

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S8

ADMINISTRATIVE DOCUMENTS

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: June 23, 1993

FROM: Sandra Benton, Technical Information Assistant
Division of Cardio-Renal Drug Products, HFD-110

SUBJECT: Prinivil (lisinopril) Tablets manufactured by Merck and Zestril (lisinopril)
Tablets manufactured by Zeneca

TO: Cardiovascular and Renal Drugs Advisory Committee Members

In a January 7, 1993 memorandum, Dr. Temple requested that when a drug that was discussed by the Advisory Committee is approved, the Division send to the members a copy of the labeling. Prinivil (lisinopril) Tablets manufactured by Merck Research Laboratories was approved for the use in the treatment of congestive heart failure (NDA 19-558/S-007) on June 14, 1993 and Zestril (lisinopril) Tablets manufactured by Zeneca Pharmaceuticals Group was approved for the use in the treatment of congestive heart failure (NDA 19-777/S-007) on June 9, 1993. A copy of the final printed labeling for both drugs are enclosed.

cc

Orig. NDAs

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