



NDA 020119/ S-010,011

SUPPLEMENT APPROVAL

Bristol-Myers Squibb
Attention: Angela Glauberzon
Associate Director, Mature Products
PO Box 4000
Princeton, JN 08543-4000

Dear Ms. Glauberzon:

Please refer to your Supplemental New Drug Applications (sNDA) S-010 dated and received July 15, 2010, and S-011 dated and received May 12, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vumon[®] (teniposide) Injection 10 mg/mL.

We acknowledge receipt of your amendments dated May 3, 2011; September 6, 2011; and September 14, 2011.

“Changes Being Effected” labeling supplement 010 provides for safety-related changes to the Warnings and Adverse Reactions sections of the Vumon package insert including the addition of metabolic acidosis, neurotoxicity statement, and other reactions of headache, confusion, and asthenia. Additionally, a statement to the Overdosage section for patients receiving higher than the recommended dose has been added.

“Changes Being Effected” labeling supplement 011 provides for updates to the Warnings and Adverse Reaction section to the package insert to include wording for effects on male fertility and incorporate rash as a possible symptom of an anaphylactic-type reaction, as well as sepsis as a consequence of myelosuppression.

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 Theresa Ferrara, Regulatory Project Manager, at (301) 796-2848.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

AMNA IBRAHIM
10/20/2011