DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-512/S-046
50-527/S-022
50-528/S-020

Warner Chilcott Company, Inc.
Attention: Deepa B. Desai, MS
Senior Manager, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Desai:

Please refer to your supplemental new drug applications dated April 27, 2007, received May 1, 2007 and May 2, 2007 (NDA 50-528/S-020), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

- NDA 50-512/S-046: Duricef® (cefadroxil monohydrate, USP) Capsules, 500 mg
- NDA 50-527/S-022: Duricef® (cefadroxil monohydrate, USP) Oral Suspension, 125 mg/5 mL, 250mg/5 mL, and 500 mg/5 mL
- NDA 50-528/S-020: Duricef® (cefadroxil monohydrate, USP) Tablets, 1 g

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 "Changes Being Effected" supplemental new drug applications provide for revisions to the Duricef® package insert, in the WARNINGS section as well as the PRECAUTIONS/Information for Patients subsection. These revisions were requested by the Agency in a letter to you dated October 27, 2006, and are associated with the potential risks of contracting *Clostridium difficile* associated disease (CDAD) as a result of antimicrobial therapy.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling submitted on April 27, 2007. These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 50-512/S-046, 50-527/S-022, and 50-528/S-020.**" Approval of these submissions 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
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, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on May 1, 2007

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

6/5/2007 08:50:06 AM