DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-560/S-051
NDA 50-589/S-013

Fujisawa Healthcare, Inc.
Attention: Marilyn Bergland
Manager, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015-2548

Dear Ms. Bergland:

Please refer to your supplemental new drug applications dated February 23, 2004, received February 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cefizox® (ceftizoxime for injection), NDA 50-560 sterile powder and Cefizox® (ceftizoxime for injection), NDA 50-589, frozen premixed solution in Galaxy container. This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We also refer to your submission dated June 25, 2002, received July 1, 2002.

These supplemental new drug applications provide for revisions to the label in response to the Final Rule entitled **"Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use"** (68FR 6062, February 6, 2003), and also address the deficiencies outlined in the Approvable letter dated September 27, 2001.

We completed our review of these applications, and they are approved, effective on the date of this letter. However, in order to update the Microbiology subsection of the Cefizox® label, it is recommended that a separate labeling supplement be submitted to address the following:

- In the **"Anaerobic Techniques"** heading, the text with strikethrough should be deleted:

    1. "~~Agar dilution results can vary widely when using this antibiotic~~ ceftizoxime~~. It is recommended that broth microdilution method be used when possible~~." [4-3].

    2. **MIC (µg/mL)**
    ~~Broth dilution~~
    ~~≤ 16~~
    ~~32~~
    ~~≥ 64~~

- In the **"Susceptibility Testing for Pseudomonas in Urinary Tract Infections"** heading, the entire heading and text with strikethrough should be deleted as follows:

~~**"Susceptibility Testing for Pseudomonas in Urinary Tract Infections"**~~
~~Most strains of *Pseudomonas aeruginosa* are moderately susceptible to ceftizoxime. Ceftizoxime achieves high levels in the urine (greater than 6000 mcg/mL at 2 hours with 1 gram IV) and, therefore, the following zone sizes should be used when testing ceftizoxime for treatment of urinary tract infections caused by *Pseudomonas aeruginosa*.~~

~~Susceptible organisms produce zones of 20 mm or greater, indicating that the test organism is likely to respond to therapy.~~

~~Organisms that produce zones of 11 to 19 mm are expected to be susceptible when the infection is confined to the urinary tract (in which high antibiotic levels are attained).~~

~~Resistant organisms produce zones of 10 mm or less, indicating that other therapy should be selected."~~

- In the **"REFERENCES"** section, the text should be updated to read as follows:

1. National Committee for Clinical Laboratory Standards. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically – Sixth Edition. Approved Standard NCCLS Document M7-A6, Vol. 23, No. 2, NCCLS, Wayne, PA, January 2003.

2. National Committee for Clinical Laboratory Standards. Performance Standards for Antimicrobial Disk Susceptibility Tests – Eighth Edition. Approved Standard NCCLS Document M2-A8, Vol. 23, No. 1, NCCLS, Wayne, PA, January 2003.

3. National Committee for Clinical Laboratory Standards. Methods for Antimicrobial Susceptibility Testing for Anerobic Bacteria – Fifth Edition. Approved Standard NCCLS Document M11-A6, Vol. 24, No. 2, NCCLS, Wayne, PA, January 2004.

4. National Committee for Clinical Laboratory Standards. MIC Testing Supplemental Tables. NCCLS Document M 100-S13 (M7), NCCLS, Wayne, PA, January 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 50-560/S-051 and NDA 50-589/S-013." 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, HFD-410
FDA
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, Regulatory Project Manager, at (301) 827-2217.

Sincerely,

{See appended electronic signature page}

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

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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