DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-239/S-008

Hoffman-LaRoche, Inc.
Attention: Anthony J. Corrado
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Mr. Corrado:

Please refer to your supplemental new drug application dated October 19, 2001, received October 22, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KYTRIL (granisetron HCL) Injection.

We acknowledge receipt of your submissions dated January 28, February 5, March 11, April 1, August 1, August 9, August 12, August 15, and August 16, 2002.

This supplemental new drug application provides for the use of KYTRIL (granisetron HCL) Injection for the prevention and treatment of postoperative nausea and vomiting.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-239/S-008." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on the information submitted, we conclude the following:

For the prevention of postoperative nausea and vomiting,

- We are waiving the pediatric study requirement for this action for this application for patients ages birth to two years.

- We are deferring submission of pediatric studies for patients ages 2 years to 16 years until July 22, 2005.

For the treatment of postoperative nausea and vomiting,

- We are waiving the pediatric study requirement for this action for this application for patients ages birth to two years.

- We are deferring submission of pediatric studies for patients ages 2 years to 16 years until July 22, 2005.

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, HF-2
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 Brian Strongin, R.Ph., M.B.A., Regulatory Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal & Coagulation Drug 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/

Joyce Korvick
8/16/02 02:37:18 PM
for Victor Raczkowski