CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 17-533/S-037

Name: Klonopin Tablets

Generic Name: clonazepam

Sponsor: Hoffmann-La Roche, Inc.

Approval Date: 1/29/02

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APPLICATION NUMBER:

NDA 17-533/S-037

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APPLICATION NUMBER:

NDA 17-533/S-037

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 17-533/S-037

Hoffman-La Roche Inc.
Attention: Duane Voss
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Voss

Please refer to your supplemental new drug application dated August 6, 2001, received August 7, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Klonopin (clonazepam) Tablets.

We also acknowledge receipt of your amendment dated October 16, 2001.

This "Changes Being Effected" supplemental new drug application provides for an update to the package insert for Klonopin Tablets to include all labeling modifications approved under NDA 20-813/Klonopin Wafer and NDA 20-813/S-001. NDA 20-813/S-001 provided for a combined package insert for the 2 products and was approved on April 26, 2001.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted October 16, 2001. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jacqueline H. Ware, Pharm.D., Regulatory Project Manager, at (301) 594-5533.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Russell Katz
1/29/02 11:08:37 AM

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APPLICATION NUMBER:

NDA 17-533/S-037

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

REGULATORY PROJECT MANAGER
LABELING REVIEW

DRUG: NDA 17-533 Klonopin® (clonazepam) Tablets

Supplements: S-037

(last approved) From SLR-031 (April 11, 2001)
Label Code: 27897884-0401

(pending action) SLR-037 (dated: August 6, 2001)
(amended: October 17, 2001)

REVIEW

SLR-037
Dated: August 6, 2001
CBE: Yes
Package Insert Label Code: 25538260-0701

The supplement provides for an update to the package insert for Klonopin Tablets to include all labeling modifications approved under NDA 20-813/Klonopin Wafer and NDA 20-813/S-001. NDA 20-813/S-001 provided for a combined package insert for the 2 products and was approved on April 26, 2001 (label code: 25538260-0701).

Label Comparison Findings:
A line-by-line comparison of the package insert submitted in S-037 (label code: 25538260-0701) was conducted using the approved package insert from NDA 20-813/S-001 as a base. A line-by-line comparison of S-037 to NDA 17-533/S-031 was also performed (label code: 27897884-0401). No changes beyond those provided for in NDA 17-533/S-037 were noted.

CONCLUSIONS

Recommend approval of supplemental application, S-037, if Neurology Team Leader concurs.

Jacqueline H. Ware, Pharm.D.
Regulatory Project Manager

Robbin Nighswander, M.S.
Supervisory Regulatory Health Project Manager

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

/s/

Jackie Ware
1/22/02 09:45:10 AM
CSO

Robbin Nighswander
1/23/02 11:57:54 AM
CSO