 pink tablets contains..." to read: "21 pink tablets, each containing...", and revise "7" to read "seven".

6. **PROFESSIONAL PACKAGE INSERT** – 21 and 28 Day):

   Please refer to the attached mocked-up copy of the following pages of your insert labeling for all of the requested labeling revisions:

   05-00039, 40, 41, 42, 43, 50, 51, 52, 53, 54, 58, 60, 61,and 65.

   The remaining pages of your insert labeling that are not included in the attached mock-up, (05-00044, 45, 46, 47, 48, 49, 55, 56, 57, 59, 62, 63, 64, and 66) are satisfactory in draft.

7. **DETAILED PATIENT LABELING INSERT**– 21 and 28 Day):

   See Comment #6 above.

8. **BRIEF SUMMARY PATIENT PACKAGE INSERT**– 21 and 28 Day):

   a. See Comment #6 above.

   b. Please refer to the attached mocked-up copy of pages 05-00018, 19, 23, 24, and 25 for additional labeling revisions.

Please revise your labels and labeling, as instructed above, and submit in draft. We will not request final print pending a decision on your proposed proprietary name.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes-

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: Mocked-up copy of certain pages of the firm's insert labeling.