



NDA 17-037/S-158

Baxter Healthcare Corporation  
Attention: Valerie Shinault  
Regulatory Affairs Associate  
2 Esterbrook Lane  
Cherry Hill, NJ 08003-4099

Dear Ms. Shinault:

Please refer to your supplemental new drug application dated October 28, 2005, received October 31, 2005, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium Injection USP.

We acknowledge receipt of your submissions dated June 19 and September 15, 2006.

Your submission of June 19, 2006 constituted a complete response to our April 28, 2006 action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to strengthen the **WARNINGS** sections in the Heparin Sodium Injection, USP, Hep-Lock (Heparin Lock Flush Solution, USP), and Hep-Lock U/P Preservative-Free (Heparin Lock Flush Solution, USP) package inserts.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below and indicated in the enclosed labeling.

In the **WARNINGS** section, **Thrombocytopenia** subsection of the package insert, in the first sentence that begins "Thrombocytopenia has been reported . . ." revise the phrase "0 to 30%" to read "up to 30%" so that the sentence reads "Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of up to 30%."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert, and submitted labeling submitted June 19, 2006). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 17-037/S-158.**" Approval of this submission by FDA is not required before the labeling is used.

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  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 Diane Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

*{See appended electronic signature page}*

George Mills, M.D.  
Director  
Division of Medical Imaging and Hematology  
Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

Enclosure

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

/s/

-----  
George Mills  
10/4/2006 09:05:34 PM