DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-685/S-011
50-686/S-014

Shionogi USA, Inc.
Attention: Michael Macalush
Senior Director, Regulatory Affairs
100 Campus Drive, Suite 105
Florham Park, NJ 07932

Dear Mr. Macalush:

Please refer to your supplemental new drug applications dated July 30, 2008, received July 31, 2008, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for the following:

- CEDAX® (ceftibuten capsules) 400 mg (NDA 50-685)
- CEDAX® (ceftibuten for oral suspension) 18 mg/mL (NDA 50-686)

We also acknowledge receipt of your submissions dated August 27, 2008.

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 the addition of "Stevens-Johnson Syndrome" to the Post-marketing subsection of the ADVERSE EVENTS section, and the deletion of the (b) (4) bottle of CEDAX® (ceftibuten for oral suspension) 18 mg/mL formulation, along with other minor changes.

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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the labels submitted July 30, 2008 and August 27, 2008. Upon receipt, we will transmit these versions to the National Library of Medicine for public dissemination. For administrative purposes, designate these submissions "SPL for approved supplements NDA 50-685/S-011 and NDA 50-686/S-014."

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
Suite 12B05
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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Attachment: Label submitted August 27, 2008.

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

/s/

Sumathi Nambiar

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