# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 19777/S15

## ADMINISTRATIVE DOCUMENTS

AUG 2 8 1992

**RECORD OF TELEPHONE CONVERSATION/MEETING**

DATE 28 Aug 92

NDA NUMBER 19-777

IND NUMBER

TELECON/MEETING

INITIATED BY
- ■ APPLICANT/ SPONSOR
- ☐ FDA

MADE
- ☐ TELEPHONE
- ■ IN PERSON

PRODUCT NAME

Zestril

FIRM NAME

ICI

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD

Kevin McKenna, ICI
Richard Pierce, ICI
James Short, FDA
Robert Wolters, FDA

TELEPHONE NO.

ICI submitted S-015 on 15 May 92 which provides for updating DMF
Lisinoprill is now manufacutred in a new building and on a larger scale than previously. Also new facilities are provided for in one step of the synthesis. The approved step is done by

Mr. Pierce identified the new facility as Bldg, #1, and stated that it was commissioned in 1989. The facility was brought online in 1990.

Mr. Pierce admitted that they had used lisinopril which had been synthesized in the new facility, including for manufacture of Zestril Tablets.

Mr. Pierce made a commitment that they will only use lisinopril in which the step was carried out at until supplement approval. He will send us a letter to this effect.

Mr. Pierce told us that Peter Smith told him that the inspection should be carried out late in the Fall. He will check with Mr. Smith next month for a more precise date.

cc: R. Wolters

SIGNATURE /S/

DIVISION HFD-110