

COR

**Division of Metabolic and Endocrine Drug Products
CONSUMER SAFETY OFFICER REVIEW #3**

Application Number: NDA 21-117

Name of Drug: Calcium Chloride Injection, USP in Plastic Syringe

Sponsor: Abbott Laboratories

Material Reviewed

Submission Date(s): January 21, 2000

Receipt Date(s): January 21, 2000 (FAX)

Background and Summary Description: The original labeling for this submission was submitted on March 26, 1999. An internal labeling meeting to review the labeling was held on November 22, 1999. A final draft revised label was assembled using the recommendations from the team members who were present at the November 22, 1999 labeling meeting. The Draft revisions were assembled and FAXED to the firm on December 29, 1999. The firm FAXED a revised label to the Division on January 12, 2000 (See FAX of Abbott's revised labeling dated January 12, 2000). Upon review of the January 12, 2000, the Sponsor was called on January 18, 2000 with revisions to the package insert. These included revisions to the INDICATIONS AND USAGE section to include only the single indication of hypocalcemia:

Other changes such as the PRECAUTIONS, Pediatric Use and DOSAGE AND ADMINISTRATION sections were also recommended. The firm submitted revised labeling dated January 21, 2000 (FAX with hard copy to follow) which included all the labeling changes recommended by the Division.

NDA 21-117

Page 2

APPEARS THIS WAY
ON ORIGINAL

Review

The revised draft label for NDA 21-117 dated January 21, 2000 (fax), Calcium Chloride, Injection USP, was compared with the January 12, 2000 draft labeling submitted by the firm except for the labeling revisions recommended by the Division in their January 20, 2000 FAX. The Firm included all the revisions recommended by the Division.

APPEARS THIS WAY
ON ORIGINAL

20 pages
REDACTED
DRAFT
LABELING

**Division of Metabolic and Endocrine Drug Products
CONSUMER SAFETY OFFICER REVIEW #2**

Application Number: NDA 21-117

Name of Drug: Calcium Chloride Injection, USP in Plastic Syringe

Sponsor: Abbott Laboratories

Material Reviewed

Submission Date(s): January 12, 2000

Receipt Date(s): January 12, 2000

Background and Summary Description: The original labeling for this submission was submitted on March 26, 1999. An internal labeling meeting to review the labeling was held on November 22, 1999. As result of that meeting revisions were recommended to the DESCRIPTIONS section, INDICATIONS AND USAGE section, PRECAUTIONS section, and DOSAGE and ADMINISTRATION sections of the package insert. In addition on the immediate label [redacted] should be added below [redacted]

[redacted] A final draft revised label was assembled using the recommendations from the team members who present at the November 22, 1999 labeling meeting. The firm FAXED a label to the Division on January 10, 2000 (See FAX of Abbott's revised labeling dated January 12, 2000). The Division agreed to all the changes suggested by Abbott. The Firm FAXED (with hard copy to follow) a revised final draft labeling on January 12, 2000.

Review

The revised draft label for NDA 21-117 dated January 12, 2000, Calcium Chloride, Injection USP, was compared with the January 10, 2000 labeling submitted by the firm and was found to be identical.

Conclusions

With the concurrence of the reviewing staff, the revised draft label for NDA 21-117 dated January 12, 2000 with recommended revisions is acceptable.

 / S / 1-14-00
Stephen McCort, Project Manager

 / S /
Enid Galliers, Chief Project Management Staff

NOTE: Additional changes discussed with the sponsor on 1/18/00

 / S /
Joanna Lewandzki, M.D., Medical Reviewer

 / S / 1/21/00
Eric Colman, M.D., Medical Team Leader

 / S / 1-14-00
David Lewis, Ph.D., Chemistry Reviewer

 / S / 1-14-00
Duu-Gong Wu, Ph.D. Chemistry Team Leader

 / S / 18-JAN-00
Robert Shore, ~~Ph.D.~~, Biopharmaceutics Reviewer
Pharm.D.

 / S /
Hae Young Ahn, Ph.D., Biopharmaceutics Team Leader

 / S / 1/18/00
Ron Steigerwalt, Ph.D., Pharmacology Reviewer

 / S /
John B. Jenkins, M.D., Division Director

APPEARS THIS WAY
ON ORIGINAL

14 pages
REDACTED
DRAFT
LABELING

**Division of Metabolic and Endocrine Drug Products
CONSUMER SAFETY OFFICER REVIEW** H 7

Application Number: NDA 21-117

Name of Drug: Calcium Chloride Injection, USP

Sponsor: Abbott Laboratories

Material Reviewed

Submission Date(s): March 26, 1999

Receipt Date(s): March 29, 1999

Background and Summary Description: The labeling for this submission was submitted on March 26, 1999. An internal labeling meeting to review the labeling was held on November 22, 1999. As result of that meeting revisions were recommended to the DESCRIPTIONS section, INDICATIONS AND USAGE section, PRECAUTIONS section, and DOSAGE and ADMINISTRATION sections of the package insert. In addition on the immediate label [redacted] should be added below [redacted]. A final draft revised label was assembled using the recommendations from the team members who present at the Noovember 22, 1999 labeling meeting. (SEE REVISED DRAFT LABEL)

Review

Revisions to the draft label for NDA 21-117 dated March 26, 1999, Calcium Chloride, Injection USP, were incorporated into the labeling from recommendations made by team members from the review team.

