

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 019810/S38/S50/S56

ADMINISTRATIVE DOCUMENTS/CORRESPONDENCE



GARY P. HOROWITZ, Ph.D.
Director, Regulatory Liaison

ASTRA MERCK

725 Chesterbrook Blvd.
Wayne, PA 19087-5677

ORIGINAL

SCF/PA
038



February 19, 1998

Lilia Talarico, M.D. - Director
Division of Gastrointestinal and
Coagulation Drug Products
HFD-180, Room 6B-45
Office of Drug Evaluation III (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

March 31, 1998
Needed.
/S/

Dear Dr. Talarico:

**NDA 19-810/S-038: PRILOSEC® Delayed-Release Capsules
(Omeprazole)
FINAL PRINTED LABELING**

Reference is made to the Supplemental New Drug Application for PRILOSEC® Delayed-Release Capsules submitted to FDA on February 26, 1996, and approved on January 15, 1998, which provides for a 40 mg dosage strength. Please also refer to our submission of final printed labeling on February 11, 1998, and the subsequent request by Maria Walsh on February 12, 1998 for additional copies of the immediate container and secondary packaging labels.

As requested by Ms. Walsh, with this letter we are submitting 18 additional copies of the immediate container and secondary packaging labels as listed below:

- Immediate container labels for unit of use bottle of 30 (no. 9082801)
- Immediate container label for bulk bottle of 100 (no. 9082701)
- Immediate container label for bulk bottle of 1000 (no. 9023100)
- Immediate container label for hospital unit dose blister cells (no. 9018500)
- Outer carton (50558) and labels for hospital unit dose package of 100 (no. 9083001 and no. 9082901)

Lilia Talarico, M.D. - Director

NDA 19-810/S-038

Page 2

Please direct any questions or requests for additional information to me at (610-695-1008) or, in my absence, to Barbara J. Blandin, Regulatory Project Manager at (610-695-1540).

Sincerely yours,



Gary P. Horowitz, Ph.D.

Director - Regulatory Liaison

Attachments

Fed Ex No. 803856826074

NDA 19-810/S-038
PRILOSEC® 40 mg Delayed-Release Capsules (Omeprazole)

Labeling: Omeprazole SCF/FA
NDA No: 19810 Rec'd. 2/20/98
Reviewed by: [Signature] 3/16/98

ROLL LABEL FOR 40 MG CAPSULE
75 CC/30 COUNT _____ UNIT OF USE BOTTLE

IMMEDIATE CONTAINER (BOTTLE) LABEL
[No. 9082801]

PRILOSEC® 40 mg
(OMEPRAZOLE)
30 Delayed-Release Capsules

ASTRA MERCK
Trademark of Astra Merck

Keep container tightly closed. Protect from light and moisture. Store between 15°C and 30°C (59°F and 86°F). The PRILOSEC (Omeprazole) Delayed-Release Capsule should be swallowed whole, and not opened, chewed, or crushed.

PRILOSEC 40

Lot

PRILOSEC® 40 mg
(OMEPRAZOLE)
30 Delayed-Release Capsules

NDC 61113-743-31

USUAL ADULT DOSAGE: See accompanying circular.
CAUTION: Federal (USA) law prohibits dispensing without prescription.
PRILOSEC is a registered trademark of Astra AB.
Manufactured by:
MERCK & CO., INC., West Point, PA 19486, USA
Dist. by: ASTRA MERCK, Wayne, PA 19087, USA

PRILOSEC 40

Lot

9082801
30 | No. 3428

LIFT HERE ↑

Labeling: Orig SCF/038
NDA No: 198100 Rqd 2/20/98
Reviewed by: TST 3/16/98

ROLL LABEL FOR 40 MG CAPSULE
120 CC/100 COUNT _____ BULK PACKAGE BOTTLE

IMMEDIATE CONTAINER (BOTTLE) LABEL
[No. 9082701]

PRIOSEC® 40 mg
(OMEPRAZOLE)
100 Delayed-Release Capsules



6113-743-68



ASTRA MERCK
Trademark of Astra Merck

Store between 15°C and 30°C (59°F and 86°F).
Store PRIOSEC Delayed-Release Capsules in a light container protected from light and moisture.
Dispense in a light container protected from light and moisture. This is a bulk package and not intended for dispensing.



