

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-684 / S-045

50-750 / S-012

ADMINISTRATIVE DOCUMENTS

AND

CORRESPONDENCE



NDA 50-684/S-045
NDA 50-750/S-012

PRIOR APPROVAL SUPPLEMENT

Wyeth Pharmaceuticals
Attention: David Urquhart
Senior Regulatory Specialist
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Urquhart:

We have received your supplemental drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Products: ZOSYN[®] (piperacillin and tazobactam for injection)(NDA 50-684)
ZOSYN[®] (piperacillin and tazobactam for injection) in Galaxy[®]
Containers(NDA 50-750)

Supplement Numbers: 50-684/S-045, 50-750/S-012

Date of Supplements: May 27, 2005

Date of Receipt: May 31, 2005

These supplemental applications, submitted as "Prior Approval Supplement" provide for reformulation of the drug product and labeling changes.

Unless we notify you within 60 days of our receipt date that the applications are not sufficiently complete to permit a substantive review, these applications will be filed under section 505(b) of the Act on July 29, 2005.

Send all electronic or mixed electronic and paper submissions to the Central Document Room at the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

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If your submission only contains paper, send it to the following address:

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products
Attention: Document Room
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any question, call Susmita Samanta, Regulatory Project Manager, at (301) 827-2128.

Sincerely,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective and Ophthalmology
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/

Frances LeSane
7/21/05 07:36:44 PM