DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-098/S-013

Abbott Laboratories
200 Abbott Park Road, D-389, J45-2
Abbott Park, IL 60064-6157

Attention: Surendera K. Tyagi, Ph.D.
Associate Director, Regulatory Affairs
Hospital Products Division

Dear Dr. Tyagi:

Please refer to your supplemental new drug application dated March 14, 2002, received March 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mivacron (mivacurium chloride) injection.

We acknowledge receipt of your submissions dated March 29, May 3, 24, and 30, 2002.

The supplemental new drug application provides for Abbott Laboratories, Rocky Mountain, North Carolina, facility as an alternate manufacturing site and a change in the shape of glass vials for Mivacron injection.

We have completed the review of this supplemental application, as amended, with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical and include the minor editorial revisions indicated, to the draft labeling submitted March 14, 2002. These revisions are terms of the approval of this application.

1. There is a typographical error in the **CLINICAL PHARMACOLOGY**: Pharmacokinetics section. The subsection "Special Populations: Geriatric Patients (≤ 60 years)" should be revised to "Special Populations: Geriatric Patients (≥ 60 years)."

2. Insert the following as the fifth paragraph in the "Dear Clinician" letter.

   "Health care professionals are strongly encouraged to report any serious adverse events that occur with the use of (Drug Name) to (Abbott's Toll Free Number) or to the FDA's MedWatch program by phone (1-800-FDA-1088), fax (1-800-FDA-0178), via the MedWatch website at www.fda.gov/medwatch, or by mail (using postage-paid form) to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787."

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-098/S-013." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Kimberly Compton, Regulatory Health Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
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
6/4/02 11:03:09 AM
for C.G. McCormick, MD