PRIOSEC

Lot

MAR 17 1998

NDC 61113-743-68

USUAL ADULT DOSAGE: See accompanying circular.
CAUTION: Federal (USA) law prohibits dispensing without prescription.
The PRIOSEC (Omeprazole) Delayed-Release Capsule should be swallowed whole and not opened, chewed, or crushed.
PRIOSEC is a registered trademark of Astra AB.
Manufactured by:
MERCK & CO., INC., West Point, PA 19486, USA
Dist. by: ASTRA MERCK, Wayne, PA 19087, USA

9082701
100 | No. 3428

Labeling: Orig 50F/FA
NDA No: 19810 Reg'd. 3/20/98
Reviewed by: TSJ 3/16/98

**BLISTER CELL LABEL FOR 40 MG CAPSULE
UNIT DOSE (2X5)**

**IMMEDIATE CONTAINER (BLISTER) LABEL
[No. 9018500]**

<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>	<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>
<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>	<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>
<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>	<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>
<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>	<p>PRIOLOSEC® 40 mg (OMEPRAZOLE) Delayed-Release Capsules Dist. by: ASTRA MERCK 9018500</p> <p>NDC 61113-743-28</p> <p>LOT D5321 EXP. MAY98</p>

NDA 19-810/S-038
PRILOSEC® 40 mg Delayed-Release Capsules (Omeprazole)

Labeling: *Orig SCF/FA 038*
NDA No: *19810* Rec'd: *2/20/98*
Reviewed by: *LSI* *3/16/98*

ROLL LABEL FOR 40 MG CAPSULE
40 OZ/1000 COUNT _____ BULK PACKAGE BOTTLE

IMMEDIATE CONTAINER (BOTTLE) LABEL
[No. 9023100]

PRILOSEC® 40 mg
(OMEPRAZOLE)

1000 Delayed-Release Capsules

NDC 61113-743-82



ASTRA MERCK
Trademark of Astra Merck

MAR 17 1998

Store between 15°C and 30°C (59°F and 86°F).
Store PRILOSEC Delayed-Release Capsules in a tight container protected from light and moisture.
Dispense in a tight container protected from light and moisture.
This is a bulk package and not intended for dispensing.
USUAL ADULT DOSAGE: See accompanying circular.
CAUTION: Federal (USA) law prohibits dispensing without prescription.
The PRILOSEC (Omeprazole) Delayed-Release Capsule should be swallowed whole and not opened, chewed, or crushed.
PRILOSEC is a registered trademark of Astra AB.
Manufactured by:
MERCK & CO., INC., West Point, PA 19486, USA
Dist. by: ASTRA MERCK, Wayne, PA 19087, USA



Lot

9023100

Exp.

1000 | No. 3428



N 3

PRILOSEC® 40 mg
(OMEPRAZOLE)
1000 Delayed-Release Capsules

NDA 19-810/S-038

PRILOSEC® 40 mg Delayed-Release Capsules (Omeprazole)

Labeling: Orig SCF/038
NDA No: 19810 RFD. 2/20/98
Reviewed by: 151 3/16/98

**ROLL LABEL FOR 40 MG CAPSULE
100 COUNT UNIT DOSE PACKAGE**

**OUTER CARTON LABEL (OVERLAP LABEL)
[No. 9082901]**

**PRILOSEC® 40 mg
(OMEPRAZOLE)**
100 Delayed-Release Capsules



MAR 17 1998
ASTRA MERCK

Trademark of Astra Merck

Manufactured by:
MERCK & CO., Inc., West Point, PA 19486, USA
Dist. by: ASTRA MERCK, Wayne, PA 19087, USA
PRILOSEC is a registered trademark of Astra AB.



9082901
100 | No. 3428



**PRILOSEC® 40 mg
(OMEPRAZOLE)**
100 Delayed-Release Capsules
NDC 61113-743-28

USUAL ADULT DOSAGE: See accompanying circular.
Protect from light and moisture.
Store between 15°C and 30°C (59°F and 86°F).
CAUTION: Federal (USA) law prohibits dispensing
without prescription.
The PRILOSEC (Omeprazole) Delayed-Release Capsule should be
swallowed whole and not opened, chewed, or crushed.
This is a bulk package and not intended for dispensing.



