



NDA 50-638/S-012

Baxter Healthcare Corporation  
Attn: Vicki L. Drews  
Director, Global Regulatory Affairs  
1620 Waukegan Road  
McGaw Park, IL 60085

Dear Ms. Drews:

Please refer to your supplemental new drug application dated March 13, 2007, received March 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Penicillin G Potassium Injection. We acknowledge receipt of your submission dated February 28, 2008. This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application has been submitted in response to an Agency letter requesting an update to the multiple sections of the labeling concerning *Clostridium difficile* associated diarrhea and an update on the microbiology breakpoints.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling text for the package insert submitted in the letter dated February 28, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 50-638/S-012."

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
10903 New Hampshire Avenue  
Building 22, Room 4447  
Silver Spring, MD 20903

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Maureen Dillon-Parker, Chief, Project Management Staff, at (301) 796-0706.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.  
Acting Director  
Division of Anti-Infective and  
Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure: Labeling text

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

/s/

-----  
Wiley Chambers  
3/1/2008 09:25:23 PM