CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S24

CORRESPONDENCE

ZENECA
Pharmaceuticals Group

1800 Concord Pike
Wilmington
Delaware 19897 USA

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NDA SUPPL NO. SEM

HAND DELIVERED

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Dr. Raymond J. Lipicky
Division Director
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

Dear Dr. Lipicky:

Re: ZESTRIL® (lisinopril)
NDA 19-777
Laboratory Transfer to New Laboratory at Guayama, Puerto Rico

The purpose of this supplemental New Drug Application is to effect the transfer of lisinopril bulk drug substance testing and ZESTRIL® (lisinopril) Tablets testing from the existing Guayama, Puerto Rico and Carolina, Puerto Rico laboratories to a new laboratory facility at Guayama, Puerto Rico.

The existing laboratory on the Guayama site will be relocated to a new laboratory built on the same site.

Currently, testing of raw materials used in the lisinopril synthesis, unmilled lisinopril testing and lisinopril stability testing are conducted at the original Guayama facility. These functions will be transferred to the new Guayama facility.

Currently, testing of excipients used in the manufacture of ZESTRIL Tablets and stability testing of ZESTRIL Tablets are conducted at the Carolina, Puerto Rico site. These functions also will be transferred to the new Guayama laboratory.

The testing of milled lisinopril and the release testing of all dosage strengths of ZESTRIL Tablets are conducted at the Carolina laboratory. This testing will continue to be conducted at the Carolina site.

Microbiological testing of water used in the lisinopril-ZESTRIL manufacturing processes will be conducted at the new Guayama laboratory. Any process-related microbiological testing conducted during the manufacture of lisinopril or ZESTRIL Tablets will also be conducted at this site.

ORIGINAL

The Carolina laboratory consists of four sections:

1. Pharmaceuticals Raw Materials Laboratory
2. Stability Laboratory (Finished Dosage Forms)
3. Microbiology Laboratory
4. Finished Dosage Release Testing Laboratory

Sections 1, 2 and 3 will be transferred to the Guayama site.

In support of this transfer, the Sponsor will relocate trained, experienced personnel from the Carolina laboratory to the Guayama facility.

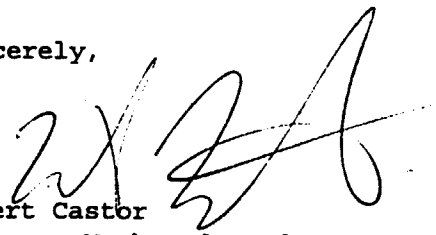
A list of the equipment being transferred to the Guayama site from Carolina is contained in Attachment 1.

A list of the personnel positions being transferred to the Guayama site from Carolina is contained in Attachment 2.

A floor plan and description of the new Guayama facility are contained in Attachment 3.

If you require any additional information, please do not hesitate to contact me.

Sincerely,



Robert Castor
Manager, Marketed Products Group
Drug Regulatory Affairs Department
(302) 886-2594
(302) 886-2822 (fax)

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