DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-457/S-006
NDA 20-906/S-002

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

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

Dear Mr. Knapp:

Please refer to your supplemental new drug applications dated August 23, 2000, received August 25, 2000, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Etopophos® (etoposide phosphate) for injection, 100 mg, 500 mg and 1gram.

These supplemental new drug applications provide for draft labeling for the Geriatric Use subsection.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the August 23, 2000 labeling text with the following minor editorial revisions previously requested in the August 26, 2002 letter for NDA 20-457/S-004.

1. Add back in to the DOSAGE AND ADMINISTRATION section, Preparation for Intravenous Administration subsection as the second paragraph (we recognize this paragraph was not included in the NDA 20-906 approval letter but feel this is an important safety concern): "Solutions of ETOPOPHOS should be prepared in an aseptic manner. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit."

2. Delete "Sterile" from before "Bacteriostatic Water...: in the Stability subsection.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted August 23, 2000). These revisions are terms of the approval of these applications.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-457/S-006 AND NDA 20-906/S-002." Approval of these submissions by FDA is not required before the labeling is used.

We also remind you to update the labeling contained in NDA 20-906 (Etopophos Preservative Free-Pharmacy Pack) to reflect previously approved revisions if marketing should ever be initiated.

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

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 Ann Staten, Regulatory Project Manager, at (301) 594-0490.

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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