DUPLICATE

Roche

Pharmaceuticals

March 24, 1999

Food and Drug Administration
Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706

Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg
Submission of Professional Labeling

Enclosed please find a revised copy of the Professional Package Insert that is intended to replace the Professional Labeling previously submitted to the Agency on March 23, 1999.

This submission includes both the annotated version and the accepted version of the professional labeling. Also included is a diskette containing the above-mentioned files in MS Word 97.

Please feel free to contact the undersigned at the numbers provided if you have any questions regarding this submission.

Sincerely,

HOFFMANN-LA ROCHE INC.

Margaret J Jack

Margaret J. Jack
Program Director
Drug Regulatory Affairs
(973) 235-4463 (Telephone)
(973) 562-3554/3700 (Fax)

Attachment
HLR 1999-708

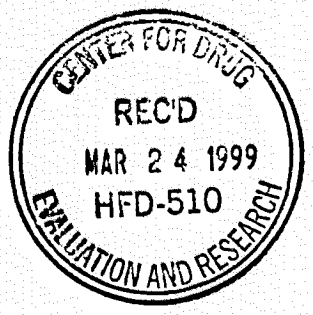
Desk Copy: Ms. Maureen Hess, CSO

BL

Roche

Pharmaceuticals

March 23, 1999



Food and Drug Administration
Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706

Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg
Submission of Professional and Patient Labeling

Reference is made to the March 22, 1999 teleconference between the Division and the Sponsor to discuss the labeling for the above-mentioned product previously provided to the Sponsor in a fax dated March 17, 1999. During that teleconference, the Sponsor agreed to send paper copies and electronic versions of the label to the Agency as soon as possible.

This submission includes the above-mentioned copies of the label we agreed to.

Please feel free to contact the undersigned at the numbers provided if you have any questions regarding this submission.

Sincerely,

HOFFMANN-LA ROCHE INC.

Margaret J. Jack

Margaret J. Jack
Program Director
Drug Regulatory Affairs
(973) 235-4463 (Telephone)
(973) 562-3554/3700 (Fax)

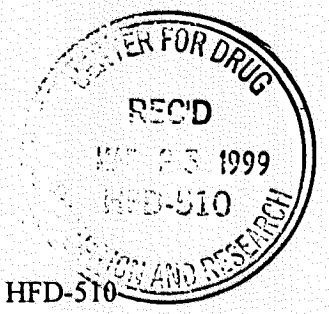
Attachment
HLR 1999-684

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

ORIGINAL NEW CORRESP

Roche

T45664



Pharmaceuticals

March 22, 1999

Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706

Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg
Narratives for Appendicitis Cases Reported in Safety Update

Reference is made to the safety update previously submitted to the Agency March 11, 1999. In that update, there were six cases of appendicitis reported in the Xendos trial. On March 18, 1999, the Agency requested the narratives for those cases. The purpose of this submission is to provide the narratives requested.

These cases of appendicitis occurred in the Xendos trial, the patients did not discontinue from the trial due to the event, the double blind code was not broken and the investigator did not consider these to be related to treatment. During the Phase 3a clinical trials, there were three cases of appendicitis, 2 cases in the Xenical treatment group and 1 in placebo treated patients.

Please contact the undersigned at the numbers provided if you have any questions regarding the data in this submission.

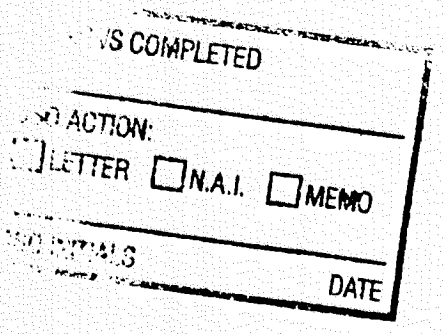
Sincerely,

HOFFMANN-LA ROCHE INC

Margaret J Jack

Margaret J. Jack
Program Director
(973) 235-4463 (telephone)
(973) 562-3700/3554 (fax)

