DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-239/S-018

Hoffman-La Roche, Inc.
Attention: Anthony Corrado
Director of Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

Dear Mr. Corrado:

Please refer to your supplemental new drug application dated September 1, 2004, received September 8, 2004, submitted section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kytril® (granisetron) Injection.

We acknowledge receipt of your submissions dated March 2, 2005 and May 20, 2005.

Your submission of May 20, 2005 constituted a complete response to our March 8, 2005 action letter.

This supplemental new drug application provides for revisions to the Package Insert (PI), PRECAUTIONS section, Drug Interactions subsection.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

In the CLINICAL PHARMACOLOGY, Subpopulations, Geriatric subsection you revised the subsection heading from "Geriatric" to read "Elderly." However, the rest of the paragraph should be revised for consistent language as follows:

> *"**Elderly***
>
> *The ranges of the pharmacokinetic parameters in ~~geriatric~~ elderly volunteers (mean age 71 years), given a single 40 mcg/kg intravenous dose of KYTRIL Injection, were generally similar to those in younger healthy volunteers; mean values were lower for clearance and longer for half-life in the ~~geriatric~~ elderly patients (see Table 1)."*

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling text for the Package Insert and submitted Package Insert (submitted May 20, 2005). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-239/S-018**." 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 Betsy Scroggs, Regulatory Health Project Manager, at (301) 796-0991.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Brian Harvey
11/23/2005 11:49:40 AM