[1 Carton contains 100 unit dose blister cells -
see carton on last page for placement of label]

NDA 19-810/S-038
PRILOSEC® 40 mg Delayed-Release Capsules (Omeprazole)

Labeling: *Orig SCF/FA 038*
NDA No: *19810* Rec'd. *2/20/98*
Reviewed by: *TSI 3/16/98*

**ROLL LABEL FOR 40 MG CAPSULE
100 COUNT UNIT DOSE PACKAGE**

**OUTER CARTON LABEL (PANEL LABEL)
[No. 9083001]**

PRILOSEC® 40 mg
(OMEPRAZOLE)

100 Delayed-Release Capsules



MAR 17 1998
ASTRA MERCK

Trademark of Astra Merck

Manufactured by:
MERCK & CO., INC., West Point, PA 19486, USA
Dist. by: ASTRA MERCK, Wayne, PA 19087, USA
PRILOSEC is a registered trademark of Astra AB.



9083001
100 | No. 3428



[1 Carton contains 100 unit dose blister cells -
see carton on last page for placement of label]

Labeling: _____
No. _____
Reviewed by: _____

MAR 17 1998



ASTRA MERCK

50558

9082901 | 100 | No. 3428
NDC 61113-743-28



Manufactured by:
MERCK & CO., Inc., West Point, PA 19486, USA
Dist. by: ASTRA MERCK, Wayne, PA 19087, USA
PRILOSEC is a registered trademark of Astra AB.



ASTRA MERCK

PRILOSEC® 40 mg
(OMEPRazole)
100 Delayed-Release Capsules



Labeling: _____
NDA No. _____
Reviewed by: _____



PRILOSEC® 40 mg
(OMEPRazole)
Delayed-Release Capsules

Dist. by: ASTRA MERCK
9018500

LOT D3321
EXP. MAY98

NDC 61113-743-28



PRILOSEC® 40 mg
(OMEPRazole)
100 Delayed-Release Capsules



ASTRA MERCK
Trademark of Astra Merck

Manufactured by:
MERCK & CO., Inc., West Point, PA 19486, USA
Dist. by: ASTRA MERCK, Wayne, PA 19087, USA
PRILOSEC is a registered trademark of Astra AB.



9083001 | 100 | No. 3428
NDC 61113-743-28



PRILOSEC® 40 mg
(OMEPRAZOLE)

100 Delayed-Release Capsules

NDC 61113-743-28

USUAL ADULT DOSAGE: See accompanying circular.

Protect from light and moisture.

Store between 15°C and 30°C (59°F and 86°F).

CAUTION: Federal (USA) law prohibits dispensing without prescription.

The PRILOSEC (Omeprazole) Delayed-Release Capsule should be swallowed whole and not opened, chewed, or crushed.
This is a bulk package and not intended for dispensing.



ASTRA MERCK



ASTRA MERCK

Trademark of Astra Merck



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NDA 19-810/S-038
PRILOSEC® 40 mg Delayed-Release Capsules (Omeprazole)

7

Labeling:

Final SUP 1/3/98

NDA No:

19810

Re'd.

2/2/98

Reviewed by:

ISI 2/3/10/98

**ACTUAL OUTER CARTON FOR 40 MG CAPSULE
100 COUNT UNIT DOSE PACKAGE
(WITH PLACEMENT OF LABELS SHOWN)**

1 Carton contains 100 unit dose blister cells

NDA 19-810/S-038

Astra Merck Inc.
Attention: Gary P. Horowitz, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

OCT 28 1997

Dear Dr. Horowitz:

Please refer to your supplemental new drug application dated February 26, 1996, received February 26, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec (omeprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated July 12, August 14, October 10, November 11, and December 3 and 18, 1996 and June 26, 1997.

The supplemental application provides for a 40 mg dosage strength.

We have completed the review of this supplemental application and it is approvable. Before this supplement may be approved, however, it will be necessary for you to do the following.

1. Regarding your proposal for intermediate hold times of 30 days _____
60 days _____ and 90 days _____:
 - A. There was significantly _____ capsules stored at _____
_____ in the physician's sample packages _____ omeprazole at _____ months)
compared with the samples stored in the 30 count bottles (_____ omeprazole at _____
months) and the HUD blister packs (_____ omeprazole at _____ months). In order
to determine the effect of _____ on the stability of the 40 mg capsules in the
different packaging configurations, please provide comparable data for the 40
mg capsules prepared with _____
 - B. As supporting evidence, please provide stability data for the 10 and 20 mg
capsules packaged in the same container/closure system and stored under the
same conditions _____. The intermediate hold times for these
capsules should be provided along with the stability data.

