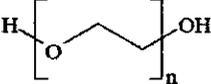
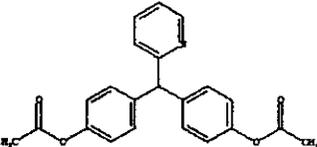


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-551

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW 1		1. Organization: HFD-180		2. NDA Number: 21-551	
3. Name and Address of Applicant (City & State): Braintree Laboratories, Inc. 60 Columbian Street West P. O. Box 850929 Braintree, MA 02185-0929				4. AF Number:	
6. Name of Drug: HalfLytely and Bisacodyl Tablets Bowel Prep Kit				5. Supplement(s):	
		7. Nonproprietary Name: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed release tablets.		Numbers	Dates
				SCS-002	9/9/04
8. Supplements Provide for: • Add _____ as an additional supplier of PEG-3350 NF;				9. Amendments and Other (Reports, etc.) Dates:	
10. Pharmacological Category: Cathartic/laxative		11. How Dispensed: Rx <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. Related IND/NDA/DMF(s): NDA 21-551	
13. Dosage Form: Tablets/ Powder for reconstitution		14. Potency: 20 mg/2L			
15. Chemical Name and Structure:   Bisacodyl				16. Records and Reports: Current Yes <input type="checkbox"/> No <input type="checkbox"/> Reviewed Yes <input type="checkbox"/> No <input type="checkbox"/>	
17. Comments: See review section. cc: NDA 21-551 HFD-180/Div File HFD-181/MFurness HFD-180/LZhou HFD-180/AAlhakim HFD-180/MYsern					
18. Conclusions and Recommendations: From a CMC perspective, this supplement can be approved.					
19. Reviewer					
Name: Zhengfang Ge, Ph.D.		Signature		Date Completed: Dec 21, 2004	

1 Page(s) Withheld

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

 § 552(b)(5) Deliberative Process

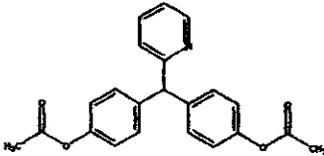
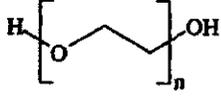
 § 552(b)(5) Draft Labeling

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/s/

Zhengfang Ge
12/21/04 03:37:27 PM
CHEMIST

Liang Zhou
12/21/04 04:18:14 PM
CHEMIST

CHEMISTS REVIEW # 1		1. Organization: HFD-180	2. NDA Number 21-551	
3. Name and Address of Applicant (City & State): Brain Tree Laboratories 60 Columbian Street West P.O.Box 850929 Braintree MA 02185			4. AF Number:	
			Supplement(s)	
6. Name of Drug: HalfLyte ^{ly} and Bisacodyl Tablets Bowel Prep Kit		7. Nonproprietary Name: PEG 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed release tablets	Number(s) SCS-003	Date(s) Oct 22, 2004
8. Supplement Provides for: Changes to the chemistry, manufacturing and controls of NDA 21-551 appropriate to the packet packaging material			9. Amendments and Other (Reports, etc.) Dates:	
10. Pharmacological Category: Osmotic agent for cleansing the bowel prior to colonoscopy		11. How Dispensed: Oral	12. Related IND/NDA/DMF(s):	
13. Dosage Form: Tablets and powder for reconstitution		14. Potency: 20 mg/2l		
15. Chemical Name and Structure:			16. Records and Reports:	
<p>Bisacodyl, USP</p> 			<p>Polyethylene Glycol</p> 	
17. Comments: See Review Notes. cc: NDA -21-551 HFD-180/Div File HFD-180/TClayton HFD-180/JKorvick HFD-180/MYsern R/D init by:LZhou MY/c:\word\sup\				
18. Conclusions and Recommendations: Based on the information provided this supplement can be approved.				
19. Reviewer				
Name: Maria E. Ysern, Review Chemist		Signature In DFS		Date Completed: Nov 5, 2004

