DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-239/S-016 & S-017

Hoffman-La Roche Inc.
Attention: Christine Hoogmoed
Senior C.M.C. Associate
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Hoogmoed:

Please refer to your supplemental new drug applications dated May 17, 2004, received May 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kytril® Injection.

These supplemental applications provide for the following:

1. S-016 provides for a change in formulation to add a 0.1 mg/1 mL single-use vial and

2. S-017 provides for the addition of an alternate secondary packaging site in Kaiseraugst, Switzerland for the 1 mg/1 mL vial and 4 mg/4 mL vial.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the following requested minor editorial revisions listed below in double-underline:

1. The submitted draft vial label (27898742-L 5/13/04) is missing the stated volume "1" for the vial and should read as follows:

   "0.1 mg/1 mL
   Single-Use Vial"

   and be located above the drug name "Kytril®".

2. The submitted draft carton label for 1 vial (27898741-C 5/13/04) is missing the stated volume "1" for the vial size in two locations contained in the carton and should read as follows:

   "0.1 mg/1 mL"

   and be located in the middle of the front panel below the established name as well as

   "1 x 0.1 mg/1 mL"
   Single-Use Vial"

   and be located at the bottom of the front panel below the Rxonly text respectively.

3. The submitted draft carton label for 5 vials (2789XXX) is missing the stated volume "1" for the vial size in 4 locations (includes the photograph of the Kytril® vial) contained in the carton and should read as follows:

   "0.1 mg/1 mL"

   and be located in the middle of the front panel below the established name and as

   "5 x 0.1 mg/1 mL Single-Use Vials"

   and be located at the bottom of the front panel below the Rxonly text, as well as the changes in #1 above to address the changes needed to include the 1 mL vial photograph located on the right side of the front panel.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the package insert (May2004) submitted May 17, 2004, container label (27898742-L) submitted May 17, 2004, carton for 1 vial (277898741-C) submitted May 17, 2004 and carton for 5 vials (2789XXXX) submitted May 17, 2004.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

This submission should be designated "FPL for approved supplement NDA 20-239/S-016." Approval of this submission by FDA is not required before the labeling is used.

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

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Betsy Scroggs, Pharm.D., Consumer Safety Officer at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
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/

Joyce Korvick
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