2. Please be advised that your proposal that the expiration date will be calculated from the
_____ will be assessed when the data requested above are evaluated.
3. Please provide the data concerning the _____ during _____ which was
collected during transfer of the manufacturing process _____
Stability data for capsules _____ with a _____ in the _____ should be

NDA 19-810/S-038

Page 3

cc:

Original NDA 19-810/S-038

HFD-180/Div. Files

HFD-92/DDM-DIAB

HFD-180/CSO/M. Walsh

HFD-180/A. Shaw

E. Duffy

DISTRICT OFFICE

APPEARS THIS WAY
ON ORIGINAL

Drafted by: M. Walsh 10/16/97

Initialed by: E. Duffy 10/16/97

Final: M. Walsh 10/16/97

filename: 19810S38.ae2

APPROVABLE (AE)

APPEARS THIS WAY
ON ORIGINAL

Division of Gastrointestinal & Coagulation Drug Products

CONSUMER SAFETY OFFICER REVIEW

Application Number: NDA 19-810/SCF-038

MAR 16 1998

Name of Drug: Prilosec (omeprazole) Delayed-Release Capsules

Sponsor: Astra Merck Inc.

Material Reviewed

Submission Date(s): February 11 and 19, 1998

Receipt Date(s): February 12 and 20, 1998

Background and Summary Description: Supplement 038 was submitted on February 26, 1996 and provides for a 40 mg capsule.

The sponsor submitted final printed labeling (FPL) on February 11, 1998 (20 copies of the package insert and one set of immediate container labels and outer carton labels for all package configurations) and February 19, 1998 (18 additional sets of immediate container labels and outer carton labels for all package configurations) in response to the January 15, 1998 approval letter.

Review

1. Package Insert

The submitted FPL, identified as "7910927" was compared to the draft labeling submitted on February 26, 1996 and the currently approved FPL, identified as "7910926" (approved on November 4, 1997 in supplement 018). The submitted FPL was identical to the currently approved labeling except for revisions to the DESCRIPTION and HOW SUPPLIED sections. These revisions are identical to the proposed revisions contained in the February 26, 1996 draft labeling and were approved on January 15, 1998.

2. Labels

The submitted FPL for the following container labels conform to the requirements set forth under 21 CFR 201.1, 201.5, 201.10, 201.15, 201.17, 201.18, 201.50, 201.51, 201.55, and 201.100.

A. Immediate container labels for the 30, 100, and 1000 count bottles.

BEST POSSIBLE COPY

Division of Gastrointestinal & Coagulation Drug Products

CONSUMER SAFETY OFFICER REVIEW

JAN - 7 1997

Application Number: NDA 19-810/SCF-038

Name of Drug: Prilosec (omeprazole) Delayed-Release Capsules

Sponsor: Astra Merck Inc.

Material Reviewed

Submission Date(s): November 11 and December 18, 1996

Receipt Date(s): November 12 and December 19, 1996

Background and Summary Description: Supplement 038 was submitted on February 26, 1996 and provides for a 40 mg capsule. A draft package insert and draft container labels included in the submission were reviewed (see CSO review dated August 20, 1996). This supplement was approvable on August 26, 1996.

The sponsor submitted final printed labeling (FPL) on November 11, 1996 for the package insert and the following container labels: 1) immediate container labels for the 30, 100, and 1000 count bottles; 2) outer carton labels (panel and overlap) for the 100 count unit dose package; and 3) outer carton for the 100 count unit dose package (containing 100 unit dose blister cells) with placement of the labels shown.

The sponsor submitted FPL for the blister cell on December 18, 1996.

REVIEW

1. PACKAGE INSERT

The submitted FPL, identified as "7910922" was compared to the draft labeling submitted in this supplement on February 26, 1996 and approvable on August 26, 1996. It was also compared to the currently approved labeling, identified as "7910921", submitted in response to the April 15, 1996 approval letter for supplement 037, because the approvable draft labeling did not include the labeling revisions approved in supplements 033, 037, and 041.

The submitted FPL was identical to the currently approved labeling except for the revisions to the DESCRIPTION and HOW SUPPLIED sections of the package insert proposed in this supplement. The revisions to the DESCRIPTION and HOW SUPPLIED sections were identical to those proposed in the approvable draft labeling.