2 Page(s) Withheld

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

 § 552(b)(5) Deliberative Process

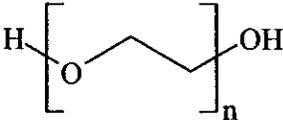
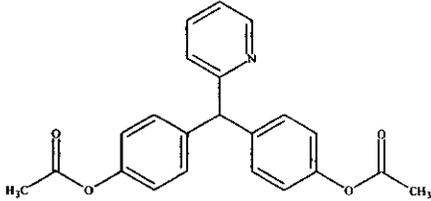
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/s/

Maria Ysern
2/8/05 02:15:50 PM
CHEMIST

Liang Zhou
2/8/05 04:29:12 PM
CHEMIST

CHEMIST'S REVIEW # 1		1. Organization: HFD-180		2. NDA Number 21-551	
3. Name and Address of Applicant (City & State): Braintree Laboratories 60 Columbian St. West P.O. Box 850929 Braintree, MA 02185-0929				4. AF Number:	
				Supplement(s)	
6. Name of Drug: HalfLyteLy and Bisacodyl Tablets Bowel Prep Kit		7. Nonproprietary Name: PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed release tablets.		Number(s) SCM-001	Date(s) Jun 28, 2004
8. Supplement Provides for: The adding of _____ as an additional supplier for the drug substance, polyethylene Glycol 3350, NF. And replacement of the _____				9. Amendments and Other (Reports, etc.) Dates:	
10. Pharmacological Category: Cathartics and Laxatives		11. How Dispensed: Oral		12. Related IND/NDA/DMF(s): NDA 21-551	
13. Dosage Form: Tablets/ Powder for reconstitution		14. Potency: 20 mg/2L			
15. Chemical Name and Structure: Polyethylene Glycol -3350				16. Records and Reports:	
					
Bisacodyl				Current Yes _ No	
				Reviewed Yes _ No	
17. Comments: See Review Notes. cc: NDA -HFD-180/Div File HFD-180/TClayton HFD-180/BJustice HFD-180MYsem R/D init by:LZhou MY/c:\word\sup\21551001.1my					
18. Conclusions and Recommendations: This supplement can be approved.					
19. Reviewer					
Name: Maria E. Ysem, Review Chemist		Signature In DFS		Date Completed: July 16, 2003	

2 Page(s) Withheld

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

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

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/s/

Maria Ysern
7/20/04 05:15:59 PM
CHEMIST

Liang Zhou
7/20/04 05:27:10 PM
CHEMIST

NDA 21-551

Half Lytely® (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl tablets)

Braintree Laboratories, Inc.

**Maria Ysern, MSc.
Division of Gastrointestinal and Coagulation Drug Products**

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CHEMISTRY REVIEW

Executive Summary Section

Chemistry Review Data Sheet

1. NDA 21-551
2. REVIEW # 2
3. REVIEW DATE: May 19, 2003
4. REVIEWER: Maria E. Ysern, MSc.
5. PREVIOUS DOCUMENTS: None

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original	Aug 15, 2002
Amendment N00C	April 14, 2003

7. NAME & ADDRESS OF APPLICANT:

Name: Braintree Laboratories, Inc.
60 Columbian Street West
Address: P.O. Box 850929
Braintree, MA 02185
Representative: Vivian Caballero, Director Regulatory Affairs
Telephone: (781) 843-2202

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Half Lytely® (PEG 3350, Sodium Chloride, Sodium bicarbonate and potassium chloride for oral solution and bisacodyl tablets)
- b) Non-Proprietary Name (USAN): PEG -3350, sodium chloride, sodium bicarbonate and potassium chloride and bisacodyl tablets.
- c) Code Name/# (ONDC only): N/A
- d) Chem. Type/Submission Priority (ONDC only):

CHEMISTRY REVIEW

Executive Summary Section

- Chem. Type: Type 3 and 4
- Submission Priority: Standard review

9. LEGAL BASIS FOR SUBMISSION:

The submission has been submitted in accordance with 21 CFR§314.50

10. PHARMACOL. CATEGORY:

Cathartics and Laxatives. Bowel cleansing prior to colonoscopy.

