DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-766/S-022

Hoffmann-La Roche, Inc.
Attention: Margaret J. Jack
Program Director
340 Kingsland Street
Nutley, NJ 07110

Dear Ms. Jack:

Please refer to your supplemental new drug application dated October 23, 2006, received October 25, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xenical (orlistat) Capsules, 120 mg.

This supplemental new drug application provides for revisions to the **General** subsection of the **PRECAUTIONS** section and to the **Other Clinical Trials or Postmarketing Surveillance** subsection of the **ADVERSE REACTIONS** section. These changes update the package insert to address post-marketing reports suggesting an association between Xenical and pancreatitis by providing information from clinical trial data on the incidence rates of choletlithiasis associated with Xenical and providing information on the association of Xenical and pancreatitis based on post-marketing reports..

We completed our review of this application and 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 labeling (package insert).

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 20-766/S-022**." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Patricia Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: draft 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/

Eric Colman
1/5/2007 02:12:46 PM
Eric Colman for Mary Parks