APPEARS THIS WAY
ON ORIGINAL

Conclusions

The revised draft label for NDA 21-117 incorporates the revisions recommended by the reviewing team for this product. The revised label with recommended revisions is acceptable and should be communicated to the Sponsor.

[Redacted] /S/ 12-27-99
Stephen McCort, Project Manager

[Redacted] /S/ Joanna Zowadzki, M.D. Medical Reviewer 12/28/99

[Redacted] /S/ 12-28-99
David Lewis, Ph.D., Chemistry Reviewer

[Redacted] /S/ 12-27-99
Duu-Gong Wu, Ph.D. Chemistry Team Leader

[Redacted] /S/ 27-DEC 99
Robert Shore, Ph.D., Biopharmaceutics Reviewer

[Redacted] /S/ 27-DEC 99
Hae Young Ahn, Ph.D., Biopharmaceutics Team Leader

[Redacted] /S/ 12/27/99
Ron Steigerwalt, Ph.D., Pharmacology Reviewer

[Redacted] /S/ 12/28/99
Solomon Sobel, M.D., Division Director

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

cc:

- Original
- HFD-510/Div. Files
- HFD-510/SMMC ~~cc~~ / D Wu / D Lewis / R Steigerwalt
- HFD-510/Solomon Sobel, M.D. E COLMAN
- HFD-505 / R Shore / HAHN
- CSO REVIEW
- IS ZOWADSKI

12 pages
REDACTED
DRAFT
LABELING

MEMORANDUM

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

DATE: January 21, 2000
FROM: Steve McCort
SUBJECT: Calcium Chloride NDA - 505(b)(2) Issues
TO: File for NDA 21-117

This is a 505(b)(2) application for 10% Calcium Chloride IV in a 10 mL Plastic Syringe. Currently the product is marketed in glass as a "grandfathered product." To support the Indications cited in their package insert, the firm has cited text book references to support the safety and efficacy of their drug product. The following is a regulatory history and background regarding the 505(b)(2) issues with this application.

/S/

Steve McCort, HFD-510

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

EXCLUSIVITY SUMMARY FOR NDA # 21-117 SUPPL # _____

Trade Name 10% Calcium Chloride Injection, in Plastic Syringe Generic Name _____

Applicant Name Abbott Laboratories HFD # 510

Approval Date If Known 1-28-2006

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?
YES / NO /

b) Is it an effectiveness supplement?
YES / NO /

If yes, what type? (SE1, SE2, etc.) _____

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES / NO /

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES / / NO / /

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

no

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such)

YES / / NO / /

If yes, NDA # _____ Drug Name _____

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES / / NO / /

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES / / NO / /

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____

NDA# _____

NDA# _____

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES / / NO / /

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____

NDA# _____

NDA# _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES / / NO / /

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES / / NO / /

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES / / NO / /

APPEARS THIS WAY
ON ORIGINAL

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES / ___ / NO / ___ /

If yes, explain: _____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES / ___ / NO / ___ /

If yes, explain: _____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

APPEARS THIS WAY
ON ORIGINAL

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1 !

IND # ____ YES /__ / ! NO /__ / Explain: _____
! _____
! _____

Investigation #2 !

IND # ____ YES /__ / ! NO /__ / Explain: _____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1 !

YES /__ / Explain _____ ! NO /__ / Explain _____
! _____
! _____
! _____

Investigation #2 !

YES /__ / Explain _____ ! NO /__ / Explain _____
! _____
! _____
! _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

ISI 1-18-80
Signature Date

Title: _____

Product

ISI 1/28/80
Signature of Office/ Date
Division Director

APPEARS THIS WAY
ON ORIGINAL

cc: Original NDA Division File HFD-93 Mary Ann Holovac

APPEARS THIS WAY
ON ORIGINAL

Section VI. Patent Certification

Appended are the Patent Certification and Exclusivity Statements per 314.94(a)(12) and 314.94(a)(3), respectively, for the subject drug.

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

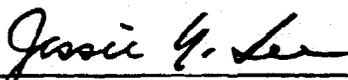
6-155



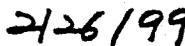
PATENT AND EXCLUSIVITY INFORMATION

1. Active Ingredient(s): Calcium Chloride Injection
2. Strength(s): 10% (100 mg/ mL)
3. Trade Name: 10% Calcium chloride Injection, USP
(10% Calcium Chloride Injection, USP
in Plastic Syringe)
4. Dosage Form: Injectable solution
10% Calcium Chloride, 10 mL
5. Route of Administration: Intravascular administration
6. Applicant Firm Name: Abbott Laboratories
7. NDA Number: To be assigned.
8. Approval Date: To be determined.
9. Exclusivity - Date first NDA could be approved and length of exclusivity period:
None
10. Applicable patent numbers and expiration date of each:
None

Per 21 CFR 314.94 (a) (12), this is a "Paragraph II Certification" stating that the patent has expired.



Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
D-389, AP30
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-3537



Date

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number: 21117 **Trade Name:** CALCIUM CHLORIDE 10% INJECTION
Supplement Number: **Generic Name:** CALCIUM CHLORIDE 10% INJECTION
Supplement Type: **Dosage Form:** INJ
Regulatory Action: AP **Proposed Indication:** Treatment of hypocalcemia

ARE THERE PEDIATRIC STUDIES IN THIS SUBMISSION?

NO, No waiver and no pediatric data.

What are the INTENDED Pediatric Age Groups for this submission?

NeoNates (0-30 Days) Children (25 Months-12 years)
 Infants (1-24 Months) Adolescents (13-16 Years)

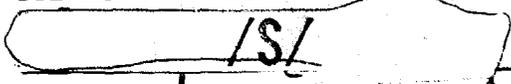
Label Adequacy Does Not Apply
Formulation Status -
Studies Needed -
Study Status -

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:

Pediatric information to NDA pending. Sponsor to submit literature references to support pediatric dosing recommendations as a supplement post-approval.

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, STEPHEN MCCORT


 Signature

1-28-2000
 Date

Section VIII. Debarment Certification

Attached are the debarment certification for this application and the list of relevant convictions for persons debarred or not debarred.

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

6-164



CERTIFICATION REQUIREMENT FOR ALL APPLICATIONS

FOR APPROVAL OF A DRUG PRODUCT

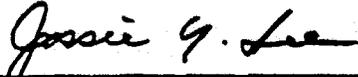
CONCERNING USING SERVICES OF DEBARRED PERSONS

Under the new law, any application for approval of a drug product submitted on or after June 1, 1992, must include:

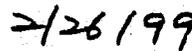
"a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsections (a) or (b) [section 306(a) or (b)], in connection with such application."

Abbott Laboratories hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Generic Drug Enforcement Act of 1992
Section 306(k) (1) of the act (21 USC 335a(k) (1)).



Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
D-389. AP30
Abbott Laboratories
200 Abbott Road
Abbott Park, Illinois 60064-3537



Date

6-165



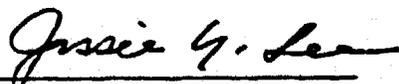
LIST OF RELEVANT CONVICTIONS FOR

PERSONS DEBARRED OR NOT DEBARRED

Per letter from the Office of Generic Drugs dated January 15, 1993, abbreviated applications must contain a list of relevant convictions, as described in section 306(a) and (b) of the GDEA*, of the applicant and affiliated persons (i.e., contractors, et. al.) responsible for the development or submission of the application, which have occurred within five years before the date of the application. Firms with no convictions to list should submit a statement to that effect.

Abbott Laboratories states that it has no such convictions to list.

*Generic Drug Enforcement Act of 1992
Section 306(k) (1) of the act (21 USC 335a(k) (1)).



Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
D-389, AP30
Abbott Laboratories
200 Abbott Road
Abbott Park, Illinois 60064-3537

2/26/99

Date

6-166



BZ

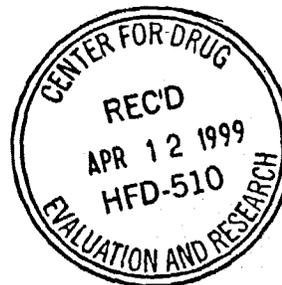
DUPLICATE

Hospital Products Division
Abbott Laboratories
One Abbott Park Road
Abbott Park, Illinois 60064-3500

ORIG AMENDMENT

April 9, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF METABOLIC AND ENDOCRINE
DRUG PRODUCTS, HFD #510
Attn: DOCUMENT CONTROL ROOM #14B-19
5600 Fishers Lane
Rockville, Maryland 20857



ATTENTION: Solomon Sobel, M.D.
Director

RE: NDA 21-117 10% Calcium Chloride Injection, USP, Plastic Syringe

GENERAL CORRESPONDENCE

Abbott Laboratories hereby provides additional information concerning the New Drug Application for the subject drug to provide for 10% Calcium Chloride Injection, USP, 10 mL Plastic Syringe, in accordance with Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. This is in response to a phone conversation between Mr. Steve McCort of FDA and Dr. Jessie Lee of Abbott Laboratories on April 6, 1999 requesting additional information for this New Drug Application. The subject drug is an [redacted] drug product. We have made minor changes in the contents of the New Drug Application. We list the changes as follows:

1. **Table of Contents:**

We have revised the Table of Contents of the New Drug Application to include a detailed index for the Microbiology of the Drug Product Section [redacted].
The revised Table of Contents is provided in EXHIBIT I.

