DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-979/S-051

Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543-4000

Attention: Steven J. Knapp
Executive Director, Life Cycle Management

Dear Mr. Knapp:

Please refer to your supplemental new drug application dated June 26, 2002, received July 3, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MEGACE® (megestrol acetate tablets, USP).

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the **WARNINGS** section of the package insert as requested by the Division of Metabolic and Endocrine Drug Products in the approval of NDA 20-264/S-009 for MEGACE® (megestrol acetate) Oral Suspension dated April 9, 2002. Additionally, the supplement includes revisions to the **Storage** and **References** sections of the package insert as requested by the Division of Oncology Drug Products in the approval of NDA 16-979/S-049 dated January 31, 2001.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted June 26, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-979/S-051." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christy Wilson, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Richard Pazdur

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