CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-387/S-003

APPROVAL LETTER

NDA 20-387/S-003

Merck Research Laboratories
Attention: Larry P. Bell, M.D.
Sumneytown Pike
West Point, PA 19486

Dear Dr. Bell:

Please refer to your November 17, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HYZAAR (losartan potassium and hydrochlorothiazide) Tablets, 50/12.5 mg.

The supplemental application provides for a change in site

We have completed the review of this supplemental application and it is approved.

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

Sincerely yours,

/S/ 12/1/95

Robert Wolters, Ph.D.
Supervisory Chemist
Division of New Drug Chemistry 1, Cardio-Renal
Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc.
Original NDA
HFC-130/JAllen
HFD-110
HFD-110/CSO
HFD-80
HFD-232
HFD-110/RMittal
HFD-110/DCunningham 11/30/95 DCunningham 12/1/95
kc/12/1/95

Approval Date: April 28, 1995

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-387/S-003

CHEMISTRY REVIEW(S)

DEC - 1 . .)

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 20-387
3. Name and Address of Applicant (City & State) Merck Research Laboratories Sumneytown Pike West Point, PA 19486		4. Supplement(s) Number(s) Date(s) S-003 11/17/95 (CM)
5. Drug Name HYZAAR Tablets	6. Nonproprietary Name Losartan Potassium and Hydrochlorothiazide	8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: A change in site for		
9. Pharmacological Category An angiotensin II receptor agonist	10. How Dispensed [X] Rx [ ] OTC	11. Related IND(s)/ NDA(s)/DMF(s) DMF
12. Dosage Form(s) Film coated tablets	13. Potency(ies) 50/12.5 mg	
14. Chemical Name and Structure		15. Records/Reports Current [ ] Yes [ ] No Reviewed [ ] Yes [ ] No

16. Comments:

The applicant requested approval of a packaging site change for

The new site is located at

An authorization letter to refer to DMF is included. Merck also has submitted stability commitment.

The new packaging site has been inspected by FDA's Philadelphia District Office on July 5 and 14, 1995. There were no FD-483's issued at these inspections.

Separate EER for this site was not requested. Another EER request for the same facility was submitted for NDA 20-092/S-009 and was acceptable on 10/23/95.

17. Conclusions and Recommendations:

AP

18. REVIEWER		
Name Danute G. Cunningham	Signature /S/	Date Completed November 30, 1995

Distribution:

[X] Original Jacket [ ] Reviewer [ ] Division File [ ] CSO [ ] District

20387S03.SUP
HFD-110/Mittal

11/30/95