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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

16-295/S-036

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-295/S-036

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

Attention: Steven J. Knapp
Executive Director, Life Cycle Management

Dear Mr. Knapp:

Please refer to your supplemental new drug application dated August 20, 2002, received August 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Droxia® (hydroxyurea capsules, USP).

We acknowledge receipt of your submissions dated September 19, 2002, and February 19, March 5, March 19, May 14, May 16, and May 20, 2003.

This supplemental new drug application provides for revisions to the labeling based on data obtained from a Phase 4 commitment study to determine the influence of renal impairment on the pharmacokinetics of hydroxyurea in adults with sickle cell disease.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

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 16-295/S-036." 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

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 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
6/26/03 03:49:44 PM