



NDA 20-896/S-016

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Attention: Joanna Waugh
Director, Drug Regulatory Affairs

Dear Ms. Waugh:

Please refer to your supplemental new drug application dated August 18, 2004, received August 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for XELODA, (Capecitabine) 150 mg and 500 mg tablets.

We acknowledge receipt of your submissions dated September 23, 2004; October 20, 2004; December 17, 2004; January 24, 2005; January 31, 2005, February 18, 2005; February 24, 2005; March 10, 2005; April 21, 2005; April 22, 2005; May 24, 2005; June 1, 2005; and June 6, 2005.

This new drug application provides for the use of XELODA (Capecitabine) oral tablets as a single agent for adjuvant treatment in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred. XELODA was non-inferior to 5-fluorouracil and leucovorin (5-FU/LV) for disease-free survival (DFS). Although neither XELODA nor combination chemotherapy prolongs overall survival (OS), combination chemotherapy has been demonstrated to improve disease-free survival compared to 5-FU/LV. Physicians should consider these results when prescribing single-agent XELODA in the adjuvant treatment of Dukes' C colon cancer.

We have completed our review of this application, as amended. It 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 agreed-upon labeling (text for the package insert and text for the patient package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and (an) unapproved new drug.

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 NDA 20-896/S016.**" 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 are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We request that all patients in the XELODA Adjuvant Colon Cancer Trial (X-ACT) be followed for 5 years or until death following completion of their therapy. A final study report should be submitted to the NDA.

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, Maryland 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
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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 Carl Huntley, Regulatory Project Manager, at 301-827-1539.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products, HFD-150
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure : Package Insert
 Patient Package Insert

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

/s/

Richard Pazdur
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