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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-387/S-013, 015 & 027

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: 1/07/03

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: Hyzaar™ Tablets Supplemental New Drug Application (NDA # 20-387, SE1-027)

Background

Losartan potassium-hydrochlorothiazide is a combination of an angiotensin II receptor antagonist and a diuretic and was approved for the treatment of hypertension (NDA # 20-387) under the product name Hyzaar™ Tablets. The sponsor submitted to the Division a supplemental application (NDA # 20-387, SE1-027; dated 9/24/02, Center receipt date, 9/25/02) requesting approval of a proposed indication for Hyzaar™ for its use as a first-line treatment for patients with severe hypertension.

Non-Clinical Information Submitted

The sponsor provides no new non-clinical pharmacology or toxicology reports in this submission.

Because the proposed supplemental indication is based on results of a clinical study and no new pharmacology/toxicology studies were conducted with this drug combination, a pharmacology/toxicology review is not necessary.

Labeling

The sponsor's proposed changes to the product labeling are limited to the clinical results. No changes in the non-clinical pharmacology/toxicology sections of the approved labeling for Hyzaar are proposed and none needed for this NDA supplement.

cc.
NDA# 20-387
HFD-110
HFD-110/CResnick
HFD-510/JElHage

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/s/

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