CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-838

APPROVAL LETTER

K. Borgoramm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-838

JUN - 4 1998

Astra Merck Inc.
Attention: Daniel J. Cushing, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Cushing:

Please refer to your April 30, 1997 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand (candesartan cilexetil) 4, 8, 16, and 32 mg Tablets.

We acknowledge receipt of your submissions dated April 28, May 6, 8, 12, 18, 20 and 22 (two), 1998.

This new drug application provides for the use of Atacand (candesartan) Tablets in the treatment of hypertension.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed package insert included with your May 18, 1998 submission. Accordingly, the application is approved effective on the date of this letter.

We note that one of the May 22, 1998 submissions contains camera-ready proofs of carton and container labeling. Please submit 20 copies of the final printed carton and container labels as soon as they are available, in no case more than 30 days after they are printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-838. Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

We note that the tentative dissolution specifications will be:

and you will monitor the dissolution of the first three batches of the 16 and 32 mg tablets placed on stability testing with the aim of revising the specifications for these strengths

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

Please submit one market package of the drug product when it is available.

If you have any questions, please contact:

Ms. Kathleen Bongiovanni
Regulatory Health Project Manager
(301) 594-5334

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA
HFD-110
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-101 (with labeling)
HFD-101/L.Carter
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
DISTRICT OFFICE
HFD-810/ONDC Division Director
HFI-20/Press Office (with labeling)
HFD-110/KBongiovanni
sb/5/18/98;5/20/98;6/1/98
R/D: JRIechocki/5/22/98
KSrinivasachar/5/26/98
AProakis/5/20/98
CResnick/5/20/98
KU/5/20/98
KMahjoob/5/21/98
AEl-Tahtawy/5/20/98
AParkeh/5/20/98
CGanley/5/27/98
NMorgenstern/5/29/98

APPROVAL (AP)

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-838

APPROVABLE LETTER

K. Berglund

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-838

APR 28 1998

Astra Merck Inc.
Attention: Daniel J. Cushing, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Cushing:

Please refer to your April 30, 1997 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand (candesartan cilexetil) 4, 8, 16, and 32 mg Tablets.

We acknowledge receipt of your submissions dated April 30, June 27, July 15 (two), 29, and 31, August 1, 4, 11, 12, 22, 26 (two), 27, and 29 (two), September 3, 5, 18, 25 and 30 (three), October 1 (two), 2 (two), 10, 13, 17, 23, 29 and 30, November 7, 18 (two), 20, 21, 25 (two) and 26 (two), December 2, 3, 5, 8, 10 (three), 12, 15, 19 (two) and 23 (two), 1997; January 5, 7 (two), 9 (two), 13 and 26, February 27, and March 10, 16, 19 (two), 20, 23, 24 and 25 (three), 1998.

The user fee goal date is April 30, 1998.

We have completed the review of this application as submitted with draft labeling and it is approvable. Before the application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed marked-up draft.

Please submit 20 copies of the printed labels and other labeling, ten of which are individually mounted on heavy weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Please submit the product-specific sampling plan referred to in your March 19, 1998 amendment.

We recommend that the final dissolution specification be:

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising
and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please contact:

Ms. Kathleen Bongiovanni
Regulatory Health Project Manager
Telephone: (301) 594-5334

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA
HFD-110
HFD-002/ORM
HFD-92/DDM-DIAB
HFD-101
HFD-101/L.Carter
HFD-40/DDMAC (with draft labeling)
DISTRICT OFFICE
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sb/3/27/98;4/1/98
R/D: JPiechocki
JShort/3/31/98
AProakis/3/31/98
CResnick/3/31/98
KU/3/31/98
SFredd/3/31/98
KMahjoob/3/31/98
AParekh/3/31/98
CGanley/3/31/98
NMorgenstern/3/31/98

APPROVABLE (AE)

APPEARS THIS WAY
ON ORIGINAL