DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-664/S-024
50-665/S-024

Bristol-Myers Squibb Company
Attention: Lori A. DeVore
Associate Director, Global Regulatory Strategy
5 Research Parkway
Wallingford, CT 06492

Dear Ms. DeVore:

Please refer to your supplemental new drug applications dated March 12, 2007, received March 19, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

- CEFZIL® (cefprozil) Tablets (NDA 50-664)
- CEFZIL® (cefprozil) for Oral Suspension (NDA 50-665)

These "Changes Being Effected" supplemental new drug applications provide for revisions to the package inserts to include information relative to recent epidemiologic and scientific data regarding *Clostriduim difficile* associated disease (CDAD).

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 13, 2007.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 J. Christopher Davi, MS Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on March 12, 2007

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

/s/

Kathrine Laessig
9/14/2007 12:58:03 PM