DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-037/S-162

Baxter Healthcare Corporation
Attention: J. Barton Kalis
Director, Global Regulatory Affairs
2 Esterbrook Lane
Cherry Hill, New Jersey 08003-4099

Dear Mr. Kalis:

Please refer to your supplemental new drug application (sNDA) dated August 20, 2008, received August 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium Injection, USP.

This supplemental new drug application proposes the addition of your trademark "Clear ID" to your immediate container label. We have completed our review of this application. This application is 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 submitted labeling (immediate container labels submitted August 20, 2008).

In approving this application, we would like to emphasize the following:

1) Approval of this application does not constitute an endorsement of the (b) (4) nor agreement or endorsement of your characterization of certain drugs as (b) (4) drugs, as evidenced in the annotated labeling submitted with your application.

2) When utilized in advertising or promotional materials, you must exercise caution not to use the "Clear ID/"TM" terminology or (b) (4) in a promotional or misleading manner

To address this concern:

Submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and the package inserts 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 20705-1266

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
Suite 12B05
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 questions, contact Marcus Cato, Regulatory Project Manager, at (301) 796-3903.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, MD
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Immediate Container Label

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

/s/

Rafel Rieves

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