CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19777/S3

APPROVAL LETTER

JAN 18 1989

NDA 19-777/S-003

ICI Pharmaceuticals Group
Attention: Mr. Robert Castor
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your November 10, 1988 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) Tablets.

We also acknowledge receipt of your amendments dated December 12, 1988 and January 13, 1989.

The supplemental application provides for a rework procedure for 10 and 20 mg Zestril Tablets.

We have completed the review of this supplemental application and it is approved. Our letter of May 19, 1988 detailed the conditions relating to the approval of this application.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

/S/ 1/18/89

Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA
HFD-110
HFD-110/CSO
HFD-80/DDIR
HFD-100
HFD-730
HFD-110/JShort/1/17/89
clb/1/17/89/1337C
R/D init: RWolters/1/17/89

APPROVAL

JHS 1/17/89

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S3

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW
(If necessary, continue any item on 8½" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION: HFD-110

2. NDA NUMBER: 19-777

3. NAME AND ADDRESS OF APPLICANT *(City and State)*:
ICI Pharmaceuticals
Wilmington, DE 19897

4. AF NUMBER: 7-612

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S003	11/10/88

6. NAME OF DRUG: Zestril Tablets

7. NONPROPRIETARY NAME: Lisinopril

8. SUPPLEMENT(S) PROVIDES FOR:
a rework procedure for 10 and 20 mg tablets.

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES:
1/13/89

10. PHARMACOLOGICAL CATEGORY: Antihypertensive

11. HOW DISPENSED: ☒ RX ☐ OTC

12. RELATED IND/NDA/DMF(S):
NDA 19-558

13. DOSAGE FORM (S): TCM

14. POTENCY (ies): 5,10 and 20 mg

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT: ☐ YES ☐ NO
REVIEWED: ☐ YES ☐ NO

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS
APPROVAL is recommended.

1-17-89

18. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
James H. Short	/S/	JAN 17 1989

DISTRIBUTION: ■ ORIGINAL JACKET ☐ REVIEWER ☐ DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

JAN - 3 1989

CHEMIST'S REVIEW
(If necessary, continue any item on 8½" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION: HFD-110	2. NDA NUMBER: 19-777
3. NAME AND ADDRESS OF APPLICANT *(City and State)*: ICI Pharmaceuticals Wilmington, DE 19897	4. AP NUMBER: 7-612
	5. SUPPLEMENT (S) — NUMBER(S): S003 — DATE(S): 11/10/88
6. NAME OF DRUG: Zestril Tablets	7. NONPROPRIETARY NAME: Lisinopril
8. SUPPLEMENT(S) PROVIDES FOR: a rework procedure for 10 and 20 mg tablets.	9. AMENDMENTS AND OTHER (Reports, etc.) DATES: 12/21/88
10. PHARMACOLOGICAL CATEGORY: Antihypertensive	11. HOW DISPENSED: ☒ Rx ☐ OTC
	12. RELATED IND/NDA/DMF(S): NDA 19-558
13. DOSAGE FORM (S): TCM	14. POTENCY *(Use)*: 5, 10 and 20 mg
15. CHEMICAL NAME AND STRUCTURE	16. RECORDS AND REPORTS — CURRENT: ☐ YES ☐ NO — REVIEWED: ☐ YES ☐ NO

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

NOT APPROVABLE

The deficiencies will be conveyed to the firm..

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
James H. Short	/S/	DEC 30 1988

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FORM FDH 2244 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

1-3-89

211

CHEMIST'S REVIEW
(If necessary, continue entry from on 8½" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION	2. NDA NUMBER
HFD-110	19-777

3. NAME AND ADDRESS OF APPLICANT (City and State)

ICI Pharmaceuticals
Wilmington, DE 19897

4. AP NUMBER: 7-612

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S003	11/10/88

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Zestril Tablets	Lisinopril

8. SUPPLEMENT(S) PROVIDES FOR:

a rework procedure for 10 and 20 mg Zestril Tablets.

