



NDA 12-142/S-107

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

Attention: Eileen Connolly
Associate Director, Global Regulatory Sciences- CMC

Dear Ms. Connelly:

Please refer to your supplemental new drug application dated June 30, 2003, received July 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CYTOXAN® (cyclophosphamide for injection, USP).

We also acknowledge receipt of your submission dated October 31, 2003, received November 3, 2003.

This supplemental new drug application provides for a new sterile, dry powder formulation of Cytoxan without any added excipient.

We completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted June 30, 2003, immediate container and carton labels submitted October 31, 2003).

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 12-142/S-107." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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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 Christy Cottrell, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

{See appended electronic signature page}

Richard Lostritto, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry I
Office of New Drug Chemistry
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/

Haripada Sarker
11/7/03 09:50:26 AM
Signing for Richard Lostritto, Ph.D.