



NDA 50443/S036

SUPPLEMENT APPROVAL

Bristol-Myers Squibb
Attention: Beatrice Anduze-Faris, M.D.
Group Director, Mature Products
Global Regulatory Sciences
P.O. Box 4000 (Mailstop D12-02)
Princeton, NJ 08543-4000

Dear Dr. Beatrice Anduze-Faris:

Please refer to your Supplemental New Drug Application (sNDA) dated January 05, 2007, received January 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Blenoxane (Blenoxane sulfate) sterile lyophilized bleomycin sulfate (15Unit/vial and 30Unit/vial).

We also refer to your submission on March 26, 2010, in response to our proposed changes.

This "Changes Being Effected" supplemental new drug application provides for revisions to Administration Precautions section, Stability section, REFERENCES section, and editorial revisions.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
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 Lisa Skarupa, Regulatory Project Manager, at (301)796-2219.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling (Package Insert)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50443	SUPPL-36	BRISTOL MYERS SQUIBB CO PHARMACEUTICA L RESEARCH INSTITUTE	BLENOXANE

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
05/10/2010
For Dr Robert Justice