9. AMENDMENTS AND OTHER (Reports, etc.) DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Antihypertensive	☒ RX ☐ OTC	

13. DOSAGE FORM (S)	14. POTENCY (Ieg)
TCM	5, 10 and 20 mg

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS

CURRENT ☐ YES ☐ NO

REVIEWED ☐ YES ☐ NO

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

NOT APPROVABLE The deficiencies will be conveyed to the firm.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
James H. Short	/S/	NOV 22 1988

DISTRIBUTION ■ ORIGINAL JACKET ☐ REVIEWER ☐ DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S3

CORRESPONDENCE

3/1

NDA 19-777/S-003

NOV 28 1988

ICI Pharmaceuticals Group
Attention: Mr. Robert Castor
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your November 10, 1988 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) Tablets.

The supplemental application provides for a rework procedure for 10 and 20 mg Zestril Tablets.

We have completed our review and find the information presented is inadequate and the supplemental application is not approvable under section 505(b)(1) of the Act and 21 CFR 314.125(b). The deficiencies may be summarized as follows:

1. Please confirm that batches reworked because the drug substance is out of specification will contain no more than % of the reworked material.

2. Please confirm that when reworking lots out of specification for the drug substance, after addition of either more drug substance or more excipients, the blend will still meet the regulatory requirement of the excipients being within % of the specified amounts.

3. Please explain the discrepancy between your statement (Exhibit 1.1(b) and 2.) that material out of physical specification may consist of % reworked material, while in Exhibit 2 following the quantitative formula you state that a reworked batch will consist of no more than % of recovered material.

4. Please define the "CL" conditions used in your stability studies.

5. Please explain why both the 10 and 20 mg lots had exactly % of reworked material.

6. Please confirm if samples were taken from each of the four reworked lots and arbitrarily divided into two lots each to get the eight lots tested for stability.

7. In order to further verify that reworked and control tablets have comparable dissolution characteristics, please include studies done at 15 minutes, and please include either individual tablet results or ranges for all your dissolution studies.

8. Please confirm that the disintegration and hardness specifications to which you refer are the same as specified in your in process controls.

9. Please provide information about the friability specification to which you refer.

10. Please explain how you compare the results of stability studies for the reworked tablets with controls if the controls were not subjected to all of the same conditions, and please justify your statement that the controls do not degrade as fast as the reworked tablets.

11. Please provide the Tables I and II referred to on p.3 of Exhibit 3.

12. Please include the control stability data.

13. Please include a statement that any tablets which are reworked will be less than one year old.

14. Please confirm that the expiration date for any batch containing reworked material will be the same as was assigned to the oldest reworked batch incorporated therein.

Within 10 days after the date of this letter, you are required to amend this supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may withdraw this supplemental application.

Sincerely yours,

/S/ 11/28/88

Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA
HFD-110
HFD-110/CSO
HFD-713/GChi
HFD-80/DDIR
HFD-110/JShort/11/23/88
clb/11/25/88/1259C
R/D init: AThompson/11/23/88

NOT APPROVABLE

11/25/88

NDA 19-777/S-003

JAN - 3 1989

ICI Pharmaceuticals Group
Attention: Mr. Robert Castor
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your November 10, 1988 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) Tablets.

We also acknowledge receipt of your amendment dated December 21, 1988.

The supplemental application provides for a rework procedure for 10 and 20 mg Zestril Tablets.

We have completed our review and find the information presented is inadequate and the supplemental application is not approvable under section 505(b)(1) of the Act and 21 CFR 314.125(b). The deficiencies may be summarized as follows:

1. Please do a comparative dissolution study on 12 tablets from one lot of the 20 mg tablets containing % reworked material, and from one lot of regular production tablets. The tablets should be assayed at 10, 20 and 30 minutes. We are requesting these intervals to allow a comparison with a comparable study done on Prinivil Tablets.

2. In your response to question 11, you provided tables on p. 1 of Exhibit 3, which were presented as Tables I and II in your original submission. We are requesting the Tables referenced in the first full paragraph on p. 3 of Exhibit 3.

We do not object to your one-time request to reprocess material older than one year.

Within 10 days after the date of this letter, you are required to amend this supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may withdraw this supplemental application.

