DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-512/S-044
NDA 50-527/S-020
NDA 50-528/S-018

Bristol-Myers Squibb Company
Attention: Joseph A. Linkewich, Pharm.D.
Director, FDA Liaison and Global Strategy Unit, Regulatory Science
P.O. Box 4000
Princeton, NJ 08453-4000

Dear Dr. Linkewich:

Please refer to your supplemental new drug applications dated September 20, 2001, received Sepember 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duricef® (cefadroxil monohydrate, USP) Capsules, 500 mg (NDA 50-512/S-044); Duricef® (cefadroxil monohydrate, USP) Oral Suspension, 125, 250, or 500 mg/5 mL (NDA 50-527/S-020); and Duricef® (cefadroxil monohydrate, USP) Tablets, 1 gram (NDA 50-528/S-018). We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section in accordance with the Final Rule entitled "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs: Addition of 'Geriatric Use' Subsection in the Labeling".

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

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

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-512/S-044, 50-527/S-020, 50-528/S-018." Approval of these submissions by FDA is not required before the labeling is used.

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 LTJG Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

5/3/02 01:30:03 PM