



NDA 16-682/S-096

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Attention: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated May 23, 2002, received May 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lactated Ringer's Injection.

Reference is also made to the June 6, 2003, telephone conversation between Mark Kopulos, Regulatory Associate, of your company and Ms. Parinda Jani of this Division.

This "Changes Being Effected" supplemental new drug application provides for a revised **ADVERSE REACTIONS** section of the package Insert.

We have completed our review of this supplemental new drug application and it is approved effective on the date of this letter.

As agreed to by Mr. Kopulos, the following changes will be made to the **ADVERSE REACTIONS** section of the package insert at the next printing.

"Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritis; periorbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing have been reported during administration of Lactated Ringer's Injection, USP. The reporting frequency of these signs and symptoms is higher in women during pregnancy."

The changes may be reported in the annual report.

We would like your prompt response to the "Information Request" letter dated June 26, 2003, to further investigate the cause of these adverse reactions.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Lisa Malandro, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Bob Rappaport
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