



NDA 20-855

Bristol-Myers Squibb
Pharmaceutical Research Institute
Attention: Susan H. Behling
Director, Regulatory Science
Worldwide Regulatory Affairs
5 Research Parkway - P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Behling:

Please refer to your new drug application (NDA) dated September 20, 2001, received September 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mesnex (mesna) Tablets.

We acknowledge receipt of your submissions dated August 24, 2001; September 24, and 27, 2001; October 2, 5, 8, 22, 25, and 29, 2001; February 13, and 22, 2002; March 4, and 12, 2002. Your submission of September 20, 2001 constituted a complete response to our March 25, 1998 action letter.

This new drug application provides for the use of Mesnex (mesna) Tablets as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis.

We have completed the review of this application, as amended, 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 enclosed labeling text. Accordingly, the application is approved effective on March 21, 2002.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 20-855." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We waived the pediatric study requirement for this action on this application on August 14, 2001.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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 Debra Vause, B.S.N., Regulatory Project Manager, at (301) 594-5724.

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

Enclosure

**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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