MJJ:LS/km
Attachment
HLR No. 1999-668



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

ORIGINAL

T48026

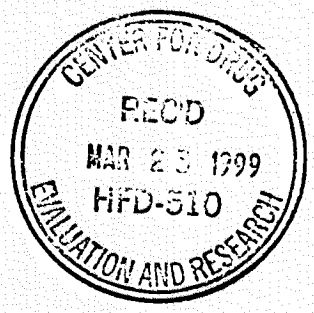
ORIG AMENDMENT

Roche

Pharmaceuticals

(rch 22, 1999

Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706



Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg
Update of Breast Cancer Information

Reference is made to the January 18, 1999 submission to the above-mentioned application, which was in response to the May 12, 1998 approvable letter and included a report entitled, "Integrated Summary of Breast Cancer Information." This report, on the aggregate data set requested in the approvable letter, provided the status of the exposure data from the Phase 3b studies and the Xendos study, and the cases of breast abnormalities and breast cancer observed in these studies as of December 31, 1998. Reference is also made to the proposal for the aggregate data set submitted October 7, 1998 and accepted by the Agency October 28, 1998. In this proposal, the Sponsor also agreed to provide monthly updates of these data. The first monthly update was provided March 2, 1999 and included the exposure data up to and including January 31, 1999. We are herewith providing the second monthly update for the exposure and (ast cancer information in the aggregate data set.

This second update includes the exposure data as of February 28, 1999 and breast cancer data as of March 17, 1999. For the Phase 3b studies, the Xenical exposure in women ≥45 years of age now exceeds the exposure in the original Phase 3a trials. Since the first monthly update with a clinical cutoff of January 31, 1999, one additional case of breast cancer in the placebo treatment group has been identified. There were no additional breast cancers reported in the Xendos study.

These findings bring the total number of breast cancer cases in the aggregate data set as of March 17, 1999 to six, five in the placebo group and one in the Xenical treatment group. Two of six cases of breast cancer were observed in women less than 45 years of age, one patient treated with Xenical (44 years of age, Phase 3b study) and one in the placebo treated group (42 years of age, Xendos study).

Please feel free to contact the undersigned at the numbers provided, if additional information is needed.

Sincerely,

HOFFMANN-LA ROCHE INC.

Margaret J Jack

Margaret J. Jack
Program Director
Drug Regulatory Affairs
(973) 235-4463 (Telephone)
(973) 562-3554/3700 (Fax)

Attachment
HLR No. 1999-669

VIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

T 46358 ORIG [illegible]MENT

Roche

Pharmaceuticals

ORIGINAL

MAR 12 1999

HFD-510

March 11, 1999

Food and Drug Administration
Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706

Ladies and Gentlemen:

4/3/99

Re: **NDA 20-766 Xenical® (orlistat) Capsules, 120 mg**
Safety Update for Post-Phase 3a Clinical Studies

Reference is made to the Agency's request for a safety update for the above-mentioned application. The Agency requested that the update include only serious adverse events and these events should be categorized into two groups--control clinical trials or post-marketing experience. The purpose of this submission is to provide the safety update requested.

This safety update report includes all serious adverse events reported following the Phase 3a studies previously included in NDA 20-766. Since the Phase 3a studies in the NDA 20-766 were completed prior to filing this application, all safety information for these studies have been previously provided to the Agency.

The serious events included in this report are the events reported in the Phase 3b studies, the Xendos study and from post-marketing experience in the countries where Xenical is currently marketed. The clinical cutoff for this data is January 31, 1999. Since Roche is providing frequent updates regarding cases of breast cancer observed in these studies, the clinical cutoff date for cases of breast cancer observed is March 1, 1999. All the serious adverse events were also compared to both the safety data in the integrated safety report for Phase 3a included in NDA 20-766 and to the draft labeling submitted January 21, 1999.

Please contact the undersigned at the numbers provided, if you have any questions regarding this report.

