



NDA 17-037/S-154/S-155/S-156

Baxter Healthcare Corporation
Attention: Sandra P. Bobila
Manager
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Ms. Bobila:

Please refer to your supplemental new drug applications dated October 8, 2004, received October 12, 2004, submitted 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 January 27 and May 12, 2005.

Your submission of May 12, 2005 constituted a complete response to our February 11, 2005 action letter.

These supplemental new drug applications provide for the following:

Supplement SCS-154 provides for (b) (4)

Supplement SCF-155 provides for formulation revision of the Hep-Lock U/P drug product and labeling changes.

Supplement SCP-156 provides for closure change from (b) (4)

The supplements proposed to revise the **DESCRIPTION, INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS, DOSAGE AND ADMINISTRATION** and **HOW SUPPLIED** sections of the PI, and revise the immediate container and carton labeling to reflect the change of sponsor and make additional editorial revisions.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted May 12, 2005, immediate container and carton labels submitted May 12, 2005).

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 these submissions "**FPL for approved supplement NDA 17-037S-154/S-155, S-156.**" Approval of these submissions by FDA is not required before the labeling is used.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Ms. Diane Moore, Regulatory Project Manager, at (301) 827-7476.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Division Director
Division of Gastrointestinal and Coagulation Drug
Products (HFD-180)
Office of Drug Evaluation III
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/

Kathy Robie-Suh
9/2/2005 09:55:09 AM
signing for Dr. Joyce Korvick