DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20264/S-017

SUPPLEMENT APPROVAL

Bristol-Myers Squibb
Attention: Angela Glauberzon
Associate Director, Mature Products
Global Regulatory Sciences
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Ms. Glauberzon:

Please refer to your Supplemental New Drug Application (sNDA) dated March 4, 2011, received March 4, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MEGACE (megesterol acetate) Oral Suspension 40 mg/mL.

We acknowledge receipt of your amendment dated October 14, 2011, which constituted a complete response to our September 2, 2011, action letter.

This "Changes Being Effected" supplemental new drug application provides for the following revisions:

1. Revision of the header "Use in HIV-Infected Women" to "Use in Women" and relocation of the section to the PRECAUTIONS section. In addition, a statement has been added to this section to state that Megace is a progesterone derivative, which may induce vaginal bleeding.
2. In this same section, the following previously approved statement has been deleted: "Although megestrol acetate has been used extensively in women for the treatment of endometrial and breast cancers, its use in HIV-infected women has been limited."
3. The following text has been added to the OVERDOSAGE section, "In post-marketing experience, limited reports of overdose have been received. Signs and symptoms reported in the context of overdose included diarrhea, nausea, abdominal pain, shortness of breath, cough, unsteady gait, listlessness, and chest pain. There is no specific antidote for overdose with MEGACE Oral Suspension. In case of overdose, appropriate supportive measures should be taken."

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY H PARKS
04/08/2012