CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-569

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-569

Tyco Healthcare Mallinckrodt
Attention: Edward R. Porter
Manager, Regulatory Affairs
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Mr. Porter:

Please refer to your new drug application (NDA) dated September 30, 2002 received September 30, 2002 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sodium Chloride Injection, USP 0.9%.

We acknowledge receipt of your submissions dated January 26 and April 18, 2006.

The January 27, 2006 submission constituted a complete response to our July 31, 2003 action letter.

This new drug application provides for the use of Sodium Chloride Injection, USP 0.9% for use in flushing compatible intravenous administration sets and indwelling intravascular access devices.

We completed our review of this application, as amended. It 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 enclosed labeling and/or submitted labeling submitted July 10, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-569**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert 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

Please submit one market package of the drug product when it is available.

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 Lynn Henley, Regulatory Project Manager, at (301) 796-1979.

Sincerely,

{See appended electronic signature page}

Rafel Rieves, M.D.
Deputy Director
Division of Medical Imaging and
Hematology Products
Office of Oncology Drug Products
Office of New Drugs
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/

Rafel Rieves
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