DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017533/S-053
NDA 020813/S-009

SUPPLEMENT APPROVAL

Hoffman-LaRoche, Inc.
c/o Genentech, Inc.
Attention: Elizabeth Wishart
Regulatory Agent
1 DNA Way, MS 241B
South San Francisco, CA 94080-4990

Dear Ms. Wishart:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received October 9, 2013, received, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Klonopin (clonazepam) tablets and Klonopin (clonazepam) orally disintegrating tablets.

These October 9, 2013, submissions constituted a complete response to our July 15, 2013, action letter.

Application	Product Name	Submitted on:	Received on:
NDA 017533/S-053	Klonopin (clonazepam) tablets	January 29, 2013	January 30, 2013
This supplement proposes:			
Removal of all reference to Klonopin (clonazepam) orally disintegrating tablets from the package insert and Medication Guide for NDA 017533			

Application	Product Name	Submitted on:	Received on:
NDA 020813/S-009	Klonopin (clonazepam) orally disintegrating tablets	January 29, 2013	January 30, 2013
This supplement proposes:			
A combined package insert and Medication Guide that make reference to Klonopin orally disintegrating tablets and Klonopin tablets for NDA 020813			

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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, contact Laurie Kelley, PA-C, Regulatory Project Manager, via telephone at (301) 796-5068 or via email at Laurie.Kelley@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Acting Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

ERIC P BASTINGS
10/31/2013