



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-493 / S-067

Baxter Healthcare Corporation
Route 120 & Wilson Road, RLT-10
Round Lake, Illinois 60073

Attn: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated July 16, 2002, and received July 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act Travasol and Ren Amin (Amino Acid) Injections.

This "Changes Being Effected" supplemental new drug application provides for revised PRECAUTIONS and WARNINGS sections of the package insert, revised immediate container and carton labels, and revised release and stability specifications including a test for aluminum determination with the acceptance criteria of NMT 25 µg/L of aluminum. The aluminum content statements are added in accordance with the requirements of 21 CFR 201.323.

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

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, HF-2
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 Lisa Malandro, Regulatory Project Manager, at (301) 827-7407.

Sincerely,

{See appended electronic signature page}

Bob A. 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

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/s/

Bob Rappaport
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