CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-386/S-019 and 029

Chemistry Review(s)

DIVISION OF CARDIO-RENAL DRUG PRODUCTS

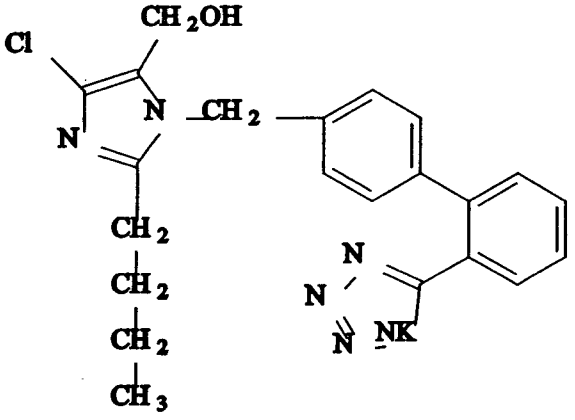
Review of Chemistry, Manufacturing, and Controls

CHEMIST'S REVIEW	1. ORGANIZATION HFD - 110	2. NDA Number 20-386
3. Name and Address of Applicant (City & State) Merck Research Laboratories Merck & Co. Inc. West Point, PA 19486		4. Supplement(s) Number(s) Date(s) SE5-029 12-21-01
5. Drug Name COZAAR	6. Nonproprietary Name Losartan Potassium	7. Amendments

7. **Supplement Provides For (Efficacy Supplement)**

a pediatric formulation to support the use of losartan in pediatric hypertensive patients.

9. Pharmacological Category: An angiotensin II receptor agonist	10. How Dispensed /x/ RX /___/ OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Oral suspension	13. Potency(ies) 2.5 mg/mL	



14. **Chemical Name and Structure**
2-butyl-4-chloro-1[[2'-(1H-tetrazol-5-yl)-[1,1'-biphenyl]-4-yl]-methyl]-1H-imidazole-5-methanol, monopotassium salt.

15. **Records/Reports**

Current

/x/ Yes /___/ No

Reviewed

/x/ Yes /___/ No

16. **Comments:** This is an efficacy supplement in which the oral suspension is prepared by the pharmacist from the marketed COZAAR 50 mg tablets.

17. **Conclusions and Recommendations:**
Based on Environmental Assessment Review of May 20, 2002 and Findings Of No Significant Impact (FONSI) recommendation by Dr. Florian Zielinski and in absence of any CMC concern, the supplement is recommended for approval from CMC prospective. The following should be recommended to the applicant:

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pages of trade

secret and/or

confidential

commercial

information

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

/s/

Ramsharan Mittal
10/18/02 04:34:52 PM
CHEMIST

Kasturi Srinivasachar
10/18/02 05:21:34 PM
CHEMIST

REVIEW OF

ENVIRONMENTAL ASSESSMENT

For

Cozaar Tablets

(50 mg Losartan Potassium)

NDA 20-386 / S-029

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products
(HFD-110)

Date Completed: May 20, 2002