2. **Request for Waiver of Bioavailability:**

The subject drug is an injectable drug. Therefore, we hereby request a waiver of the bioavailability test requirements per 21 CFR 320.22 (b)(1). We also include the safety information for the container/closure system in the Clinical/Medical Justification Section. The waiver request and revised Clinical/Medical Justification Section are provided in EXHIBIT II.

3. **Microbiology of the Drug Product Section:**

[redacted]

We also referenced the location of the executed batch records for Section B.4. "Information Included in the Batch Records". The revised sections are included in EXHIBIT III.



Dr. S. Sobel
Page Two
April 9, 1999

We trust that this submission is complete. Please contact me if you have any questions or need additional information concerning this submission.

Sincerely,

ABBOTT LABORATORIES

APPEARS THIS WAY
ON ORIGINAL

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

APPEARS THIS WAY
ON ORIGINAL

JYL:jl

G:\4-99fda.jyl\5
attachment

MEMORANDUM OF A T/CON

Meeting Date: January 18, 2000

Time: 2:00pm

Location: PKLN 14B-56

Application: NDA 21-117; 10% Calcium Chloride Injection, USP in Plastic Syringe

Type of Meeting: T/Con/Labeling

Meeting Recorder: Steve McCort, Project Manager

FDA Attendees:

Eric Colman, M.D., Medical Team Leader, HFD-510

Joanna Zawadzki, M.D., Medical Reviewer, HFD-510

Steve McCort, Project Manager, HFD-510

Abbott Laboratories:

Mary Baker, Pharm.D., Regulatory Affairs

Jessie Lee, Ph.D., Manager, Regulatory Affairs

Keith Bitzinger, Label Editor, Regulatory Affairs

Discussion:

In the discussion with FDA, the Firm agreed to change the INDICATIONS AND USAGE section to include only the single indication of hypocalcemia

Other changes such as the PRECAUTIONS, Pediatric Use and DOSAGE AND ADMINISTRATION sections were recommended. The Firm was told that these labeling revisions would be sent to the firm on final approval of our medical staff.

Conclusion:

The Firm was told that the labeling revisions from FDA would be sent to the firm on final approval of our medical staff and would be communicated to the Firm by end of business day January 19, 2000.

/S/

Stephen McCort, Project Manager

**MEMORANDUM OF MEETING MINUTES
LABELING MEETING - INTERNAL**

Meeting Date: November 22, 1999
Time: 10:00 am
Location: PKLN 14B-56

Application: NDA 21-117; Calcium Chloride Injection, USP, Plastic Syringe

Type of Meeting: Labeling Meeting Internal

Meeting Chair: Gloria Troendle

Meeting Recorder: Steve McCort

Attendees:

Gloria Troendle, M.D., Deputy Director
Joanna Zawadzki, M.D., Medical Reviewer
David Lewis, Ph.D., Chemistry Reviewer
Duu-Gong Wu, Ph.D., Chemistry Team Leader
Ron Steigerwalt, Ph.D., Pharmacology Team Leader
Hae Young Ahn, Ph.D., Biopharmacology Reviewer
Robert Shore, Pharm. D., Biopharmacology Reviewer
Steve McCort, Project Manager

Background:

The firm submitted labeling in the original application dated March 26, 2000. A labeling amendment was submitted on April 9, 2000 in which a side by side comparison of the labeling of the glass syringe with the plastic syringe was submitted. The labeling meeting was held internally within the Division on November 22, 1999.

Conclusion:

Recommendations were made but not finalized at the meeting. Final revised comments to the labeling would be communicate to Steve McCort at a later date.

The labeling revisions were assembled and Faxed to the Firm on December 29, 1999.

Minutes Prepared: 
Steve McCort, Project Manager

Attachments/Handouts: See copy of labeling Revisions FAXED to the firm on December 29, 1999

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: January 24, 2000

FROM: Eric Colman, M.D.

APPEARS THIS WAY

SUBJECT: Pediatric Labeling

TO: File for NDA 21-117

After internal discussion among the medical staff regarding the pediatric labeling for NDA 21-117, it was decided that the firm should be asked to provide additional dosing information for the pediatric population. The firm will be requested to commit to submitting a supplement post-approval that provides the dosing information and appropriate labeling for the pediatric population.

ES/

1/24/00

Eric Colman, M.D.
Acting Med. Team Leader
HFD-510

APPEARS THIS WAY

cc:

NDA-21-117
HFD-510/DivFile
HFD-510/EColman/JZawadzki
HFD-002/JJenkins

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELECON

DATE: January 24, 2000

APPLICATION NUMBER: NDA 21-117; Calcium Chloride Injection

BETWEEN:

Name: Jessie Lee, Ph.D.
Phone: 847-937-5513
Representing: Abbott Laboratories

AND

Name: Steve McCort
Division of Metabolic and Endocrine Drug Products, HFD-510

SUBJECT: Pediatric Labeling

Per the memo with Dr. Eric Colman, Acting Medical Team Leader, Abbott was called to request a commitment

Dr. Jessie Lee of Abbott thought that this commitment would be no problem for Abbott Laboratories and that they would send a letter documenting this commitment to the file for this NDA.