11. DOSAGE FORM:

Tablets/ Powder for reconstitution. (The sponsor's proposal was to call it a Bowel Prep —
On consult to Dr. Boring, Labeling and Nomenclature Committee, his advice was that it be named a
kit —

12. STRENGTH/POTENCY:

20 mg/ 2 Liters

13. ROUTE OF ADMINISTRATION:

Oral

14. Rx/OTC DISPENSED: Rx

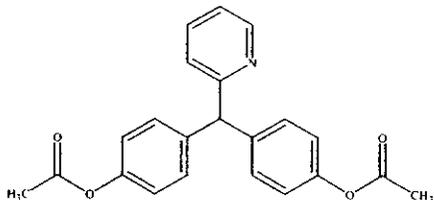
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note26]:

____ SPOTS product – Form Completed

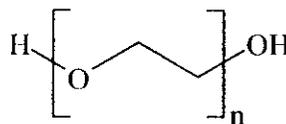
X Not a SPOTS product

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

Bisacodyl, USP



Polyethylene Glycol



CHEMISTRY REVIEW

Executive Summary Section

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
	I			2			
	II			1	Adequate	Jan 23, 2003	
	IV						
	IV			1	Adequate	Jan 7, 1998 (Chem review #7)	
	IV				4		Approved for NDA19-797
	IV			2	4		Formula provided in the NDA
	IV			1	Adequate	Feb 28, 2003	
	IV			1	Adequate	Dec 20, 2002	Also in NDA 19-797
	IV			4	N/A		NF product. CoA provided
	IV			1	Adequate	04-11-90	Responses to letter were pending
	IV			4	N/A		USP product, CoA provided
	IV			4	N/A		Vol. 1.18 page 405.
	III			1	Adequate	Jun 13, 02	Information is also provided in the NDA pages 415-417
	III			4	N/A		Information and 21 CFR status in the NDA
	IV			4	N/A		Enough information provided in the DMF, 21 CFR references provided
	III			4	N/A		Enough information provided in the NDA Vol. 1.18 pg 409
	III			1	Adequate	Aug 24, 2000	review Information in

CHEMISTRY REVIEW

Executive Summary Section

	III			4	N/A		NDA Information in the NDA
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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	19-797	Drug Substance information

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics			
EES	, was withdrawn as testing facility without prejudice	April 14, 2003	
Pharm/Tox	N/A		
Biopharm	N/A		
LNC/ Oct 11, 2002	Consulted October 11, 2003.	Response May 6, 2003	Dr. Boring recommended that this product be named a kit with each individual component individually labeled with the specific established name for that component.
Methods Validation	N/A		
EA	N/A		
DMETS/Sent Aug 15 2002	Consulted Aug 15, 2002	Response May 19, 2003	DMETS does not recommend the proposed trade name.

19. ORDER OF REVIEW (OGD Only): N/A

CHEMISTRY REVIEW

Executive Summary Section

The application submission(s) covered by this review was taken in the date order of receipt. ____
Yes ____ No ____ If no, explain reason(s) below:

The Chemistry Review for NDA 21-551

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This NDA can be approved. The manufacturing sites have been inspected and all were found adequate with exception of _____, which was withdrawn by the company as a testing facility without prejudice.

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

The sponsor should provide an adequate rationale for the dissolution method proposed. It is recommended the use of the USP delayed Release Method. This issue should be addressed within six months of the approval

II. Summary of Chemistry Assessments

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

Drug Product:

Consists of two main components:

2Liter Nulytely (Polyethylene Glycol, Sodium Chloride, USP, Sodium Bicarbonate, USP, Potassium Chloride USP) and
Bisacodyl delayed release Tablets (Bisacodyl, USP).

All the raw materials used in the manufacture of 2 liter Nulytely and Bisacodyl tablet core are USP or NF materials. The characteristics for the 2 Liter Nulytely components are identical to those presented in NDA 19-797. Detailed information regarding Bisacodyl USP is found in DMF _____

The Division of Clinical Biopharmaceutics reviewed the dissolution method and they have recommended that the sponsor submit an adequate rationale for the dissolution method.
(See Biopharmaceutics review 05/13/03)

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

Half Lytely Bowel Prep System is administered orally. The patient should only consume clear liquids, no solids, no milk the day before the scheduled exam and no antacids should be given for at least one hour before beginning the regimen.

