CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75951

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: 75-951 **Date of Submission: August 25, 2000**
Applicant's Name: Barr Laboratories, Inc.
Established Name: Norethindrone Acetate Tablets USP, 5 mg

Labeling Deficiencies:
1. CONTAINER (50's)- Satisfactory in draft.

2. PHYSICIAN'S INSERT
   a. DESCRIPTION - Revise ( ) to read "anhydrous lactose" in the last sentence of this section.
   b. PRECAUTIONS (General)-
      i. Replace the current number 6 and number seven with the following:

         6. Data suggest that progestin therapy may have adverse effects on lipid and carbohydrate metabolism. The choice of progestin, its dose, and its regimen may be important in minimizing these adverse effects, but these issues will require further study before they are clarified. Women with hyperlipidemias and/or diabetes should be monitored closely during progestin therapy.

      ii. Renumber the current number 8 and number 9 as number 7 and 8 respectively.

3. PATIENT PACKAGE INSERT - Satisfactory in draft.

Please revise your labels and labeling, as instructed above, and submit 12 copies of final printed labels and labeling.

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.

/S/

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