Sincerely,

HOFFMANN-LA ROCHE INC

Margaret J Jack

Margaret J. Jack
Program Director
(973) 235-4463 (telephone)
(973) 562-3700/3554 (fax)

MJJ:LS/km
Attachment
IND No. 1999-576

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

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

Hess

MEMORANDUM OF TELECON

DATE: March 4, 1999

APPLICATION NUMBER: NdA 20-766; Xenical (orlistat)

BETWEEN:

Name: Peggy Jack
Phone: (973) 235-4463
Representing: Hoffmann-La Roche

AND

Name: Maureen Hess, MPH, RD
Division of Metabolic and Endocrine Drug Products, HFD-510

SUBJECT: 1/6/99 Request for Waiver of Pre-Approval Reinspections

Telephone call to Peggy Jack to inform her that the Office of Compliance has waived all reinspections.

/S/ [redacted]

Maureen Hess
Consumer Safety Officer

APPEARS THIS WAY ON ORIGINAL

cc: Original NdA 20-766
HFD-510/Div. File
HFD-510/Maureen Hess

TELECON

BM

ORIGINAL

Roche

Pharmaceuticals

March 2, 1999

MAR 03 1999
HFD-510
EVALUATION AND RESEARCH

Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706

Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg
Update of Breast Cancer Information

Reference is made to the January 18, 1999 submission to the above-mentioned application, which was in response to the May 12, 1998 approvable letter and included a report entitled, "Integrated Summary of Breast Cancer Information." This report, on the aggregate data set requested in the approvable letter, provided the status of the exposure data from the Phase 3b studies and the Xendos study, and the cases of breast abnormalities and breast cancer observed in these studies as of December 31, 1998. Reference is also made to the proposal for the aggregate data set submitted October 7, 1998 and accepted by the Agency October 28, 1998. In this proposal the Sponsor also agreed to provide monthly updates on this data. The purpose of this submission is to provide the first monthly update for the exposure and breast cancer information in the aggregate data set.

This first update includes the exposure data as of January 31, 1999 and breast cancer data as of March 1, 1999. For the Phase 3b studies, the Xenical exposure in women ≥45 years of age now exceeds the exposure in the original Phase 3a trials. Since December 31, 1998, five new breast abnormalities have been identified in Phase 3b, with two of these now being confirmed as breast cancer, one patient in the Xenical treatment group and the other in placebo treatment group. There were no additional breast abnormalities or breast cancer reported in the Xendos study.

These findings bring the total number of breast cancer cases in the aggregate data set as of March 1, 1999 to five, four in the placebo group and one in the Xenical treatment group. Two of five cases of breast cancer were observed in women less than 45 years of age, one patient treated with Xenical (44 years of age, Phase 3b study) and one in the placebo treated group (42 years of age, Xendos study).

Please feel free to contact the undersigned at the numbers provided, if additional information is needed.

Sincerely,

BEST POSSIBLE

HOFFMANN-LA ROCHE INC.

Margaret J Jack

Margaret J. Jack
Program Director
Drug Regulatory Affairs
(973) 235-4463 (Telephone)
(973) 562-3554/3700 (Fax)

MJJ:LS/km
HLR No. 1999-493

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

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

Roche

Pharmaceuticals

January 25, 1999

Ms. Maureen Hess
Food and Drug Administration
Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research, Rm. 14B04
5600 Fishers Lane
Rockville, Maryland 20857-1706

Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg
FDA Request for Draft Labeling on Diskette

As per your request, enclosed please find the draft professional package insert and the draft patient package insert on a diskette that has been scanned for viruses. This text has been converted to MS Word 95 from MS Word 97, so that this file can be read from either version.

A hard copy of this information was previously sent to you on January 21, 1999.

Please feel free to contact the undersigned if you have any questions regarding this submission at the numbers provided.