Sincerely yours,

1/3/89

Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA
HFD-110
HFD-110/CSO
HFD-713/GChi
HFD-80/DDIR
HFD-110/JShort/12/30/88
clb/1/3/89/1321C

1/3/89

NOT APPROVABLE

COPY 1

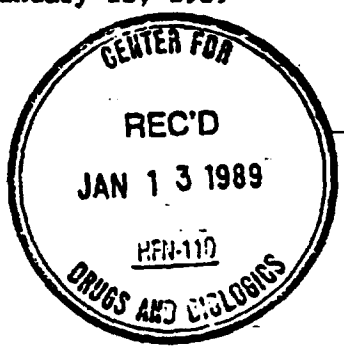
ICI Pharmaceuticals Group

ICI Pharma
Stuart Pharmaceuticals

NDA SUPPL AMENDMENT
SCS-003 (RC)

HAND DELIVERED

January 13, 1989



Dr. Robert J. Wolters
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. Wolters:

Re: ZESTRIL® (lisinopril) Tablets 10 mg and 20 mg
NDA 19-777
Rework Procedure

The purpose of this submission is to respond to your letter of January 3, 1989.

Item 1: Attached as Attachment 1 is a comparative dissolution study conducted on 12 tablets from each of one lot of 20 mg ZESTRIL® Tablets containing % reworked material and one lot of production tablets assayed at 10, 20 and 30 minutes intervals.

Results indicate that the dissolution characteristics of 20 mg ZESTRIL Tablets containing % reworked material are comparable to the dissolution characteristics of 20 mg ZESTRIL regular production tablets.

Item 2: The table references in p. 3 of Attachment 3 were incorrect.

The following paragraph in page 3 of Attachment 3:

should have read:

"The tablets were compared based on the predicted rates of degradation as mg of lisinopril/12 months (Table I, II and III) and on mg DKP (degradation product) (Table IV) at 6 months. The DKP degradation level of the rework setdowns was slightly higher

ORIGINAL

than the Ballydine controls; however, the difference in lisinopril degradation rate was found not to be statistically significant for all lots at all conditions. In addition, there are no differences between the % ZESTRIL rework tablets and % ZESTRIL rework tablets."

Tables I, II and III were explained under SECTION A: Lisinopril Potency on page 1 of Attachment 3, and Table IV was explained under SECTION B: Degradation Products on page 1 of Attachment 3.

A corrected copy of the Attachment 3 write-up, a brief introduction which had been omitted from the original submission and Tables I-IV are enclosed for your convenience as Attachment 2.

Sincerely,

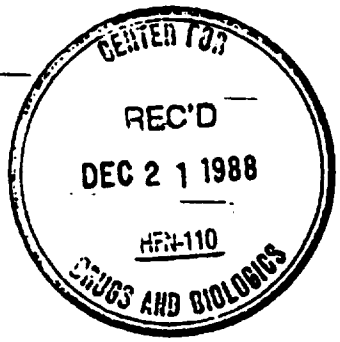
Robert Castor
Manager
Technical Regulatory Affairs and Compliance
Drug Regulatory Affairs Department
(302) 575-2594

RC/cmh
Enclosure

HAND DELIVERED

December 21, 1988

NDA SUPPL AMENDMENT



Robert J. Wolters, Ph.D.
Supervisory Chemist
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. Wolters:

Re: ZESTRIL® (lisinopril)
NDA 19-777/S-003

The purpose of this submission is to respond to your letter of November 28, 1988.

1. PLEASE CONFIRM THAT BATCHES REWORKED BECAUSE THE DRUG SUBSTANCE IS OUT OF SPECIFICATION WILL CONTAIN NO MORE THAN % OF THE REWORKED MATERIAL.

   The applicant confirms that reworked batches will contain no more than % of reworked material.

2. PLEASE CONFIRM THAT WHEN REWORKING LOTS OUT OF SPECIFICATION FOR THE DRUG SUBSTANCE, AFTER ADDITION OF EITHER MORE DRUG SUBSTANCE OR MORE EXCIPIENTS, THE BLEND WILL STILL MEET THE REGULATORY REQUIREMENT OF THE EXCIPIENTS BEING WITHIN 10% OF THE SPECIFIED AMOUNTS.

   The applicant confirms that after reworking the blend, all excipients will be within 10% of the specified amounts except the lubricant (magnesium stearate NF) which will be within % of the specified amount as set out in the subject New Drug Application.

3. PLEASE EXPLAIN THE DISCREPANCY BETWEEN YOUR STATEMENT (EXHIBIT 1.1(b) AND 2.) THAT MATERIAL OUT OF PHYSICAL SPECIFICATION MAY CONSIST OF % REWORKED MATERIAL, WHILE IN EXHIBIT 2 FOLLOWING THE QUANTITATIVE FORMULA YOU STATE THAT A REWORKED BATCH WILL CONSIST OF NO MORE THAN % OF RECOVERED MATERIAL.

