21-093

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-093

Trade Name: Atacand HCT

Generic Name: candesartan cilexetil-hydrochlorothiazide

Sponsor: AstraZeneca LP

Approval Date: September 5, 2000

Indication(s): For the treatment of hypertension

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CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				
Approvable Letter	X			
Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)				
Administrative Document(s)	X			
Correspondence	X			

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP - 5 2000

NDA 21-093

AstraZeneca LP
Attention: Ms. Cindy Lancaster
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Ms. Lancaster:

Please refer to your new drug application (NDA) dated September 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand HCT (candesartan cilexetil-hydrochlorothiazide) 16-12.5 and 32-12.5 mg Tablets.

We acknowledge receipt of your submissions dated August 8, 14, and 25, 2000. Your submission of August 14, 2000 constituted a complete response to our July 19, 2000 approvable letter.

This new drug application provides for the use of Atacand HCT (candesartan cilexetil-hydrochlorothiazide) 16-12.5 and 32-12.5 mg Tablets for the treatment of hypertension.

We have completed the review of this 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 submitted final printed labeling (package insert and immediate container and carton labels included in your August 14, 2000 submission). Accordingly, the application is approved effective on the date of this letter.

We remind you of your agreement to provide the results from the conditions prior to launch and your commitment to monitor moisture content and tablet hardness on the first three commercial batches and to obtain Agency concurrence before terminating these tests on future annual batches.

We also remind you of your agreement to adopt, prior to commercial launch of the product, the following dissolution method and specifications:

CC/HCTZ 16/12.5 mg tablet
Medium:
Apparatus:
Speed:
Specifications:

CC/HCTZ 32/12.5 mg tablet
Medium:
Apparatus:
Speed:
Specifications:

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.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

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

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

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, please contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

/S/

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-093

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 21-093

AstraZeneca LP
Attention: Ms. Cindy M. Lancaster
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Ms. Lancaster:

Please refer to your new drug application (NDA) dated September 28, 1999, received September 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand HCT (candesartan cilexetil-hydrochlorothiazide) 16-12.5 and 32-12.5 mg Tablets.

We acknowledge receipt of your submissions dated October 13 and 29, November 5, December 9, 17, 22, and 23 (two), 1999, and January 5, 26, and 27, February 28 (two), March 31, April 28 (two), May 19, 24 and 25, June 14, 16, and 30, and July 7, 2000.

This new drug application provides for the use of Atacand HCT (candesartan cilexetil-hydrochlorothiazide) 16-12.5 and 32-12.5 mg Tablets for the treatment of hypertension.

We have completed the review of this application, as amended, and it is approvable. Before this 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 labeling.

Please adopt the following dissolution method and specifications:

CC/HCTZ 16/12.5 mg tablet

CC/HCTZ 32/12.5 mg tablet

We remind you of your agreement to provide the results from the prior to launch and your commitment to monitor moisture content and tablet hardness on the first three commercial batches and obtain Agency concurrence before terminating these tests on future annual batches.

Please submit 20 copies of the final printed labeling ten of which are individually mounted on heavy weight paper or similar material. Alternately, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999).

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

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

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

If you have any questions, please contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

/S/

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Marked-up Draft Labeling

31 pages redacted from this section of the approval package consisted of draft labeling