Sincerely,

HOFFMANN-LA ROCHE INC

Margaret J. Jack

Margaret J. Jack
Program Director
(973) 235-4463 (telephone)
(973) 562-3700/3554 (fax)

APPEARS THIS WAY ON ORIGINAL

MJJ:LS/km
Attachment
HLR No. 1999-183

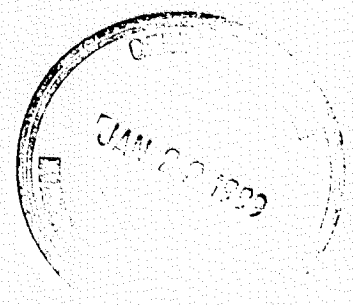
Hoffmann-La Roche Inc. 340 Kingsland Street
Nutley, New Jersey 07110-1199

Roche

Pharmaceuticals

January 21, 1999

Food and Drug Administration
Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706



Ladies and Gentlemen:

Re: **NDA 20-766 Xenical® (orlistat) Capsules, 120 mg**
Rationale and Supporting Documentation for
Draft Labeling Previously Submitted 1/18/99

Reference is made to the sponsor's submission dated January 18, 1999 which was in response to the Agency's approvable letter dated May 12, 1998 for the above-named application. The purpose of this submission is to provide the rationale and supporting documentation for the draft labeling as mentioned in the submission of January 18, 1999.

Reference is also made to sponsor's previous submissions dated July 23, 1997, February 5, 1998 and April 9, 1998 which included draft labeling (professional and patient) for this application. Since it is our understanding that these previous labeling submissions were not reviewed by the Agency, the labeling included in the submission dated January 18, 1999 and in this submission supercedes those previous labeling submissions.

Reference is also made to the Agency's faxes dated March 27, 1997, April 28, 1997, April 29, 1997 and June 27, 1997 which included comments on the early versions of the sponsor's draft labeling. We have re-reviewed the Agency's input and the labeling in both the January 18, 1999 submission and in this submission includes the Agency's recommendations delineated in these faxes.

This submission includes professional and patient labeling and supporting documentation. All the Agency's previous requests with regard to labeling have been included and addressed in this draft labeling. The Agency's faxes addressed both general comments on the label as well as specific issues on specific text included in the previous versions of the draft label. The general comments on the label are addressed in the next paragraph of this letter and the specific issues on labeling text are addressed in the section of this submission identified as "Issues (1-25)".

In the fax dated June 27, 1997 the Agency had three general comments on the labeling which included that all tables should have titles, "tid" should be replaced by "three times a day" and p-values for pooled data should be deleted. Table titles have now been included throughout the label as requested. Although "tid"can be replaced with "three times a day", we have searched the electronic PDR and find that over 160 professional packages inserts use tid or t.i.d. compared to approximately 70 PIs using three times a day. We will comply with whichever designation the Agency requires but find that "tid" has been previously acceptable to the Agency for other products. Regarding the request to remove the p-value for

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

pooled data, we also note in the June 27 fax, the Agency requested us to designate which risk factors (based on pooled analysis) are not statistically significant. We note that pravastatin included the results of a pooled analysis and the p-value for that analysis is in their approved labeling. We also note that FOSAMAX includes the term "statistically significant" when referring to a pooled analysis in their approved labeling as well. It is our opinion that to discuss statistical significance or non-significance for a pooled analysis is misleading without the corresponding p-value. Please see the "Issues" section of this submission for a further discussion of the p-value for pooled analyses. For these reasons we have retained the p-values for pooled analyses in the draft label at this time.

Specific issues on labeling text are addressed in the section of this submission identified as "Issues (1-25)". The "Issues" section of the submission cites the Agency's issue, the sponsor's suggested text, the sponsor's rationale for the suggested text and, when necessary, it also references the supporting documentation. For ease of review the professional draft labeling has **[ISSUE No.]** imbedded in the text to indicate where the Agency had previously commented on specific text. The corresponding Issue No. in the "Issue" section of the submission contains a detailed discussion and suggested resolution of the issue for the Agency's further consideration.

Please feel free to contact the undersigned if you have any questions regarding this submission at the telephone and fax numbers provided.

Sincerely,

HOFFMANN-LA ROCHE INC.

