CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-229

CHEMISTRY REVIEW(S)

ADDENDUM

Date: May 5, 2005
From: Maria Ysern, MSc, Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Through: Liang Zhou, PhD, Division of Gastointestinal and Coagulation Drug products, HFD-180
To: NDA 21-229

It was brought to our attention that in section 16 of the review (Chemical Name, Structural Formula) the name Omeprazole magnesium was inadvertently substituted by Esomeprazole. This has been corrected, see addendum to the review.

NDA 21-229

PRILOSEC OTC™

The Procter & Gamble Co, Agent
Astra Zeneca LP, Sponsor

Maria E. Ysern

Division of Gastrointestinal and Coagulation Drug Products

Table of Contents

Chemistry Review Data Sheet

1. NDA or ANDA 21-229

2. REVIEW # 1 (Resubmission)

3. REVIEW DATE: April 16, 2003

4. REVIEWER: Maria E. Ysern, MSc.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	27-Jan-2000
Review # 1	02-Nov-2000
DR Letter	02-Nov-2000
Telecon	13-Nov-2000
NA Letter	27-Nov-2000
Review #2	2-Aug-2002
Amendment BC	15-Nov-2000
Amendment AZ	12-Feb-2002

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
21-229 Resubmission	Dec 20, 2003
Amendment BL	Feb 24, 2003
Amendment BC	Mar 7, 2003

7. NAME & ADDRESS OF APPLICANT:

Name: The Procter and Gamble Company

Address: Health Care Research Center
8700 Mason-Montgomery Road, Mason, Ohio
45040-9462

Representative: Douglass Ws. Bierer, PhD
Director, Regulatory Affairs.

Telephone: 513-622-2314

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: PRILOSEC OTC™
b) Non-Proprietary Name (USAN): Omeprazole Magnesium Delayed-Release Tablets
c) Code Name/# (ONDC only):
d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: 2,3 S
- Submission Priority: Standard

9. LEGAL BASIS FOR SUBMISSION:
N/A

10. PHARMACOL. CATEGORY: Proton Pump Inhibitor.
Indication: Acid reducer. Treatment of frequent heartburn.

11. DOSAGE FORM:
Delayed release tablets.

12. STRENGTH/POTENCY:
20 mg

13. ROUTE OF ADMINISTRATION:
Oral

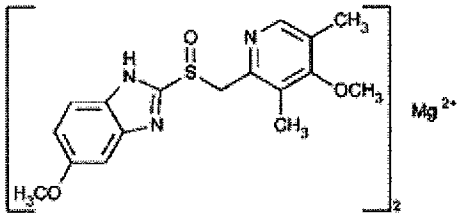
14. Rx/OTC DISPENSED: ___Rx _X__OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):
_____SPOTS product – Form Completed

__X__ Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Correction: Should have said : Omeprazole Magnesium



5-Methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1-benzimidazole, magnesium salt

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED
[redacted]	II	[redacted]	[redacted]	1	Adequate	31-Jul-2002
	II			1	Adequate	31-Jul-2002
	II			1	Adequate	31-Jul-2002
	III			1	Adequate	23-Jan-2001
	III			1	Adequate	02-Aug-2002

[redacted]	III	[redacted]	1	Adequate Adequate	02-Aug-2002 26- Feb-2002
[redacted]	III	[redacted]	1	Adequate	25-Oct-1999 18-Aug-2000

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

Document	Application number	Description
NDA	19-810	Omeprazole
IND	[redacted]	

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	Acceptable Resubmitted for update	18-Sep-2000 21-Jan-2003	Note: [redacted] site was found not acceptable, this site was withdrawn by the company Overall Compliance Acceptable 14-Apr-2003

Pharm/Tox	N/A		
Biopharm	N/A		
LNC	N/A		
Methods Validation	pending		
OPDRA	N/A		
EA	N/A		
Microbiology	N/A		

The Chemistry Review for NDA 21-229

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From the standpoint of CMC this application can be approved.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable :

None

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug Substance:
Omeprazole magnesium. This is the magnesium salt of Omeprazole, approved as Prilosec. Description provided in DMFs [redacted] and [redacted]

The same formulations were used for preclinical and marketing.