APPEARS THIS WAY
ON ORIGINAL

/S/

1-24-00

Steve McCort
Project Manager, HFD-510

cc: Original NDA 21-117
HFD-510/Div. File
HFD-510/Steve McCort
HFD-510/EColman/JZawadzki

APPEARS THIS WAY
ON ORIGINAL

TELECON

ABBOTT

Hospital Products Division

Abbott Laboratories
1388 Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-8157

January 24, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF METABOLIC AND ENDOCRINE
DRUG PRODUCTS, HFD #510

Attn: DOCUMENT CONTROL ROOM #14B-19
5600 Fishers Lane
Rockville, Maryland 20857

ATTENTION: John K. Jenkin, M.D.
Acting Director

VIA FAX (301) 443-9282

Re: NDA 21-117 10% Calcium Chloride Injection, USP in Plastic Syringe

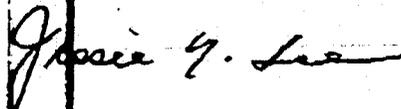
MINOR AMENDMENT - POSTAPPROVAL COMMITMENT

Abbott Laboratories hereby amends the above-referenced new drug application for the subject drug. This letter is in response to a telephone conversation held between Mr. Steve McCort of FDA and Dr. Jessie Lee of Abbott Laboratories on January 24, 2000 requesting a postapproval commitment to the above-referenced NDA.

Abbott Laboratories commits to supplement this application with dosing information for pediatric population and to provide the final printed labeling within three months from the date of the NDA approval of the 10% Calcium Chloride Injection.

We trust that this submission is complete. If there are any further questions, please contact me.

Sincerely,
ABBOTT LABORATORIES



Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

G11-2000fda.jyU12

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: January 21, 2000

FROM: Steve McCort

APPEARS THIS WAY
ON ORIGINAL

SUBJECT: NDA 21-117; 10% Calcium Chloride Injection- Pending Issues

TO: John K. Jenkins, M.D.
Acting Director, HFD-510

Pediatric Labeling and Pediatric Page Pending - (See Dr. Colman's E-Mail message - Pediatric Page). Dr. Colman in the E-Mail message notes that the safety and effectiveness of the drug product are based upon similar conditions between the adult and pediatric populations. However the **Dosage and Administration** section of the package insert does not include dosing instructions for pediatric patients. Dr. Colman and Dr. Zawadzki will call Abbott to ask them to submit to the NDA dosing information/instructions for the pediatric population before the NDA can be approved.

/S/

Steve McCort
Project Manager, HFD-510

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: October 29, 1999
FROM: Steve McCort, Project Manager, HFD-510
SUBJECT: Planning Dates - Timelines
TO: File for NDA 21-117; Calcium Chloride

Due to resource constraints during the months of November and December, 1999 an E-Mail was sent to the team members on October 26, 1999 in which the Action performance goal date was moved up from December 1, 1999 to January 29, 2000.

As a follow-up to the E-Mail, a concurrence was achieved to the following goal dates:

1. Final Reviews due January 5, 2000
2. Date to Dr. Sobel due January 19, 2000
3. Action Performance Goal Date January 29, 2000

/S/ 10-29-99

Steve McCort
Project Manager, HFD-510

APPEARS THIS WAY
ON ORIGINAL

M^a receipt

NDA 21-117

APR 5 1999

Abbott Laboratories
Attention: Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
200 Abbott Park Road D-389 AP30
Abbott Park, IL 60064-6157

Dear Dr. Lee:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: 10% Calcium Chloride Injection, USP, 10 mL, in Plastic Syringe
Therapeutic Classification: Standard (S)
Date of Application: March 26, 1999
Date of Receipt: March 29, 1999
Our Reference Number: NDA 21-117

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 28, 1999, in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be January 29, 2000, and the secondary user fee goal date will be March 29, 2000.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within 120 days of receipt of your pediatric drug development plan, we will notify you of the pediatric studies that are required under section 21 CFR 314.55.

If you believe that this drug qualifies for a waiver of the study of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 10 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a

NDA 21-117

Page 2

waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. If you do not submit a Proposed Pediatric Study Request within 120 days from the date of this letter, we will presume that you are not interested in obtaining pediatric exclusivity and will notify you of the pediatric studies that are required under section 21 CFR 314.55. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.

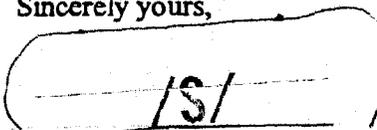
Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, contact Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely yours,



4.5.99

Emd Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research



Hospital Products Division

Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

January 21, 2000

JAN 21 2000

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF METABOLIC AND ENDOCRINE
DRUG PRODUCTS, HFD #510
Attn: DOCUMENT CONTROL ROOM #14B-19
5600 Fishers Lane
Rockville, Maryland 20857

ATTENTION: John K. Jenkin, M.D.
Acting Director

VIA FAX (301) 443-9282

Re: NDA 21-117 10% Calcium Chloride Injection, USP in Plastic Syringe

MINOR AMENDMENT – DRAFT LABELING

Abbott Laboratories hereby amends the above-referenced new drug application for the subject drug. This letter is in response to the faxed letters dated December 29, 1999 and January 20, 2000 requesting revision of the labeling for the 10% Calcium Chloride Injection.