Margaret J Jack

Margaret J. Jack
Program Director
(973) 235-4463 (telephone)
(973) 562-3700/3554 (fax)

MJJ:LS/km
Attachment
HLR No. 1999-151

DUPLICATE

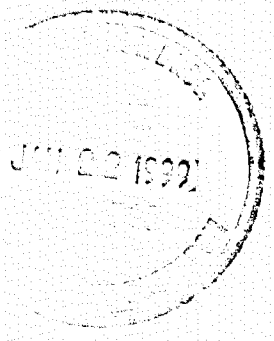
ORIG AMENDMENT

BC

Roche

Pharmaceuticals

January 21, 1999



Food and Drug Administration
Division of Metabolism and Endocrine Drug Products, HFD-150
Office of Drug Evaluation II
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20852-1706

Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules
Amendment to Pending Original NDA:
Chemistry, Manufacturing and Controls -
Revised Master Production Batch Record

Reference is made to Hoffmann-La Roche's Original New Drug Application NDA 20-766 for Xenical (orlistat) Capsules, submitted on November 26, 1996. In accordance with 21 CFR §314.60, we submit herewith a Chemistry, Manufacturing, and Controls amendment to the subject pending Original NDA. The amendment includes a revised Master Production Batch Record. All other information remains unchanged from that submitted in the Original NDA and amendments thereto.

The information contained in this amendment is CONFIDENTIAL and is not to be disclosed to any person outside the Food and Drug Administration without prior notification and written consent from Hoffmann-La Roche Inc.

In conformance with 21 CFR §314.71(b), and as indicated at the end of this letter, an identical field copy of this supplement has been prepared for simultaneous submission to the New Jersey District Office of the FDA. The undersigned hereby certifies that the copy submitted to the District Office is identical to that submitted to the Division of Metabolism and Endocrine Drug Products.

Hoffmann-La Roche Inc. hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

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

Please feel free to contact the undersigned if you have any questions concerning this amendment.

Sincerely,

HOFFMANN-LA ROCHE INC.

Virginia A. Pate

Virginia A. Pate
Program Manager
Drug Regulatory Affairs
(973) 562-3550 (telephone)
(973) 562-3700/3554 (fax)

VAP/LS:km
HLR No. 1999-148

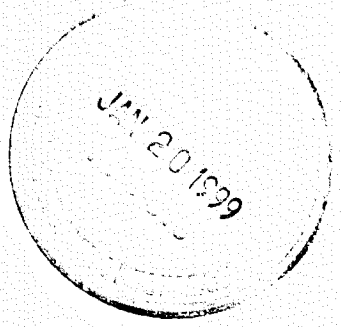
Desk Copies (s): Maureen Hess, MPH, RD

Field Copy: Ms. Regina Brown
Pre-Approval Program Director
Food and Drug Administration
120 North Central Drive
North Brunswick, NJ 08902

Roche

January 18, 1999

Food and Drug Administration
Division of Metabolism and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ATTN: DOCUMENT CONTROL ROOM 14B-19
5600 Fishers Lane
Rockville, Maryland 20857-1706



Ladies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg
Response to May 12, 1998 Approvable Letter /
Integrated Summary of Breast Cancer Information

Reference is made to the Agency-issued approvable letter for the above-mentioned application dated May 12, 1998 which states that final approval of this application is contingent upon the submission and review of additional data that support a conclusion that orlistat does not increase the risk of breast cancer. The letter further states that the data, in aggregate, should come from exposure in approximately as many women 45 years of age and older and approximately as many women-years of treatment with orlistat 120 mg t.i.d. and placebo as was in the Phase 3a controlled clinical trials. Reference is also made to the July 22, 1998 teleconference with the Division during which the size of the aggregate data set was clarified and to the Sponsor's submission of October 7, 1998 which included Roche's proposal for the aggregate data set to be provided in response to the approvable letter. On October 28, 1998, the Agency accepted the Sponsor's October 7, 1998 proposal.

