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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-386/S-032

Pharmacology Review(s)



Memorandum DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF CARDIO-RENAL DRUG PRODUCTS

Date: 10/17/02

FROM: Anthony G. Proakis, Ph.D., Pharmacologist, HFD-110

THROUGH: Charles A. Resnick, Ph.D., Supervisory Pharmacologist, HFD-110

TO: Douglas Throckmorton, M.D., Director, Division of CardioRenal Drug Products, HFD-110
Ed Fromm, Regulatory Health Project Manager, HFD-110

SUBJECT: Cozaar™ Tablets Supplemental New Drug Application (NDA # 20-386, SE1-032)

Background

Losartan potassium is an angiotensin II receptor antagonist and was approved for the treatment of hypertension (NDA # 20-386) under the product name Cozaar™ Tablets. The sponsor submitted to the Division a supplemental application (NDA # 20-386, SE1-032; dated 7/25/02, Center receipt date, 7/30/02) requesting approval of a proposed indication for Cozaar™ for the reduction in the risk of cardiovascular morbidity and mortality in hypertensive patients with left ventricular hypertrophy.

Non-Clinical Information Submitted

The sponsor provides numerous published non-clinical pharmacology reports describing the effects of losartan in animal models of hypertension, left ventricular hypertrophy, myocardial infarction cardiomyopathy and stroke.

Because the proposed supplemental indication is based on results of a clinical study, review of the non-clinical pharmacology reports is not needed, particularly since results of these non-clinical studies are merely exploratory and not included in the product labeling.

Labeling

The sponsor provides no new non-clinical toxicology or safety studies in this submission.

The sponsor's proposed changes to the product labeling are limited to the clinical results and contain no changes from the previously approved summaries of the non-clinical studies. Therefore, a pharmacology/toxicology review of this NDA supplement is not necessary.

cc.

NDA# 20-386

HFD-110

HFD-110/CResnick

HFD-510/JelHage

Text of Proposed Labeling

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/s/

Anthony Proakis
10/17/02 01:19:08 PM
PHARMACOLOGIST

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10/17/02 01:48:11 PM
PHARMACOLOGIST

There have been no safety updates since the original submission of July 26, 2002.