



NDA 50-588/S-027

AstraZeneca Pharmaceuticals LP
Attention: Lynley K. Thinnes
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Thinnes:

Please refer to your supplemental new drug application dated October 11, 2000, received October 12, 2000, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cefotan® (cefotetan disodium) for Injection. 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 acknowledge receipt of your submission dated October 21, 2002 in response to our May 24, 2002 approvable letter.

This supplement propose the following changes: The addition of a paragraph that provides pharmacokinetic information for the elderly under the **CLINICAL PHARMACOLOGY** section, and the addition of a *Geriatric Use* subsection under the **PRECAUTIONS** section in order to comply with the Final Rule on Geriatric Labeling.

We have completed our review of this supplemental new drug application, it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 21, 2002.

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, 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 LTJG 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

**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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