   Exhibit I should be modified to read:

   i. Product not within specifications in regard to Active Ingredient or Physical Specifications (ie, content uniformity, weight, variation, dissolution, physical appearance, disintegration etc.). Such product shall be reduced to a suitable particle size, blended to ensure uniform distribution and assayed for the active ingredient.

ORIGINAL

The material shall then be recovered by blending in quantities (not to exceed % by weight) into granulations, which have been adjusted to compensate for active ingredient, after assay, found not to be within specified limits.

ii. Product exhibiting tabletting difficulties during manufacturing may be salvaged by: (a) the addition of minimal quantities of excipient materials. The unit tablet weight will be increased to compensate for this additional excipient; (b) utilizing the steps detailed in Section i above for product with Active Ingredient or Physical Specification problems.

The attached Exhibit I sets out the complete corrected procedure.

4. PLEASE DEFINE THE "CL" CONDITIONS USED IN YOUR STABILITY STUDIES.

The "CL" condition used in the stability studies is a Climate Lab at 30°C and 80% relative humidity.

5. PLEASE EXPLAIN WHY BOTH THE 10 AND 20 MG LOTS HAD EXACTLY % OF REWORKED MATERIAL.

A recovery level of % was included in our process development plan to provide a back-up option in the event that stability data would not support a % recovery level. Both recovery levels were evaluated for the 10 and 20 mg strengths. The exact value of % describes the portion of recovery material for the finished recovery batch weight. For example, 10 kg of recovery material added to a virgin batch quantity of 100 kg produces a total recovery batch size of 110 kg. The recovery portion of this batch represents % of the total batch size.

6. PLEASE CONFIRM IF SAMPLES WERE TAKEN FROM EACH OF THE FOUR REWORKED LOTS AND ARBITRARILY DIVIDED INTO TWO LOTS EACH TO GET THE EIGHT LOTS TESTED FOR STABILITY.

The virgin granulation and tablets for recovery were generated from production scale batches for both the 10 and 20 mg strengths. These materials were milled/blended and compressed at Pilot scale. Separate 9.09 and 25% recovery batches were generated using materials for each production scale batch. The following illustrates this material trace:

Production Batch (Virgin granulation and tablets for recovery)	——————>	Milling/blending and compression of a % recovery batch
	——————>	Milling/blending and compression of % recovery batch

A total of four reworked lots were used to provide materials for the stability setdown of the eight recovery lots.

7. IN ORDER TO FURTHER VERIFY THAT REWORKED AND CONTROL TABLETS HAVE COMPARABLE DISSOLUTION CHARACTERISTICS, PLEASE INCLUDE STUDIES DONE AT 15 MINUTES, AND PLEASE INCLUDE EITHER INDIVIDUAL TABLET RESULTS OR RANGES FOR ALL YOUR DISSOLUTION STUDIES.

   a) The dissolution specification for this product is greater than or equal to % of label claim in minutes. As this dissolution work was done as part of a stability study and not to determine a dissolution profile, only minutes dissolution data were generated for all the subject studies.

   b) The ranges of the dissolution studies are included in Attachment I.

8. PLEASE CONFIRM THAT THE DISINTEGRATION AND HARDNESS SPECIFICATIONS TO WHICH YOU REFER ARE THE SAME AS SPECIFIED IN YOUR PROCESS CONTROLS.

   The disintegration and hardness specifications referred to in the document are the in-process control limits currently in place for QA releases of non-rework ZESTRIL® (lisinopril) batches. Current in-process control limits are:

   Disintegration: less than minutes
   Hardness: 3.6 - 8.6 kg

9. PLEASE PROVIDE INFORMATION ABOUT THE FRIABILITY SPECIFICATION TO WHICH YOU REFER.

   The friability specification referred to in the document is the in-process control limit currently in place for QA release of non-rework batches. The current in-process control limit is . % maximum.

