DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-801/S-023

Abbott Laboratories
200 Abbott Park Road, D-389 J45-2
Abbott Park, IL 60064-6133

Attention: Surendera K. Tyagi
Associate Director, Regulatory Affairs

Dear Mr. Tyagi:

Please refer to your supplemental new drug application dated December 5, 2003, received December 8, 2003, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sterile Water for Injection, USP, in Plastic Vials.

This supplemental new drug application provides for the following changes:

1. An additional storage condition (5°C) for the 2.5 mL SWFI in 5 mL Ansyr Syringe.

2. An increase in maximum batch size to (b)(4)----------

3. A new location for marketed product stability testing (Rocky Mount, North Carolina) for the 2.5 mL SWFI in 5 mL Ansyr Syringe.

4. A change in the limit for bacterial endotoxins (b)(4)---------- to not more than 0.25 EU/mL to be consistent with nomenclature used in the USP.

5. A replacement label adhesive for the 2.5 mL SWFI in 5 mL Ansyr Syringe.

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

The final printed labeling (FPL) must be identical to the patient package insert, immediate container, and carton labels submitted on December 5, 2003.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-801/S-023." Approval of this submission by FDA is not required before the labeling is used.

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 Pratibha Rana, Regulatory Project Manager, at (301) 827-7431.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Division 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 this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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