Four Bisacodyl tablets are to be swallowed with water, and then wait for a bowel movement or maximum 6 hours and begin taking the Half Lytely solution at a rate of 240 ml (8 oz) every ten minutes until the rectal effluent is clear or two liters are consumed.

The Half Lytely solution is prepared by filling the container to the 2 liter mark with water, cap the bottle and shake to dissolve ingredients. The reconstituted solution may be refrigerated and should be used within 48 hours.

Executive Summary Section

C. Basis for Approvability or Not-Approval Recommendation

Adequate CMC information is provided in this NDA to support the to be marketed safe and effective product.

III. Administrative

A. Reviewer's Signature

See DFS

B. Endorsement Block

Maria Ysern, MSc., Review Chemist/Date: Same date as draft review

Liang Zhou, PhD, ChemistryTeamLeader/ Date

Alice Kacuba, Project Manager /Date

C. CC Block:

NDA 21-551

HFD-180 BJustice

HFD-180/ Div File/NDA 21-551

HFD-180/LZhou

HFD-180/MYsern

HFD-180/AKacuba

R/D Init: LZhou

MY/Final/c:/word/nda/215512093R.my

27 Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

Withheld Track Number: Chemistry- 1

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/s/

Maria Ysern
5/20/03 02:54:47 PM
CHEMIST
Amendmen to review #1

Marie Kowblansky
5/20/03 03:06:39 PM
CHEMIST

Marie Kowblansky is Acting Team Leader for Liang Zhou

CHEMISTRY REVIEW

NDA 21-551

Half Lytely® (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl tablets)

Braintree Laboratories, Inc.

Maria Ysern, MSc.

Division of Gastrointestinal and Coagulation Drug Products

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S DRUG SUBSTANCE [Name, Manufacturer]	9
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III. List Of Deficiencies To Be Communicated	33

CHEMISTRY REVIEW

Executive Summary Section

Chemistry Review Data Sheet

1. **NDA 21-551**
2. **REVIEW # 1**
3. **REVIEW DATE:** May 6, 2003
4. **REVIEWER:** Maria E. Ysern, MSc.
5. **PREVIOUS DOCUMENTS:** None

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original	Aug 15, 2002
Amendment N00C	April 14, 2003

7. NAME & ADDRESS OF APPLICANT:

Name: Braintree Laboratories, Inc.
Address: 60 Columbian Street West
P.O. Box 850929
Braintree, MA 02185
Representative: Vivian Caballero, Director Regulatory Affairs
Telephone: (781) 843-2202

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Half Lytely® (PEG 3350, Sodium Chloride, Sodium bicarbonate and potassium chloride for oral solution and bisacodyl tablets)
- b) Non-Proprietary Name (USAN): PEG -3350, sodium chloride, sodium bicarbonate and potassium chloride and bisacodyl tablets.
- c) Code Name/# (ONDC only): N/A
- d) Chem. Type/Submission Priority (ONDC only):

CHEMISTRY REVIEW

Executive Summary Section

- Chem. Type: Type 3 and 4
- Submission Priority: Standard review

9. LEGAL BASIS FOR SUBMISSION:

The submission has been submitted in accordance with 21 CFR§314.50

10. PHARMACOL. CATEGORY:

Cathartics and Laxatives. Bowel cleansing prior to colonoscopy.

11. DOSAGE FORM:

Tablets/ Powder for reconstitution. (The sponsor's proposal was to call it a Bowel Prep —
On consult to Dr. Boring, Labeling and Nomenclature Committee, his advice was that it be named a
kj'

12. STRENGTH/POTENCY:

20 mg/ 2 Liters

13. ROUTE OF ADMINISTRATION:

Oral

14. Rx/OTC DISPENSED: Rx

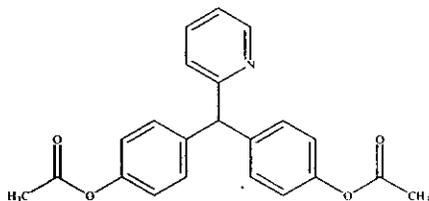
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note26]:

