



NDA 016295/S-040

**SUPPLEMENT APPROVAL**

Bristol-Myers Squibb  
Attention: Beatrice Anduze-Faris, M.D.  
Group Director, Mature Products  
Global Regulatory Sciences  
P.O. Box 4000 (Mailstop D12-02)  
Princeton, NJ 08543-4000

Dear Dr. Beatrice Anduze-Faris:

Please refer to your Supplemental New Drug Application (sNDA) dated April 24, 2007, received April 24, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DROXIA® (hydroxyurea capsules, USP) 200 mg, 300 mg, 400 mg and HYDREA® (hydroxyurea capsules, USP) 500 mg.

We also refer to your submissions dated July 1, 2008 and April 30, 2010.

This “Changes Being Effected” supplemental new drug application adds hepatotoxicity text in the WARNINGS and PRECAUTIONS section, revises the REFERENCES section, provides editorial corrections, and removes the Bristol-Myers Squibb Oncology logo.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B-05  
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 Lisa Skarupa, Regulatory Project Manager, at (301)796-2219.

Sincerely,

*{See appended electronic signature page}*

Robert L. Justice, M.D., M.S.  
Director  
Division of Drug Oncology Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-16295	SUPPL-40	BRISTOL MYERS SQUIBB CO	DROXIA

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

/s/

ROBERT L JUSTICE  
05/07/2010