DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-512/S-045
NDA 50-527/S-021
NDA 50-528/S-019

Warner Chilcott
A Division of Galen (Chemical) Limited
Attention: Deepa Desai
Manager, Regulatory Affairs
Rockaway 80 Corporate Center
100 Enterprise Drive, Suite 280
Rockaway, NJ 07866

Dear Ms. Desai:

Please refer to your supplemental new drug applications dated June 9, 2003, received June 18, 2003 (NDA 50-528/S-019) and July 8, 2003 (NDA 50-512/S-045 and NDA 50-527/S-021), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duricef® (cefadroxil monohydrate, USP) Capsules (NDA 50-512), Duricef® (cefadroxil monohydrate, USP) Oral Suspension (NDA 50-527), and Duricef® (cefadroxil monohyrate, USP) (NDA 50-528). 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 applications, submitted as "Supplement - Changes Being Effected in 30 days" supplements, propose changes to be in compliance with the systemic antibacterial drug products labeling regulations as found in 21 CFR 201.24.

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 copies of the final printed labeling (FPL) electronically 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 supplements NDA 50-512/S-045, NDA 50-527/S-021 and NDA 50-528/S-019." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about these drug products (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 these NDAs 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 LT 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: labeling

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

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