_____ SPOTS product – Form Completed

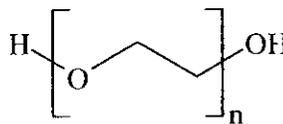
X Not a SPOTS product

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

Bisacodyl, USP



Polyethylene Glycol



CHEMISTRY REVIEW

Executive Summary Section

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
-	I			2			
/	II			1	Adequate	Jan 23, 2003	
	IV						
-	IV			1	Adequate	Jan 7, 1998 (Chem review #7)	
-	IV				4		Approved for NDA19-797
/	IV			2	4		Formula provided in the NDA
/	IV			1	Adequate	Feb 28, 2003	
	IV			1	Adequate	Dec 20, 2002	Also in NDA 19-797
-	IV			4	N/A		NF product. CoA provided
-	IV			1	Adequate	04-11-90	Responses to letter were pending
-	IV			4	N/A		USP product, CoA provided
-	IV			4	N/A		Vol. 1.18 page 405.
-	III			1	Adequate	Jun 13, 02	Information is also provided in the NDA pages 415-417
-	III			4	N/A		Information and 21 CFR status in the NDA
-	IV			4	N/A		Enough information provided in the DMF, 21 CFR references provided
-	III			4	N/A		Enough information provided in the NDA Vol. 1.18 pg 409
-	III			1	Adequate	Aug 24, 2000	review Information in

CHEMISTRY REVIEW

Executive Summary Section

—	III	—	—	4	N/A	NDA Information in the NDA
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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	19-797	Drug Substance information

18. STATUS:

ONDC:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics			
EES	— was withdrawn as testing facility without prejudice	April 14, 2003	
Pharm/Tox	N/A		
Biopharm	N/A		
LNC/ Oct 11, 2002	Consulted October 11, 2003.	Response May 6, 2003	Dr. Boring recommended that this product be named a kit with each individual component individually labeled with the specific established name for that component.
Methods Validation	N/A		
EA	N/A		
DMETS/Sent Aug 15 2002	Consulted Aug 15, 2002 PENDING		

19. ORDER OF REVIEW (OGD Only): N/A

CHEMISTRY REVIEW

Executive Summary Section

The application submission(s) covered by this review was taken in the date order of receipt. ____
Yes ____ No ____ If no, explain reason(s) below:

The Chemistry Review for NDA 21-551

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This NDA can be approved. The manufacturing sites have been inspected and all were found adequate with exception of _____ which was withdrawn by the company as a testing facility without prejudice.

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

No Phase IV commitments at this time.

II. Summary of Chemistry Assessments

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

Drug Product:

Consists of two main components:

2 Liter Nulytely (Polyethylene Glycol, Sodium Chloride, USP, Sodium Bicarbonate, USP, Potassium Chloride USP) and

Bisacodyl delayed release Tablets (Bisacodyl, USP).

All the raw materials used in the manufacture of 2 liter Nulytely and Bisacodyl tablet core are USP or NF materials. The characteristics for the 2 Liter Nulytely components are identical to those presented in NDA 19-797. Detailed information regarding Bisacodyl USP is found in DMF _____

The dissolution method might be unsuitable for the delayed release tablets. It will be reviewed by the Division of Clinical Biopharmaceutics and could probably become a Phase IV commitment for the sponsor.

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

Half Lytely Bowel Prep System is administered orally. The patient should only consume clear liquids, no solids, no milk the day before the scheduled exam and no antacids should be given for at least one hour before beginning the regimen.

Four Bisacodyl tablets are to be swallowed with water, and then wait for a bowel movement or maximum 6 hours and begin taking the Half Lytely solution at a rate of 240 ml (8 oz) every ten minutes until the rectal effluent is clear or two liters are consumed.

The Half Lytely solution is prepared by filling the container to the 2 liter mark with water, cap the bottle and shake to dissolve ingredients. The reconstituted solution may be refrigerated and should be used within 48 hours.

