DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-239/S-021
NDA 20-305/S-014
NDA 21-238/S-007

SUPPLEMENT APPROVAL

Hoffmann-La Roche, Inc.
Attention: Anthony J. Corrado
Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Corrado:

Please refer to your supplemental new drug applications dated February 5, 2009, received February 6, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Supplement	Drug Product
NDA 20-239	S-021	Kytril (granisetron hydrochloride) Injection
NDA 20-305	S-014	Kytril (granisetron hydrochloride) Tablets
NDA 21-238	S-007	Kytril (granisetron hydrochloride) Oral Solution

We also refer to our August 3 and September 15, 2009, emails to you containing labeling revisions.

These "Prior Approval" supplemental new drug applications provide for revisions to the Precautions and Adverse Reactions sections of the Kytril package insert.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text enclosed, and identical to that emailed to you on September 15, 2009.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling, and that emailed to you on September 15, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-239, NDA 20-305, and NDA 21-238."

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package inserts, at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D.
Deputy Director, Safety
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert – Injection
Package Insert - Oral

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20239	SUPPL-21	HOFFMANN LA ROCHE INC	KYTRIL
NDA-20305	SUPPL-14	HOFFMANN LA ROCHE INC	KYTRIL
NDA-21238	SUPPL-7	HOFFMANN LA ROCHE INC	KYTRIL (GRANISETRON HCL) 0.2MG/ML

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/s/

JOYCE A KORVICK
10/07/2009