



ANDA 77-989

Baxter Healthcare Corporation  
Anesthesia and Critical Care  
Attention: Eleanor Lescano  
Regulatory Affairs Specialist  
2 Esterbrook Lane  
Cherry Hill, NJ 08003-4099

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 15, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fosphenytoin Sodium Injection USP, 50 mg PE/mL (75 mg/mL), packaged in 100 mg PE/2 mL, and 500 mg PE/10 mL single-dose vials. [PE = phenytoin sodium equivalents].

Reference is also made to your amendment dated June 14, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Fosphenytoin Sodium Injection USP, 50 mg PE/mL (75 mg/mL), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Cerebyx Injection, 50 mg PE/mL (75 mg/mL), of Parke Davis.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these

submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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

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Gary Buehler

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