



NDA 21-065/S-009

Galen (Chemicals) Limited
Care of: Warner Chilcott, Inc. (U.S. Agent)
Attention: Ms. Deepa Desai, Manager, Regulatory Affairs
Rockaway 90 Corporate Center
100 Enterprise Drive, Suite 280
Rockaway, New Jersey 07866

Dear Ms. Desai:

Please refer to your supplemental new drug application dated August 21, 2002, received August 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for femhrt (norethindrone acetate/ethinyl estradiol tablets).

We acknowledge receipt of your submissions dated February 26 and March 4, 2003; and January 8, 2004.

Your submission of January 8, 2004, constituted a complete response to our December 2, 2003, action letter.

This supplemental new drug application provides for revisions to the package (professional) insert and patient package insert to add information related to the Women's Health Initiative trial (WHI) of estrogen plus progestin in postmenopausal women. The revisions update the overall labeling.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) for the patient package insert must be identical to the patient package insert submitted March 4, 2003. The FPL for the package (professional) insert must be identical to the package insert submitted January 8, 2004, except for the following changes agreed upon during the January 15, 2004, telephone conversation between you and Ms. Bronwyn Collier, Associate Director for Regulatory Affairs in the Office of Drug Evaluation III:

1. Revise the boxed warning to be identical to the text recommended in the January 7, 2003 letter, except that the reference to information about the WHI will be to the WARNINGS section rather than the PHARMACOLOGY; Clinical Studies section.
2. Delete Item 17 under PRECAUTIONS; A. General (Lipoprotein metabolism).
3. Delete the reference to information in the CLINICAL PHARMACOLOGY; Clinical Studies in item 4 under PRECAUTIONS; Drug/Laboratory Test Interactions.

These revisions are terms of the approval of this application. The approved labeling text of the package (professional) insert which includes the revisions listed above and the text of the patient package insert is attached to this letter.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-065/S-009." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

If you have any questions, call George Lyght, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel A. Shames, M.D.
Director
Division of Reproductive and Urologic Drug
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Daniel A. Shames
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