CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-711/S-009
50-710/S-011

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: May 17, 2002

TO: NDA 50-710/S-011, Zithromax Oral Suspension
NDA 50-711/S-009, Zithromax Tablets, 250 mg
NDA 50-784, Zithromax Tablets, 500 mg

FROM: Judit Milstein, Regulatory Project Manager
Division of Anti-Infective Drug Products

SUBJECT: **Labeling for supplements is incorporated into labeling for NDA 50-784**

NDA 50-710/S-011, and 50-711/S-009, were submitted February 7, 2001, as part of a bundled supplement that also includes NDA 50-670/S-018, 50-693/S-006, 50-730/S-008 and 50-733/S-007.

These supplements provide for removal of reference to the previously available capsule formulation, revisions to the renal and hepatic clearance data, addition of new pharmacokinetic data to support the dosing in pediatric patients in the fed state, addition of results of drug-drug interactions studies, and editorial changes.

Review completed by the PK reviewer, dated May 17, 2002, addresses all the supplements.

NDA 50-710 and 50-711 have a common label. Considering that NDA 50-784 pertains to the 500 mg tablets, proposed changes for the labeling supplements as delineated in the PK review, were incorporated into the label for NDA 50-784. As a consequence, NDA 50-710, 50-711, and 50-784 have a common label, that includes harmonized PK information, as well as labeling derived from the review of NDA 50-784.

No action is taken at this time on NDA 50-670/S-018, 50-693/S-006, 50-730/S-008 and 50-733/S-007.

The Agency requested the sponsor to modify the CLINCAL PHARMACOLOGY and PRECAUTIONS-Drug Interactions sections of the label for the remaining supplements based on the template provided in the labeling for NDA 50-784. This request was discussed with the sponsor at a telecon on May 21, 2001.

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

/s/

Judit Milstein
5/24/02 03:29:22 PM
CSO

Frances LeSane
5/24/02 03:43:05 PM
CSO

John Alexander
5/24/02 03:51:02 PM
MEDICAL OFFICER

Project Manager Meomorandum for azithromycin labeling supplements

Janice Soreth
5/24/02 04:04:32 PM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-711/S-009

PRIOR APPROVAL SUPPLEMENT

Pfizer Pharmaceuticals
Attention: Mr. Victor Clavelli
Director, Drug Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Mr. Clavelli:

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

Name of Drug Product: Zithromax® (azithromycin) Tablets

NDA Number: 50-711

Supplement Number: S-009

Date of Supplement: February 7, 2001

Date of Receipt: February 8, 2001

This supplement provides for changes into five categories the removal of references previously available in the capsules formulation, results drug-drug interaction studies, data in renally and hepatically impaired patients, data in support the dosing of Zithromax (azithromycin for oral suspension) the fed state, minor editorials corrections.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products,
HFD-520
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products,
HFD-520
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Jose R. Cintron, R.Ph., M.A., Sr. Regulatory Management Officer/Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

/s/

Jose Cintron
4/2/01 07:18:42 AM