Drug Product:
The drug product consist of a number of enteric –coated pellets compressed into a tablet. The applicant calls this a "Multiple Unit Pellet System"(MUPS Tablet).
Strength: 20 mg.
Formulation and drug product manufacturing is described in DMF [redacted]

B. Description of How the Drug Product is Intended to be Used

This product is for adults (18 years and older) with frequent heartburn (heartburn 2 or more days a week). It is not intended for those who have heartburn infrequently (one episode of heartburn per week or less, or for those who want immediate relief

First course of treatment is to swallow one 20 mg tablet with a glass of water before eating in the morning. Take everyday for 14 days, no more than one tablet per day. The same 14 day course of therapy may be repeated every 4 months.
For more than 14 days or more often than 4 months needs to be directed by a physician.
It is important not chew or crush the tablets or crush the tablets in food.

Expiration dating period and recommended storage conditions : 24 months, Store at [redacted] [USP controlled room temperature].

C. Basis for Approvability or Not-Approval Recommendation

The pending labeling comments have been addressed. From the standpoint of CMC this application can be approved.

III. Administrative

A. Reviewer's Signature

See DFS

B. Endorsement Block

Chemist Name/Maria Ysern, MSc.
Chemistry Team Leader/Liang Zhou, PhD
Project Manager Name/Melissa Furness

C. CC Block

See DFS

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/s/

Maria Ysern
5/5/05 12:44:58 PM
CHEMIST

Liang Zhou
5/5/05 02:22:00 PM
CHEMIST

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application : NDA 21229/000
Org Code : 180
Priority : 23S

Sponsor: ASTRAZENECA LP
1800 CONCORD PIKE
WILMINGTON, DE 198038355

Stamp Date : 27-JAN-2000
PDUFA Date : 20-JUN-2003
Action Goal : 20-JUN-2003
District Goal: 28-SEP-2000

Brand Name : PRILOSEC 1(OMEPRAZOLE MAGNESIUM)20MG TAB
Estab. Name:
Generic Name: OMEPRAZOLE MAGNESIUM
Dosage Form: (DELAYED RELEASE TABLET
Strength : 20 MG

FDA Contacts:			
M. WALSH	Project Manager	(HFD-103)	301-827-3959
A. SHAW	Review Chemist	(HFD-800)	301-827-5918
L. ZHOU	Team Leader	(HFD-180)	301-827-1251

Overall Recommendation: ACCEPTABLE on 14-APR-2003by J. D AMBROGIO(HFD-322) 301-827-9049

[redacted] on 09-OCT-2002by S. FERGUSON(HFD-322) 301-827-9009

ACCEPTABLE on 18-SEP-2000by J. D AMBROGIO(HFD-322) 301-827-9049

Establishment : [redacted] FEI : [redacted]

DMF No: AADA:

Responsibilities: [redacted]

Profile : TCT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 16-MAR-00
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : [redacted] FEI : [redacted]

[redacted]

DMF No: AADA:

Responsibilities: [redacted]

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 16-MAR-00
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : [redacted] FEI : [redacted]
ASTRA PHARMACEUTICAL PRODUCTION AB
SODERTALJE, , SW

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 30-AUG-00
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 9615999 FEI : 3003342394
ASTRA PRODUCTION TABLETS AB
GARTUNAVAGAN
SODERTALJE, , SW SK102NA

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

Profile : TCT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 18-SEP-00
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : [redacted] FEI : [redacted]

DMF No: AADA:

Responsibilities: [redacted]

Profile : TCT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 16-MAR-00
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : 1012256 FEI : 1012256
MERCK AND CO INC
3517 RADIUM SPRINGS RD
ALBANY, GA 31708

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 18-FEB-00
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : 1017175 FEI : 1017175

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

PROCTER AND GAMBLE MFG CO
100 SWING ROAD
GREENSBORO, NC 27409

DMF No: AADA:

Responsibilities: FINISHED DOSAGE PACKAGER

Profile : TCT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 07-JUL-00
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : [redacted] FEI : [redacted]

[redacted]

DMF No: AADA:

Responsibilities: [redacted]

Profile : TCT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 14-APR-03
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

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_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Maria Ysern
4/24/03 02:30:44 PM
CHEMIST

Liang Zhou
4/24/03 02:54:37 PM
CHEMIST

NDA 21-229

Prilosec 1

Arthur B. Shaw, Ph.D.