THE FPL FOR THE PACKAGE INSERT IS ACCEPTABLE.

NDA 19-810/S-038

Astra Merck Inc.
Attention: Michael C. Elia, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

APR - 4 1997

Dear Dr. Elia:

Please refer to your supplemental new drug application dated February 26, 1996, received February 26, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec^(R) (omeprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated July 12, August 14, October 10, November 11, and December 3 and 18, 1996. The User Fee goal date for this application is May 12, 1997.

This supplemental application provides for a 40 mg dosage form.

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

1. Explain why there is a difference between the limits for the _____ for the _____ . Please be advised that the _____ for the _____ for the 20 mg _____ as described in the Annual Report dated December 29, 1995 are unacceptable and cannot be used for the 40 mg _____
2. Submit your evaluation of the new test for _____
3. Provide the data to demonstrate the statement, "The comparison of the _____ from the _____ to the _____ parts for these batches confirms the amount of _____ added is appropriate for PRILOSEC[®] 40 mg."
4. Provide data to demonstrate the stability of 40 mg capsules manufactured from _____ . Please be advised that the data provided for _____ used for the manufacture of 10 and 20 mg capsules do not provide enough information to support a 90 day holding period for the _____ used to manufacture 40 mg capsules.
5. Explain how the expiration date will be calculated for the 40 mg drug product manufactured from _____ If the

proposed _____ are used (90 days each for _____) then there may be a _____ of as much as nine months between the initial _____ and the release of the final product.

6. Perform a _____ test on an appropriate sample size (e.g. 10 times the dosage unit) of the _____, since there is no _____ test for _____ and since the _____ is critical to the stability of the drug product.
7. Explain how the capsules to be taken from _____ as part of the sampling plan are selected to ensure that they are representative of _____ and how they are "randomly sampled". In addition explain how each of the _____ bottles is utilized for testing. For instance, are all tests performed on each bottle? It appears that each bottle represents a _____ of the _____. Explain whether the bottles are maintained in sequence.
8. Provide the data underlying the histogram on page 40 and provide a statistical analysis by lot. The data as presented do not justify a Q _____.
9. Explain the discrepancy between the table on page 13 of the cover letter (which states that the 30 count Unit of use will have a child-resistant closure) and the table on page 47 (Attachment 15), which states that the _____ non-child-resistant closure will be used for the 30 count bottle.
10. Submit stability data from three lots from the container/closure configuration _____ since the data from one lot is not evaluable.
11. Re-analyze the stability data from the _____. Please note that pooling of the data is not valid (even if demonstratable statistically) since there are significant differences in the manufacturing process at the two different sites.
12. Provide a statistical analysis of stability data for each packaging configuration and provide the separate expiration dates for each packaging configuration, separating the _____ configurations.

Within 10 days after the date of this letter, you are required to amend the 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 proceed to withdraw the supplemental application. Any amendments should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

NDA 19-810/S-038
Page 3

If you have any questions, please contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely yours,

**APPEARS THIS WAY
ON ORIGINAL**

Stephen B. Fredd, M.D.
Director
Division of Gastrointestinal and Coagulation
Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:

Original NDA 19-810/S-038
HFD-180/Div. files
HFD-820/ONDC Division Director
DISTRICT OFFICE
HFD-92/DDM-DIAB
HFD-180/M. Walsh
HFD-180/A. Shaw
E. Duffy

ISI 4/4/97

**APPEARS THIS WAY
ON ORIGINAL**

Drafted by: M. Walsh 4/3/97

Initialed by: A. Shaw 4/3/97

E. Duffy 4/3/97

S. Fredd 4/3/97

final: M. Walsh 4/3/97

NOT APPROVABLE (NA)

NDA 19-810/S-050

Astra Merck Inc.
Attention: Gary P. Horowitz, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

OCT 29 1997

Dear Dr. Horowitz:

Please refer to your supplemental new drug application dated April 28, 1997, received April 30, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec^(R) (omeprazole) Delayed-Release Capsules.

The supplemental application provides for packaging the physician's samples in a new alternate secondary package _____.

We have completed the review of this supplemental application and it is approvable. Before this supplement may be approved, however, it will be necessary for you to submit a sample of the proposed secondary package.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

This change may not be implemented until you have been notified in writing that this supplemental application is approved.