We have revised the labeling based on the Agency's comments. Please note that we also made some editorial changes in the format for mL, Injection and mEq under the DOSAGE AND ADMINISTRATION section. The annotated labeling for the container, carton and package insert is provided in Exhibit I. The final printed labeling for the container, carton and package insert is attached in Exhibit II.

We also provided in this package two diskettes containing the PDF files for the container, carton and package insert labeling. The PDF files can be read using Microsoft Word Explorer with Adobe Reader viewing program.

We trust that this submission is complete. If there are any further questions, please contact me.

Sincerely,
ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

G:\1-2000\da.jyl\9
Attachment



J. Jenkin
Page Two
January 12, 2000

4. **CARTON LABEL:** The agency recommended to add the statement [redacted]. We did not define the concentration, mmol/ml, anywhere in the insert. To minimize the confusion of the end users, we would like to revise the statement to: [redacted]. This statement is consistent with the information provided in the DOSAGE AND ADMINISTRATION section.
5. **PACKAGE INSERT – CAUTION statement:** Similar to item 4, we added the statement of [redacted] in the CAUTION statement on the Title page.

The annotated labeling for the container, carton and package insert is provided in Exhibit I. The final printed labeling for the container, carton and package insert is attached in Exhibit II.

We also provided in this package two diskettes containing the PDF files for the container, carton and package insert labeling. The PDF files can be read using Microsoft Word Explorer with Adobe Reader viewing program.

We trust that this submission is complete. If there are any further questions, please contact me.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

G:\1-2000\da.jyl\2

Attachment



BL

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

December 16, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF METABOLIC AND ENDOCRINE
DRUG PRODUCTS, HFD #510
Attn: DOCUMENT CONTROL ROOM #14B-19
5600 Fishers Lane
Rockville, Maryland 20857
ATTENTION: Solomon Sobel, M.D.
Director

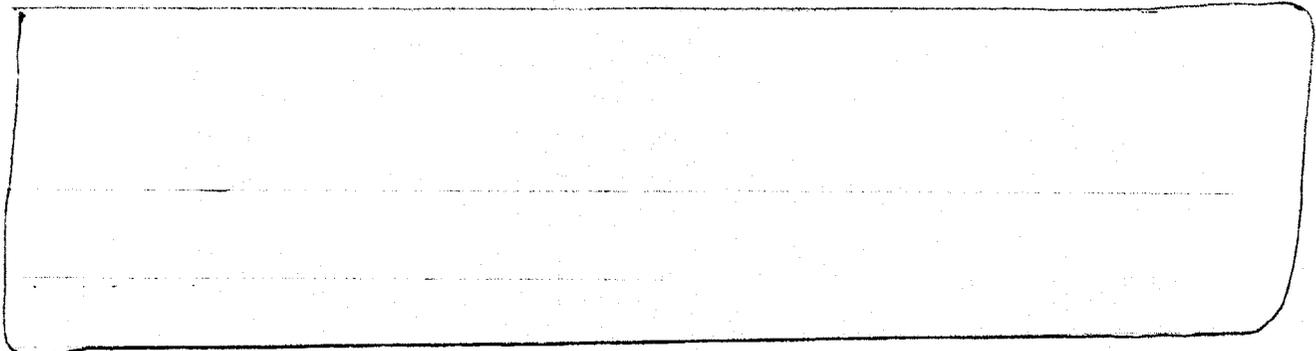


VIA FAX (301) 827-0878

Re: NDA 21-117 10% Calcium Chloride Injection, USP in Plastic Syringe

TELEPHONE AMENDMENT

Abbott Laboratories hereby amends the above-referenced new drug application for the subject drug. This letter is in response to phone conversations held between Dr. David Lewis of FDA, and Dr. Jessie Lee of Abbott Laboratories on December 15 and 16, 1999.



