



NDA 20-073/S-016

CBE-0 SUPPLEMENT

HLR Technology Corporation
c/o Hoffman-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Attention: Lynn DeVenezia-Tobias
Program Manager

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated April 3, 2007, received April 4, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Romazicon (flumazenil) Injection.

We acknowledge receipt of your email correspondences dated October 3 and 4, 2007.

This "Changes Being Effected" supplemental new drug application provides for modification of the **OVERDOSAGE** section of the package insert (PI).

We have completed our review of this application, as amended, and 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 text for the Package Insert.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "SPL for approved supplement NDA 20-073/S-016." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Dominic Chiapperino, Regulatory Project Manager, at (301) 796-1183.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and
Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport
10/4/2007 05:14:55 PM