Division of Gastrointestinal and
Coagulation Drug Products

APPEARS THIS WAY
ON ORIGINAL

Table of Contents

APPEARS THIS WAY
ON ORIGINAL

Chemistry Review Data Sheet

1. NDA 21-229
2. REVIEW #: 2
3. REVIEW DATE: August 2
4. REVIEWER Arthur B. Shaw, Ph.D.
5. PREVIOUS DOCUMENTS:

Original	27-Jan-2000
REVIEW #1	02-Nov-2000
DR Letter	02-Nov-2000
Telecon	13-Nov-2000
NA Letter	27-Nov-2000

6. SUBMISSION BEING REVIEWED:

Amendment BC	15-Nov-2000
Amendment AZ	12-Feb-2002

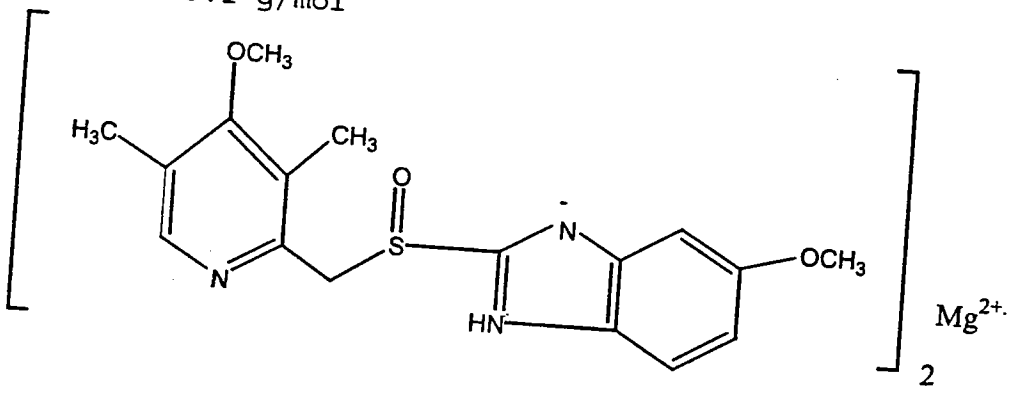
7. NAME & ADDRESS OF APPLICANT:

Name:	AstraZeneca LP
Address:	155725 Chesterbrook Blvd Wayne PA 19087-5677
Representative:	Gary Horowitz

8. DRUG PRODUCT NAME/CODE/TYPE:
   a) Proprietary Name: Prilosec 1 Note that the applicant was informed that this name was not acceptable in the NA letter. They have not responded satisfactorily to this.
   b) Non-Proprietary Name (USAN): Omeprazole magnesium
   c) Code Name/# : N/A
   d) Chem. Type/Submission Priority
      - Chem. Type 1
      - Submission Priority: S
9. LEGAL BASIS FOR SUBMISSION: New drug
10. PHARMACOL. CATEGORY: Proton pump inhibitor
11. DOSAGE FORM: Delayed release tablet
12. STRENGTH/POTENCY: 20 mg
13. ROUTE OF ADMINISTRATION Oral
14. Rx/OTC DISPENSED: __Rx _X_OTC
15. ___X_____Not a SPOTS product
16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT

N Bis (1*H*-Benzimidazole,5-methoxy-2-[(S)-[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl)sulfinyl]-),magnesium salt, trihydrate

$(C_{17}H_{18}N_3O_3S)_2Mg$
CAS Number 5382-33-5
MW= and 713.1 g/mol



17. RELATED/SUPPORTING DOCUMENTS

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	STATUS[2]	DATE REVIEW COMPLETED
				Adequate	23-Jan-2001
				Adequate	02-Aug-2002 See Container-Closure Section in Review Notes
				Adequate	02-Aug-2002
				Adequate	26-Feb-2002
				Adequate	25-Oct-1999
				Adequate	18-Aug-2000
				Adequate	31-Jul-2002
				Adequate	31-Jul-2002
				Adequate	31-Jul-2002

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	19-810	Omeprazole

18. STATUS

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE
EES	AC	18-Sep-2000
Methods Validation	See review notes	
EA	Categorical Exclusion requested	
Pharm/Tox	N/A	
DMETS (Trade Name)	Prilosec 1 Not acceptable	19-Apr-2002