C. Basis for Approvability or Not-Approval Recommendation

Adequate CMC information is provided in this NDA to support the to be marketed safe and effective product.

CHEMISTRY REVIEW

Executive Summary Section

III. Administrative

A. Reviewer's Signature

See DFS

B. Endorsement Block

Maria Ysem, MSc., Review Chemist/Date: Same date as draft review

Liang Zhou, PhD, ChemistryTeamLeader/ Date

Alice Kacuba, Project Manager /Date

C. CC Block:

NDA 21-551

HFD-180 BJustice

HFD-180/ Div File/NDA 21-551

HFD-180/LZhou

HFD-180/Mysem

HFD-180/AKacuba

R/D Init: LZhou

MY/Final/c:/word/nda/215512092R.my

26 Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

Withheld Track Number: Chemistry 2

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Maria Ysern
5/8/03 05:00:05 PM
CHEMIST

Liang Zhou
5/8/03 05:05:43 PM
CHEMIST

The firm requests Categorical Exclusion from conducting an Environmental Assessment (EA). The May 8, 2003 CMC review states that this is appropriate for this application.

Alice Kacuba 5-14-03

Alice Kacuba
Regulatory Health Project Manager

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : NDA 21551/000 Sponsor: BRAINTREE LABORATORIES INC
Org Code : 180 60 COLUMBIA ST
Priority : 3S BRAINTREE, MA 02185

Stamp Date : 16-AUG-2002 Brand Name : HALF LYTELY 20MG/2L TABLETS
PDUFA Date : 16-JUN-2003 Estab. Name:
Action Goal : 16-JUN-2003 Generic Name: HALF LYTELY 20MG/2L TABLETS
District Goal: 17-APR-2003 Dosage Form: (FOR ORAL SOLUTION)
Strength : 2 L

FDA Contacts: A. KACUBA Project Manager (HFD-180) 301-827-7310
M. YSERN Review Chemist (HFD-180) 301-827-7310
L. ZHOU Team Leader (HFD-180) 301-827-1251

Overall Recommendation: ACCEPTABLE on 23-APR-2003 by J. D AMBROGIO (HFD-322) 301-827-9054
WITHHOLD on 16-APR-2003 by J. D AMBROGIO (HFD-322) 301-827-9054

Establishment : CFN : 1224850 FEI : 1000513636
BRAINTREE LABORATORIES INC
270 CENTRE ST
HOLBROOK, MA 02343

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

Profile : LIQ OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 28-MAR-03
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : FEI :

DMF No: _____

AADA:

Responsibilities: _____

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-OCT-02
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : _____ FEI : _____

DMF No: _____

AADA:

**APPEARS THIS WAY
ON ORIGINAL**

Establishment : CFN : _____

FEI : _____

No:

AADA:

Responsibilities: FINISHED DOSAGE STABILITY TESTER

Profile : CTL OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 12-NOV-02

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : _____

FEI : _____

APPEARS THIS WAY
ON ORIGINAL

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

possibilities: —

Profile : TCT OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 28-OCT-02
 Decision : ACCEPTABLE
 Reason : DISTRICT RECOMMENDATION

Establishment : CFN : — FEI : —

DMF No: — AADA:

Responsibilities: —

Profile : CSN OAI Status: NONE
 Milestone: OC RECOMMENDATION
 Milestone Date: 23-OCT-02
 Decision : ACCEPTABLE
 Reason : BASED ON PROFILE

Establishment : CFN : — FEI : —

DMF No: — AADA:

Responsibilities: —

Profile : CSN OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 22-OCT-02
 Decision : ACCEPTABLE
 Reason : BASED ON PROFILE

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

DMF No: AADA:

Responsibilities: —

Profile : TCT OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 30-OCT-02
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : — FEI : —
/

DMF No: AADA:

Responsibilities: —

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 23-OCT-02
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : — FEI : —
/

DMF No: AADA:

Responsibilities: —

Profile : LIQ OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-OCT-02

ACCEPTABLE

Reason:

BASED ON PROFILE

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

The Methods Validation will be requested in the action letter.

Alice Kacuba 5 12 03

Alice Kacuba

Regulatory Health Project Manager