10. PLEASE EXPLAIN HOW YOU COMPARE THE RESULTS OF STABILITY STUDIES FOR THE REWORKED TABLETS WITH CONTROLS IF THE CONTROLS WERE NOT SUBJECTED TO ALL OF THE SAME CONDITIONS, AND PLEASE JUSTIFY YOUR STATEMENT THAT THE CONTROLS DO NOT DEGRADE AS FAST AS THE REWORKED TABLETS.

   a) The reworked tablets and the controls were subjected to all of the same conditions in the comparison of stability study results. The conditions are: RT (room temperature = 25°C), 30°C, 40°C, 50°C, HC (humidity chamber = 40°C and 80% relative humidity), CL (climate lab = 30°C and 80% relative humidity;), and LB (light box).

   b) The statement that "the controls do not degrade as fast as the reworked tablets" can be more clearly stated as "although the calculated degradation rate of the active appears to be slightly higher for the rework versus the control tablets, a statistical analysis of the rates using a homogeneity of slopes shows no significant difference between the two manufacturing processes." (See Table II of Attachment II.)

11. PLEASE PROVIDE THE TABLES I AND II REFERRED TO ON P. 3 OF EXHIBIT 3.

Attached as Attachment II are Tables I and II referred to on p. 3 of Exhibit 3 in our submission of November 10, 1988.

12. PLEASE INCLUDE THE CONTROL STABILITY DATA.

Included are the stability studies of the controls (Attachment III). Ranges of dissolution studies for these controls are included in Attachment IV.

13. PLEASE INCLUDE A STATEMENT THAT ANY TABLETS WHICH ARE REWORKED WILL BE LESS THAN ONE YEAR OLD.

ICI Pharmaceuticals currently has a small quantity of material that will qualify for recovery operations. A portion of this material is now over a year old. As a one-time occurrence, we would like the option of reworking this material.

ICI Pharmaceuticals will incorporate the one-year limit following rework of existing inventories.

14. PLEASE CONFIRM THAT THE EXPIRATION DATE FOR ANY BATCH CONTAINING REWORKED MATERIAL WILL BE THE SAME AS WAS ASSIGNED TO THE OLDEST REWORKED BATCH INCORPORATED THEREIN.

ICI Pharmaceuticals confirms that the expiration date for any batch containing reworked material will be the same as was assigned to the oldest reworked batch incorporated therein.

Sincerely,

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

RC/cmh

SUPPL NEW CORRES

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 5, 1988

Dr. Robert J. Wolters
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. Wolters:

Re: ZESTRIL® (lisinopril) Tablets Revork Procedure
NDA 19-777/S-003

The purpose of this submission is to acknowledge receipt of your letter of November 28, 1988 setting out the deficiencies contained in our Supplemental New Drug Application of November 10, 1988.

Please be advised that it is our intent to file an amendment to this Supplemental Application responding to the issues raised in your letter to us by December 29, 1988.

Sincerely,

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

RC/dmj
Submitted in triplicate

NAI
K. Bongiovanni
12-13-88

ORIGINAL

COPY 1

ICI Pharmaceuticals Group

ICI Pharm
Stuart Pharmaceutical

HAND DELIVERED

November 10, 1988

Dr. Robert J. Wolters
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

NDA NO. 19-777 REF. NO. S-003
NDA SUPPL FOR... S.C.S.

Dear Dr. Wolters:

Re: ZESTRIL® (lisinopril) Tablets 10 mg and 20 mg
NDA 19-777
Rework Procedure

The purpose of this submission is to provide a rework procedure for ZESTRIL® (lisinopril) Tablets 10 mg and 20 mg.

The applicant proposes to salvage up to % of milled, recovered ZESTRIL Tablets blended with virgin granulation. Recovered ZESTRIL Tablets 20 mg will be blended with ZESTRIL 20 mg virgin granulation. The ZESTRIL 10 mg recovery batches may be manufactured using any combination of 5 mg and 10 mg milled, recovered tablets since the 5 mg and 10 mg formulations are common quantitatively.

The following information is submitted in support of this application:

1. Recovery or salvage directions (Exhibit 1).

2. Qualitative and Quantitative rework formulations and manufacturing directions for ZESTRIL Tablets 10 mg and 20 mg (Exhibit 2).

3. A stability report comparing ZESTRIL Tablets 10 mg and 20 mg made with % virgin material with reworked (up to %) ZESTRIL Tablets 10 mg and 20 mg, showing no significant difference and supporting a 30-month expiry period.

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

RECEIVED
NOV 10 1988
CENTER FOR DRUGS AND BIOLOGICS

Sincerely,

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

RC/cmh
Enclosure

ORIGINAL