The Chemistry Review for NDA 21-229

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability:

Approvable. There are two labeling comments.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable:

None

II. Summary of Chemistry Assessments

A. Description of Drug Product and Drug Substance:

- Drug Product Description: The drug product consists of a number of enteric-coated pellets compressed into a tablet. The applicant calls this a "Multiple Unit Pellet System" = MUPS Tablet. There is only one strength, 20 mg
- Drug Substance Description: Omeprazole magnesium. This is the magnesium salt of omeprazole, approved as Prilosec. Described in DMFs —— and ——
- Formulation and Drug Product Manufacturing: Described in DMF ——
- Comparison of Preclinical and Marketing Formulations: The same formulations were used for preclinical and marketing.
- Additional Drug Product Information: All of the information regarding the drug substance and drug product are contained in DMFs.

B. Description of How the Drug Product is Intended to be Used:

- Recommended dosage: 20 mg once a day for treatment of heartburn. The drug is not intended for treatment of episodic heartburn.
- The drug product is not intended for co-administration with another drug.
- Intended for OTC use
- Expiration dating period and recommended storage conditions. 24 months, USP Controlled room temperature

III. Administrative

A. Reviewer's Signature: See DFS

B. Endorsement Block R/D/ init by Liang Zhou 05-Aug-2002

C. CC Block: See DFS

3 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Arthur B. Shaw
8/7/02 11:28:54 AM
CHEMIST

Liang Zhou
8/7/02 04:22:27 PM
CHEMIST

NDA #21-229

Drug Product Proprietary Name: Prilosec 1

USAN Name: esomeprazole magnesium

Chemical Type/Therapeutic Class: 1S

Type of Letter: Not Approvable

Tertiary Chemistry Review #1

EA:	Acceptable. See E-mail review addendum dated 14 November 2000.
EER:	EER Summary Report dated 31 October 2000 lists all sites as ACCEPTABLE.
Microbiology;	Not Applicable. Solid Oral Dosage form.
Trade Name:	Under review by OPDRA. Review chemist recommends "delayed release" between "omeprazole" and "tablets" on the PI, carton, and blister labeling.
Methods Validation:	Unsatisfactory. Applicant has not supplied a set of specifications for drug substance or drug product in this application. Addtionally, the applicant has not submitted a complete methods validation package.
CMC:	Chemistry Review #1 dated 30 October 2000 found the information presented in DMFs —— and —— for the drug substance to be adequate. However this chemistry review also states that the information in DMF —— was found not adequate in a review dated 11 October 2000 and a deficiency letter was sent on 12 October 2000. Additionally DMFs —— and —— for blister packaging components were also found not adequate. The chemistry review of this NDA also states that the complete drug substance and drug product specifications should be included in this NDA.

The conclusion of Chemistry Review #1 is that this NDA is APPROVABLE.

John J. Gibbs, Ph.D.
Director, Chemistry Division II

/s/

John J. Gibbs
11/21/00 02:17:01 PM
CHEMIST

APPEARS THIS WAY
ON ORIGINAL

Walsh

NOV - 1 2000

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

1.NDA:# 21-229 **2. CHEM REVIEW #** 1 **3.REVIEW DATE:** 30-Oct-2000

4.SUBMISSIONS REVIEWED

	DOCUMENT	CDER	ASSIGNED
Original	27-Jan-2000	27-Jan-2000	27-Jan-2000

5. NAME & ADDRESS OF APPLICANT:

AstraZeneca LP
725 Chesterbrook Blvd
Wayne PA 19087-5677

6. DRUG PRODUCT NAME:

Proprietary:	Prilosec 1
Nonproprietary/USAN:	omeprazole magnesium
Chem.Type/Ther.Class:	1S
Code names:	H 199/18