The purpose of this submission is to respond to the Agency's approvable letter and provide the aggregate data set detailed in the October 7, 1998 proposal. This submission includes a report entitled "Integrated Summary of Breast Cancer Information" which provides the additional exposure data for orlistat 120 mg t.i.d. and placebo from the aggregate data set and a detailed discussion of the three cases of breast cancer observed, all of which occurred in the placebo treatment group. These findings confirm that there is no biological association between Xenical and breast cancer and that patients treated with Xenical are not at increased risk for the development of breast cancer. Proposed draft labeling for Xenical is also included in Appendix 6 of this report.

A separate submission containing the same draft labeling as included herein, but which includes the rationale, discussion and supporting documentation for the Sponsor's proposed draft labeling is being provided under a separate cover.

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

Roche

Please feel free to contact the undersigned if you have any questions regarding this submission at the numbers provided.

Sincerely,

HOFFMANN-LA ROCHE INC

Margaret J Jack

Margaret J. Jack
Program Director
(973) 235-4463 (telephone)
(973) 562-3700/3554 (fax)

MJJ:LS/km
Attachment
HLR No. 1999-125

Roche

Pharmaceuticals

uary 6, 1999

od and Drug Administration
vision of Metabolism and Endocrine Drug Products, HFD-150
ffice of Drug Evaluation II
enter for Drug Evaluation and Research
00 Fishers Lane
ockville, Maryland 20852-1706

adies and Gentlemen:

Re: NDA 20-766 Xenical® (orlistat) Capsules, 120 mg / Ro 18-0647
New Correspondence – Request for Waiver of Pre-Approval Reinspections

Reference is made to Hoffmann-La Roche's Original New Drug Application NDA 20-766 for Xenical (orlistat) Capsules, submitted on November 26, 1996, withdrawn on August 27, 1997, and resubmitted on November 14, 1997. In addition, an approvable letter for this application was issued May 12, 1998 and the sponsor will be responding to that letter during January 1999. Based upon the following summary of FDA inspections at Xenical-related manufacturing facilities, we herewith request a waiver of any reinspections at these facilities as a condition of approval for the pending NDA.

The inspections for each of the manufacturing sites submitted in NDA 20-766 are summarized in Attachment I. In addition to the pre-approval inspection for the manufacture of Xenical capsules in March 1997, Roche Nutley was most recently inspected in the 2nd Quarter 1998 for other capsule products and found to comply with CGMPs. The inspection for the active pharmaceutical ingredient (API), orlistat, at Roche Basel is current. Only the [redacted] sites for the [redacted] have not been inspected within two years. However, after [redacted] the API is returned to Basel for testing and release prior to shipment to Roche Nutley. Roche Nutley then manufactures Xenical capsules. Inspections of the final intermediate manufacturing facilities are also current until March 1999.

As we anticipate that the Agency may find this application approvable in the 1st or 2nd Quarter of 1999, we believe that final approval should not be delayed for reinspections at sites already found to be acceptable by FDA. In fact, Section 505(b)(4)(F) of the Food and Drug Administration Modernization and Accountability Act of 1997 states that no action of the reviewing division may be delayed based on the results of a pre-approval inspection or other information from field personnel, or the lack of information from the field (such as delays in conducting such an inspection), unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

As outlined in this correspondence, compliance with CGMPs has been demonstrated for the primary manufacturing sites, and particularly the Roche sites responsible for quality control and release of the drug substance and drug product. Based on the information provided, reinspection of the manufacturing facilities for Xenical should be waived so as not to delay approval of NDA 20-766.

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

Please feel free to contact the undersigned at (973) 562-3550 if you have any questions concerning this correspondence.

Sincerely,

HOFFMANN-LA ROCHE INC.

Margaret Jack for

Virginia A. Pate
Program Manager
Drug Regulatory Affairs
(973) 562-3550 (telephone)
(973) 562-3700/3554 (fax)

VAP/LS:km
HLR No. 1999-40

Desk Copy: Maureen Hess, Project Manager