We trust that this submission is complete. If there are any further questions, please contact me.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl
G:\12-99fda.jyl
Attachment



Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

AUG 2 1999

July 30, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF METABOLIC AND ENDOCRINE
DRUG PRODUCTS, HFD #510
Attn: DOCUMENT CONTROL ROOM #14B-19
5600 Fishers Lane
Rockville, Maryland 20857
ATTENTION: Solomon Sobel, M.D.
Director

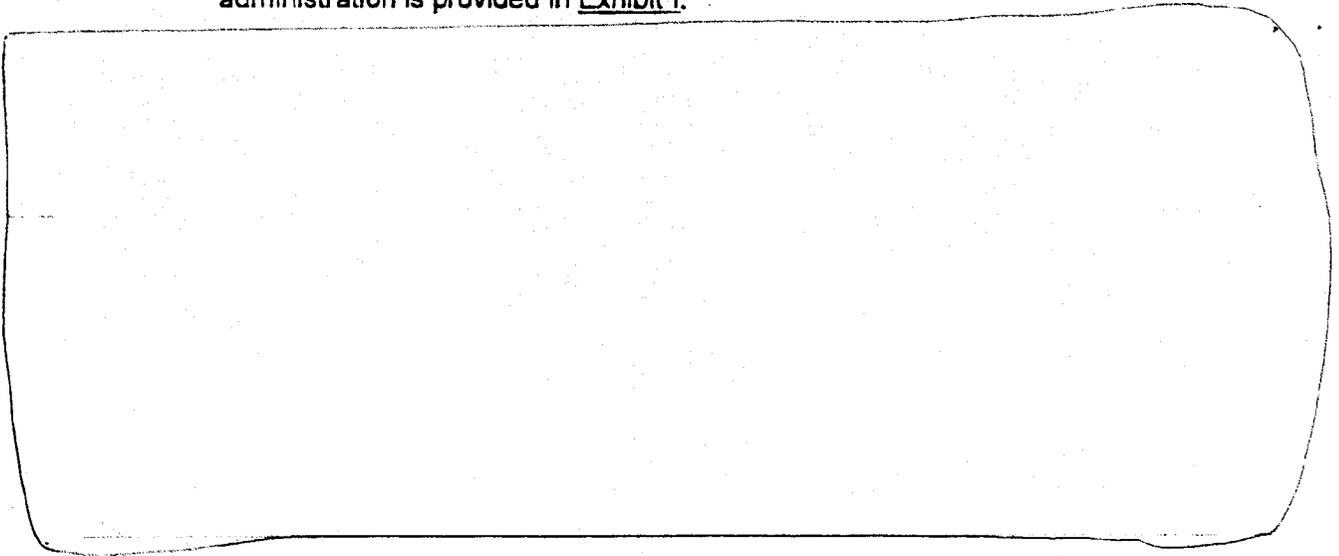
MINOR AMENDMENT

Re: NDA 21-117 10% Calcium Chloride Injection, USP in Plastic Syringe

Abbott Laboratories hereby amends the above-referenced new drug application for the subject drug. This is in response to the Agency's faxed letter of July 15, 1999 requesting additional information. The Agency's comments are as follows:

COMMENT: "While the application is fileable for pending NDA 21-117, 10% Calcium Chloride Injection, USP in Plastic Syringe, the following information is requested:
1. Biopharmaceutics: Please provide literature with summaries on the bioavailability of Calcium Chloride after IV administration."

RESPONSE: The medical literature on the bioavailability of Calcium Chloride after IV administration is provided in Exhibit I.





Dr. S. Sobel
Page Two
July 30, 1999

We trust that this submission is complete. If there are any further questions, please contact me.

Sincerely,

ABBOTT LABORATORIES

APPEARS THIS WAY
ON ORIGINAL

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

G:\7-99fda.jyl\57

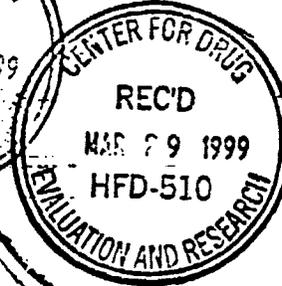
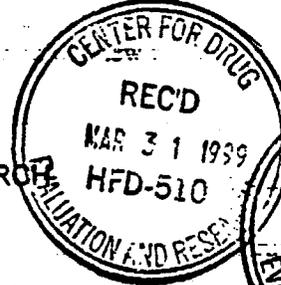
Attachment



Hospital Products Division
 Abbott Laboratories
 One Abbott Park Road
 Abbott Park, Illinois 60064-3500

March 26, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
 DIVISION OF METABOLIC AND ENDOCRINE
 DRUG PRODUCTS, HFD #510
 Attn: DOCUMENT CONTROL ROOM #14B-19
 5600 Fishers Lane
 Rockville, Maryland 20857



ATTENTION: Solomon Sobel, M.D.
 Director

RE: NDA 21-117 10% Calcium Chloride Injection, USP, Plastic Syringe

ORIGINAL NEW DRUG APPLICATION

Abbott Laboratories hereby submits this original New Drug Application for the subject drug to provide for 10% Calcium Chloride Injection, USP, 10 mL Plastic Syringe, in accordance with Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. The subject drug is an [redacted] drug product.

The dosage forms and manufacturing site may be described as follows:

| <u>List Number</u> | <u>Fill Concentration</u> | <u>Size/ Type Volume</u> | <u>Container</u> | <u>Manufacturing Facility</u> |
|--------------------|---------------------------|--------------------------|-----------------------|-------------------------------|
| 1631 | 10% | 10 mL | 10 mL Plastic Syringe | Rocky Mount, North Carolina |

Abbott Laboratories is filing this original NDA in accordance with various guidances furnished by CDER concerning packaging changes for established drug products from glass to plastic primary containers. The Agency has determined that the process for submitting currently marketed small volume parenteral products, which contains an active ingredient not previously approved under an application submitted under section 505(b), in glass containers to be packaged in plastic containers shall be via a new drug application.