7. PHARMACOLOGICAL CATEGORY: proton pump inhibitor

8. INDICATION: Treatment and prevention of heartburn

9. DOSAGE FORM: delayed release tablet

10. STRENGTH: ——— 20 mg

11. ROUTE OF ADMINISTRATION: oral

12. HOW DISPENSED: __ Rx X OTC

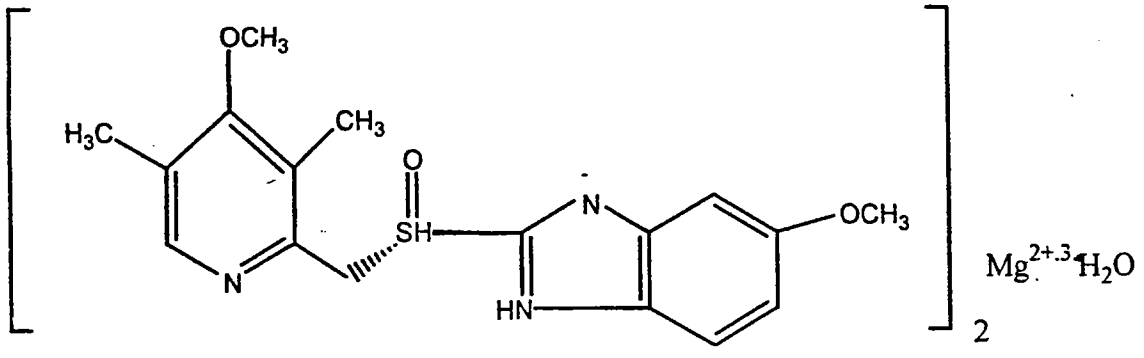
13. CHEMICAL IDENTIFICATION:

N Bis (1*H*-Benzimidazole,5-methoxy-2-[(S)-[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl)sulfinyl]-),magnesium salt, trihydrate

$(C_{17}H_{18}N_3O_3S)_2Mg \times 3H_2O$

CAS Number 217087-09-7

MW= 767.2 g/mol (trihydrate) and 713.1 g/mol (anhydrous basis)



14. **SUPPORTING DOCUMENTS:** DMF —— and —— for drug substance. DMF —— for drug product. See table below. For Container Closure DMFs see table below.

15. **RELATED DOCUMENTS** NDA 19-810

16. **CONSULTS:** None

17. **REMARKS/COMMENTS:** The DMF reviews for the drug substance are considered "Acceptable." However the DMF for the drug product, ——, was found to be inadequate in a review dated October 11, 2000. A deficiency letter was sent on October 12, 2000. The applicant should provide the specifications and test methods in the NDA, updated to reflect changes in the DMFs. There are deficiencies in the DMFs for some of the packaging components.

17. **CONCLUSIONS & RECOMMENDATIONS:** Approvable. The applicant should be sent a Discipline Review Letter.

[/S/] 11/1/00
Arthur B. Shaw, Ph.D.
Review Chemist HFD-180

[/S/] 11/1/00
Liang Zhou, Ph.D.
Chemistry Team Leader, HFD-180

cc:
NDA 21-229
HFD-180/Division File/NDA 21-229
HFD-181/CSO
HFD-180/LTalarico
HFD-180/LZhou
HFD-180/HGallo-Torres
HFD-180/AShaw
R/D Init by: LZhou 31-Oct-2000
f/t/ABS 31-Oct-2000
C:\Final\21229 Prilosec 1 Chem Review #1.doc

A. **DRUG SUBSTANCE:** All information in DMFs —— and —— The DMFs are **ACCEPTABLE.**

B. **DRUG PRODUCT:** All information in DMF ——. The DMF is not acceptable. The applicant has provided a table of "Specifications" on Page 11 of Volume 1.004 of the NDA.

Parameter		20 mg
Appearance		A pink, oblong, biconvex, film-coated tablet debossed P1 on one side
Identity Omeprazole	Positive	
Identity Mg	Positive	
Omeprazole Content	—— of stated amount*	
Content Uniformity (omeprazole)	Meets USP	
Drug Release	Q NLT —— after — minutes using USP "Drug release-Enteric coated articles, buffer stage" at — rpm in Dissolution	
Related substances	Total Any single known substance Any single unknown substance	NMT — NMT —— NMT ——

The specifications were discussed in the review of DMF —— and found to be not acceptable. There were a number of other parts of the DMF for which more information is required.

COMMENT: The applicant should be advised that DMF —— for the drug product is not acceptable.

