DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-766/S-019

Hoffman-LaRoche, Inc.
Attention: Margaret J. Jack
Program Director
340 Kingsland Street
Nutley, New Jersey, 07110-1199

Dear Ms. Jack:

Please refer to your supplemental new drug application dated December 22, 2004, received December 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xenical (Orlistat) Capsules.

We acknowledge receipt of your submissions dated December 22, 2003, June 22, July 13, August, 17, October 21, 2004.

This supplemental new drug application provides for labeling changes in the package insert to include data from the Xendos Study.

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 and with the minor editorial revisions listed below.

- Removed the unnecessary the footnote for Table 6 that reads, "orlistat - placebo"

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submissions should be designated "FPL for approved supplement NDA 20-766, S-019." 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 note that you have fulfilled the pediatric study requirement for this application.

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 Oluchi Elekwachi, PharmD, MPH, Regulatory Project Manager, at (301) 827-6381.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: PI Approved Labeling

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

/s/

David Orloff

10/22/04 10:07:30 AM