CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:	**20738**
Trade Name:	**Tevetan**
Generic Name:	**Eprosartan mesylate**
Sponsor:	**SmithKline Beecham**
Approval Date:	**December 22, 1997**
Indication:	**Management of essential hypertension**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 20738

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				X
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)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative Document(s)	X			
Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 20738

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-738

DEC 22 1997

SmithKline Beecham Pharmaceuticals
Attention: Ms. Linda Rebar
1250 South Collegeville Road, UP4455
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Ms. Rebar:

Please refer to your October 11, 1996 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Teveten (eprosartan mesylate) 300 and 400 mg Tablets.

We acknowledge receipt of your amendments and correspondence dated October 9, 17, and 31, November 5 and 7, and December 16, 1997.

The user fee goal date is May 7, 1998.

This new drug application provides for the use of Teveten Tablets for use in the management of essential hypertension.

We have completed the review of this application, including the submitted draft labeling, 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 enclosed marked-up draft. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is 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 20-738. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

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

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.

Please refer to your submission of October 31, 1997. Based on the additional data submitted, the dissolution method and specification should still be:

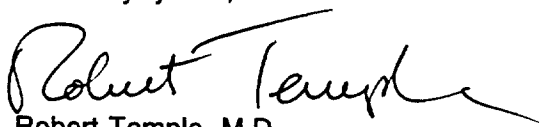
Please submit one market package of the drug product when it is available.

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:

Ms. Diana Willard
Regulatory Health Project Manager
(301) 594-5311

Sincerely yours,



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

Enclosure

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20738

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-738

OCT 10 1997

SmithKline Beecham Pharmaceuticals
Attention: Ms. Linda Rebar
1250 South Collegeville Road, UP4455
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Ms. Rebar:

Please refer to your October 11, 1996 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Teveten (eprosartan mesylate) 300 and 400 mg Tablets.

We acknowledge receipt of your amendments and correspondence dated October 30 and 31 (two), November 19 and 22 (two), December 5, 9, 10, 13, 16, 17, and 18, 1996; January 10, 14, 15, 21, 22, 23, 24, and 29, February 5, 6, 12, 18 (two), 19, and 24, March 4, 5, 6, 7, 10, 13, 14, 21, and 28, April 1, 11, 14, 15 (two), 21, 22 (two), 25 (two), and 30, May 6, 7, 15, and 20, June 9, 17, 20, and 26, and July 1, 2 (two), 3, 11 (two), 23 (two), 24, 28, and 31, August 6, 7, 11, 13, and 15, September 4, 8, and 10, and October 2, 1997.

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 the following information:

In addition, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be essentially identical in content to the enclosed marked-up draft and should contain the requested information. If additional information relating to the safety or effectiveness of this drug becomes available, revision of the FPL may be required.

Please note the following particular aspects of the draft labeling:

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

Under 21 CFR 314.50(d)(5)(vi)(b), we request that you update your NDA by submitting all safety information you now have regarding your new drug. Your August 6, 1997 submission outlines a proposal for the Safety Update that is acceptable to the Division.

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.

Should you have any questions, please contact:

Ms. Diana Willard
Regulatory Health Project Manager
Telephone: (301) 594-5311

Sincerely yours,

Robert Temple 10/16/97

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

Enclosure