



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-295/S-039
NDA 16-295/S-036 FA

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

Attention: Steven J. Knapp
Executive Director, Global Regulatory Sciences

Dear Mr. Knapp:

Please refer to your supplemental new drug application dated December 16, 2005, received December 19, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrea® and Droxia® (hydroxyurea) Capsules, 200 mg, 300 mg, 400 mg, and 500 mg.

This supplemental new drug application provides for revisions to the labeling to add text describing cutaneous vasculitic toxicity and safe handling instructions to both the Hydrea® and Droxia® labeling, and to add skin ulcer text to the Droxia® Patient Information leaflet.

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

We also refer to your submission dated June 21, 2004, received June 29, 2004, containing final printed labeling in response to our June 26, 2003, letter approving S-036 for Hydrea® and Droxia®. We have reviewed the labeling that you submitted in accordance with our June 26, 2003, letter and we find it acceptable.

The final printed labeling (FPL) must be identical to the submitted labeling (package inserts for Hydrea® and Droxia® and patient package insert for Droxia® submitted December 16, 2005).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 16-295/S-039.**" Approval of this submission by FDA is not required before the labeling is used.

Submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the submitted labeling dated December 16, 2005. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-1347.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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/

Ann Farrell
9/19/2006 08:56:04 AM
Farrell for Justice