

NDA 50-605/S-032
NDA 50-672/S-014

Glaxo Wellcome Inc.
Attention: Anne N. Stokley, M.S.P.H.
Product Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Stokley:

Please refer to your supplemental new drug applications dated September 14, 1998, received September 15, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceftin® (cefuroxime axetil) Tablets (NDA 50-605) and Ceftin® (cefuroxime axetil) for Oral Suspension (NDA 50-672). We note that 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 submissions dated March 18, 1999, July 21, 1999, and August 10, 1999.

These supplemental new drug applications provide for the use of Ceftin® (cefuroxime axetil) Tablets and Oral Suspension for the treatment of acute bacterial maxillary sinusitis in pediatric patients as follows:

1. In the **Pediatric Use** subsection of the **PRECAUTIONS** section, addition of the following sentences:

“The safety and effectiveness of CEFTIN have been established for pediatric patients aged 3 months to 12 years for acute bacterial maxillary sinusitis based upon its approval in adults. Use of CEFTIN in pediatric patients is supported by pharmacokinetic and safety data in adults and pediatric patients, and by clinical and microbiological data from adequate and well-controlled studies of the treatment of acute bacterial maxillary sinusitis in adults and of acute otitis media with effusion in pediatric patients. It is also supported by post-marketing adverse events surveillance. (See **CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION, and CLINICAL STUDIES**).”

2. In the **DOSAGE AND ADMINISTRATION** section, addition of dosing information for pediatric patients (who can swallow tablets whole) as follows:

“Acute bacterial maxillary sinusitis, 250 mg b.i.d., 10 days”

3. In the **DOSAGE AND ADMINISTRATION** section, addition of dosing information for

pediatric patients (3 months to 12 years) using oral suspension as follows:

“Acute bacterial maxillary sinusitis, 30 mg/kg/day divided b.i.d., 1000 mg daily maximum dose, 10 days”

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). However, in accordance with the final rule for “Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of ‘Pediatric Use’ Subsection in the Labeling”, published December 13, 1994, please replace the words “children” or “infants and children” with the words “pediatric patients” in the **DOSAGE AND ADMINISTRATION** section your labeling. Please include these revisions in your FPL submission.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-605/S-032, 50-672/S-014." Approval of these submissions by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have fulfilled the pediatric study requirement at this time.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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, contact Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure