**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-305/S-010, NDA 21-238/S-005

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 applications dated September 1, 2004, received September 8, 2004, submitted section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kytril® (granisetron hydrochloride) Tablets (NDA 20-305) and Kytril® (granisetron hydrochloride) Oral Solution.

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

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

These supplemental new drug applications provide for revisions to the PRECAUTIONS section, Drug Interactions subsection.

We completed our review of these applications, as amended. These applications are 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 and submitted Package Insert (submitted May 20, 2005).

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 these submissions "**FPL for approved supplement NDA 20-305/S-010 and NDA 21-238/S-005**." Approval of these submissions 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 IIICenter for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Brian Harvey
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