If you have any questions, please contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely yours,

ES

10/29/97

APPEARS THIS WAY
ON ORIGINAL

Eric P. Duffy, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

NDA 19-810/S-050

Page 2

cc:

Original NDA 19-810/S-050

HFD-180/Div. Files

HFD-92/DDM-DIAB

HFD-180/CSO/M. Walsh

HFD-180/A. Shaw

E. Duffy

DISTRICT OFFICE

APPEARS THIS WAY
ON ORIGINAL

Drafted by: M. Walsh 10/28/97

Initialed by: E. Duffy 10/29/97

Final: M. Walsh 10/29/97

filename: 19810S50.ae

APPROVABLE (AE)

NDA 19-810

Astra Merck Inc.
Attention: Gary P. Horowitz, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

JAN - 5 1998

Dear Dr. Horowitz:

Please refer to your new drug application submitted pursuant to section 505(b) of the Federal Food, Drug, Cosmetic Act for Prilosec (omeprazole) Delayed-Release Capsules.

We also refer to the meeting held on December 8, 1997, between representatives of your firm and this Agency.

A copy of our minutes of that meeting is enclosed. We request that you also submit a copy of your meeting summary. Please indicate any significant difference in your understanding of the meeting outcomes.

If you have any questions, please contact me at (301) 443-0487.

Sincerely yours,

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Maria R. Walsh, M.S.
Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

enclosures

NDA 19810
Page 2

cc:

Original NDA
HFD-180/Div. Files
HFD-180/CSO/M. Walsh

final: M. Walsh 1/5/98

GENERAL CORRESPONDENCE (MINUTES SENT)

**APPEARS THIS WAY
ON ORIGINAL**

MEMORANDUM OF TELECON

DATE: August 18, 1997

APPLICATION NUMBER: 19-810/S-050; Prilosec (omeprazole) Delayed-Release Capsules

BETWEEN:

Name: Gary Horowitz, Ph.D.
Phone: (610) 695-1008
Representing: Astra Merck, Inc.

BEST POSSIBLE COPY

AND

Name: Maria R. Walsh, M.S.
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Request for copy of submission to DDMAC

BACKGROUND: NDA 19-810/S-050, submitted April 28, 1997, provides for an alternate secondary packaging of physician samples by _____
The currently approved Hospital Unit Dose primary package for the 20 mg and 10 mg capsules will be packaged into _____ which contain personalized physician prescription blanks _____

TODAY'S CALL: I called Dr. Horowitz and requested that the sponsor submit a sample of the proposed secondary package to the Division of Drug Marketing, Advertising, and Communications for review. Dr. Horowitz agreed to do so and the call was then concluded.

Maria R. Walsh, M.S.
Regulatory Project Manager

cc: Original 19-810/S-050
HFD-180/Div. File
HFD-180/M.Walsh
HFD-180/A.Shaw
E.Duffy

TELECON

MEMORANDUM OF TELECON

DATE: September 3, 1997

APPLICATION NUMBER: 19-810/S-050; Prilosec (omeprazole) Delayed-Release Capsules

BETWEEN:

Name: Barbara Blandin
Phone: (610) 695-1008
Representing: Astra Merck, Inc.

BEST POSSIBLE COPY

AND

Name: Maria R. Walsh, M.S.
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Second Request for copy of submission to DDMAC

BACKGROUND: NDA 19-810/S-050, submitted April 28, 1997. provides for an alternate secondary packaging of physician samples by _____ The currently approved Hospital Unit Dose primary package for the 20 mg and 10 mg capsules will be packaged into _____ which contain personalized physician prescription blanks _____

I called Dr. Gary Horowitz on August 18, 1997 and requested that the sponsor submit a sample of the proposed secondary package for review by the Division of Drug Marketing, Advertising, and Communications. He agreed to do so.

TODAY'S CALL: I called Dr. Horowitz's office and spoke with Ms. Barbara Blandin in Dr. Horowitz's absence. I asked her about the status of the Division's August 18, 1997 request for submission of a sample of the proposed secondary package. She replied that the sponsor is working on it and will submit it as soon as possible. The call was then concluded.

Maria R. Walsh, M.S.
Regulatory Project Manager

cc: Original 19-810/S-050
HFD-180/Div. File
HFD-180/Maria R. Walsh
HFD-180/A. Shaw

E. Duffy

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