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APPLICATION NUMBER: NDA 19777/S2

CORRESPONDENCE

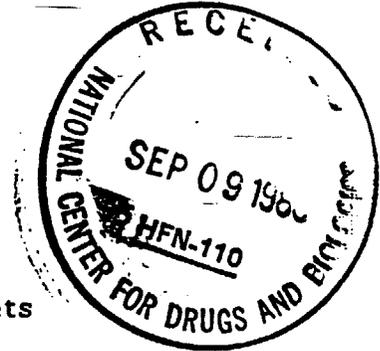


NDA NO. 19-777 REF. NO. S-002
NDA SUPPL FOR. SEP

September 9, 1988

HAND DELIVERED

Division of Cardio-Renal
Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
HFD No. 110, Room No. 16B-30
5600 Fishers Lane
Rockville, MD 20857



Gentlemen:

Re: ZESTRIL® (lisinopril) Tablets
NDA 19-777
Packaging Clarification

The purpose of this submission is to clarify the sponsor's intention with respect to the packaging of ZESTRIL® (lisinopril) Tablets in blister packages as set out in the sponsor's New Drug Application 19-777 and Drug Master File . The applicant will package ZESTRIL Tablets in blister packs (samples and unit dose packaging) using the following components:

1. Aluminum foil manufactured by
2. Clear Staufen PVC, type and type manufactured by ICI Americas Inc.

Attached for your convenience are the sponsor's specifications for these materials and a copy of a letter for each supplier authorizing the Agency to access their pertinent Drug Master Files on the sponsor's behalf.

A copy of this letter is being submitted to both the sponsor's New Drug Application 19-777 and Drug Master File

Sincerely,

Robert Castor
Assistant Manager
Technical Regulatory Affairs and Compliance
Drug Regulatory Affairs Department
(302) 575-2594

RC/mjb
Attachment

ORIGINAL