



NDA 50-605/S-031  
NDA 50-672/S-013

GlaxoSmithKline  
Attention: Anne Stokley, M.S.P.H.  
Product Director, Regulatory Affairs  
5 Moore Drive  
Research Triangle Park, NC 27709

Dear Ms. Stokley:

Please refer to your supplemental new drug applications dated May 14, 1998, received May 15, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceftin® (cefuroxime axetil) tablets (NDA 50-605/S-031) and Ceftin® (cefuroxime axetil powder) for oral suspension (NDA 50-672/S-013). We note that these applications are 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 January 7, 2000.

These supplemental new drug applications provide for the following;

1. The addition of increased prothrombin time, hepatic impairment including hepatitis and cholestasis, seizure, and renal dysfunction to the **ADVERSE REACTIONS, POSTMARKETING EXPERIENCE WITH CEFTIN PRODUCTS** subsection;
2. The following statements were added to the **General** subsection under **PRECAUTIONS**:  

"Cephalosporins may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated."
3. The **Carcinogenesis, Mutagenesis, Impairment of Fertility** and **Pregnancy** subsections under **PRECAUTIONS** were updated.

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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

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The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 7, 2000). These revisions are terms of the approval of these applications.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. 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 supplements NDA 50-605/S-031, 50-672/S-013." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, 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

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/s/

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Janice Soreth  
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