DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-073/S-011

Hoffman-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Attention: Lynn DeVenezia-Tobias
Program Manager, Drug Regulatory Affairs

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated March 23, 2001, received March 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Romazicon (flumazenil) Injection.

We acknowledge receipt of your submission dated December 8, 2003.

Your submission of December 8, 2003 constituted a complete response to our June 3, 2003 action letter.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY**, **PRECAUTIONS**, **ADVERSE REACTIONS**, and **DOSAGE AND ADMINISTRATION** sections of the package insert.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 8, 2003 and attached to 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, 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 Sara Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
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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