NDA 16-295/S-034

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

04 APR 2001

Attention: Joseph A. Linkewich, Pharm.D.
Director, FDA Liaison and Global Strategy Unit, Regulatory Science

Dear Dr. Linkewich:

Please refer to your supplemental new drug application dated March 26, 2001, received March 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HYDREA and DROXIA (hydroxyurea capsules, USP).

Your submission of March 26, 2001, constituted a complete response to our August 10, 2000, action letter.

This supplemental new drug application provides for modification of the WARNINGS, Pregnancy section of the package inserts.

We have completed the review of this supplemental 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 submitted final printed labeling (package insert submitted March 26, 2001, patient package insert submitted March 26, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christy Wilson, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research