APPEARS THIS WAY
ON ORIGINAL

C. **CONTAINER/CLOSURE SYSTEM:** The drug product will be packaged in [redacted] and a [redacted] (one tablet per pouch, for promotional purposes)

Component	Manufacturer	DMF	LOA Date	Page	Item Referenced	Result
[redacted]			23-Jul-99	21	[redacted] 4403/97, 4003e/97, 4006/97, and 4006e/97	Inadequate 07-Sep-2000
			21-Jul-99	19	Sec 12.2 [redacted]	Inadequate 09-Aug-2000
					Sec 10.6 [redacted]	Inadequate 03-Oct-2000
			19-Jul-99	17	Sec 98 [redacted]	Adequate 25-Oct-1999 Sue-Ching Lin
			19-Jul-99	18	Sec 107 [redacted]	Adequate 18-Aug-2000 Ray Frankewich
			21-Jul-99	24	[redacted]	Adequate

COMMENT: The applicant should be informed that DMFs [redacted] and [redacted] for blister packaging components were found to be inadequate.

D. **LABELING:** The Division of OTC drugs and OPDRA are reviewing most aspects of the labeling. The only chemistry issues are:

1. The name of the active ingredient:

   This is "omeprazole magnesium 20.6 mg (equivalent to 20 mg)." **ACCEPTABLE**

2. There is a statement "Do not chew or crush tablet." This is appropriate since this is a delayed-release formulation. **ACCEPTABLE**
3. The Carton and Package Insert name the drug as:

   [redacted]

   The blister backing states:

   [redacted]

The words "delayed release" should appear in the title.

COMMENT: The applicant should be advised to add the words "delayed Release" between "omeprazole" and "tablets" in the Carton Label, Package Insert, and Blister labeling.

E. **ESTABLISHMENT INSPECTION**

All sites are **ACCEPTABLE** See Appendix

F. **LIST OF CHEMISTRY DEFICIENCIES AND COMMENTS:**

1. You are advised that DMF —— for the drug product is not acceptable.
2. Provide a complete set of specifications for the drug substance and the drug product in the NDA. Also provide a complete methods validation package.
3. You are advised that DMFs —— and —— for materials used in the blister packages have been found to be deficient and the holders have been notified.
4. You are advised to add the words "delayed Release" between "omeprazole" and "tablets" in the Carton Label, Package Insert, and Blister labeling.

Appendix

31-OCT-2000 Page 1 of 3

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 21229/000 Priority: 2S Org Code: 180
Stamp: 27-JAN-2000 Regulatory Due: 27-NOV-2000 Action Goal: District Goal: 28-SEP-2000
Applicant: ASTRAZENECA
725 CHESTERBROOK BLVD
WAYNE, PA 190875677
Brand Name: PRILOSEC 1(OMEPRAZOLE MAGNESIUM)20MG TAB
Established Name:
Generic Name: OMEPRAZOLE MAGNESIUM
Dosage Form: DRT (DELAYED RELEASE TABLET
Strength: 20 MG

FDA Contacts: M. WALSH (HFD-180) 301-827-7310 , Project Manager
A. SHAW (HFD-180) 301-827-7310 , Review Chemist
L. ZHOU (HFD-150) 301-594-5765 , Team Leader

Overall Recommendation:

ACCEPTABLE on 18-SEP-2000 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: [redacted] DMF No:
AADA No:

Profile: TCT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 16-MAR-2000
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: [redacted]

Establishment: [redacted] DMF No:
AADA No:

Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 16-MAR-2000
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: [redacted]

Establishment: [redacted] DMF No:
AADA No:

[redacted]

Profile: CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 30-AUG-2000

Responsibilities: [redacted]

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Establishment: **9615999**
ASTRA PRODUCTION TABLETS AB

SODERTALJE, , SW

DMF No:
AADA No:

Profile: **TCT** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **18-SEP-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment: **1012256**
MERCK AND CO INC
3517 RADIUM SPRINGS RD
ALBANY, GA 31708

DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **18-FEB-2000**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

Establishment: **1017175**
PROCTER AND GAMBLE MFG CO
100 SWING ROAD
GREENSBORO, NC 27409

DMF No:
AADA No:

Profile: **TCT** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **07-JUL-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE PACKAGER**

Establishment: [redacted]

DMF No:
AADA No:

Profile: **TCT** OAI Status: **NONE**

Responsibilities: ---

31-OCT-2000

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-2000**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: [redacted]

DMF No:
AADA No:

Profile: **TCT** OAI Status: **NONE** Responsibilities: [redacted]
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **16-MAR-2000**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