The Agency has corresponded with Abbott Laboratories on the process of submitting new drugs in plastic containers. This correspondence includes a letter from Dr. Roger Williams, FDA, to Dr. Thomas F. Willer, dated September 3, 1996, and a letter from Dr. Murray Lumpkin, FDA, to Dr. Thomas F. Willer dated November 6, 1998 with MAPP 6020.2 in the attachment. The correspondence references are provided in ATTACHMENT I.

2

S. Sobel, M.D.
Page Two
March 26, 1999

We submit this new drug application in accordance with MAPP 6020.2, "Applications for Parenteral Products in Plastic Immediate Containers," issued September 6, 1996. Calcium Chloride Injection was on the market in 1938 and was grandfathered under the 1938 Food, Drug and Cosmetic Act. Abbott currently markets Calcium Chloride Injection in an Abboject® glass container.

Per Dr. Lumpkin's letter of November 6, 1998, simple literature/medical textbook information may be used to support the safety and efficacy of a submission like 10% Calcium Chloride Injection under section 505(b)(2). We conducted an extensive electronic medical literature and textbook search for the information to support the efficacy of the 10% Calcium Chloride Injection. The medical literature/textbook search covered the period from 1937 to the present. To support the safety of the drug product, we conducted a review of reported adverse events for the 10% Calcium Chloride Injection and no reports on safety were found. The adverse event search timeframe was from 1990 to the present. Medical rationale for 10% Calcium Chloride is provided in the ATTACHMENT II.

We sent a letter to Dr. Murry Lumpkin, CDER, pursuing clarification on the applicability of the user fee for the submission of 10% Calcium Chloride Injection packaged in a plastic syringe on February 26, 1999. The letter explained that limited amount of information from the medical literature/medical textbook will be provided in the NDA submission to support the safety and efficacy of the 10% Calcium Chloride Injection. Abbott Laboratories interpreted the medical literature as non-clinical data. Per phone conversation between Mr. Michael Jones, FDA, and Dr. Jessie Lee, Abbott Laboratories, on March 17, 1999, Mr. Jones provided an interpretation of such medical information as equivalent to clinical data. Therefore, a full amount of NDA user fee will be applied to the NDA submission of the 10% Calcium Chloride Injection. We have provided the User Fee Cover Sheet in each volume of this submission with the User Fee ID #

The Agency has reviewed and approved a continuing stream of submissions for other products packaged in this polypropylene plastic syringe over the last year. We include the information herein for your reference.

Center Director for Pharmaceutical Research
Center for Drug Evaluation and Research

| <u>NDA/ANDA Number</u> | <u>Product</u> | <u>Approval Date</u> |
|-------------------------|---------------------------------|----------------------|
| NDA 19-445/S-002 | 50% Dextrose Injection | 1/27/98 |
| ANDA 75-005 | Iopamidol Injection | 2/24/98 |
| NDA 19-030/S-008 | Bretylium Tosylate Injection | 3/13/98 |
| NDA 18-801/S-014 | Sterile Water for Injection | 8/14/98 |
| NDA 19-222/S-006 | 5% Dextrose Injection | 9/17/98 |
| ANDA 40-302 | 1% & 2% Lidocaine HCl Injection | 9/28/98 |
| ANDA 75-136 | Verapamil Injection | 10/20/98 |
| NDA 19-217/S-004 | 0.9% Sodium Chloride Injection | 11/18/98 |
| NDA 19-445/S-004, S-006 | 25% Dextrose Injection | 11/23/98 |



S. Sobel, M.D.
Page Three
March 26, 1999

The subject drug is a prescription drug and not an over-the-counter drug. Abbott Laboratories Hospital Products Division will manufacture the 10 mL finished dosage form at its currently approved Rocky Mount, North Carolina facility (CFN 1021343). Please refer to Drug Master File 1561 for a full description of this Abbott Laboratories, Hospital Products Division facility.

Please refer to the accompanying Table of Contents for a list of the data supporting this newly prepared NDA submission. These data have been presented in six volumes consistent with the items described in the 21 CFR Part 314 "Application for FDA Approval to Market a New Drug or An Antibiotic Drug". In compliance with 21 CFR 314.94 covering FDA preapproval inspections of manufacturing sites, Abbott Laboratories has submitted a complete true copy of the CMC section from this application ("designated as the field copy") to the FDA district office (Atlanta, Georgia) with inspection responsibilities for the Abbott Laboratories Hospital Products Division manufacturing site (Rocky Mount, North Carolina) listed in this application. The signed true copy certification is located in the Section IX, Page 6-167.

We request twenty-four months expiration dating for this product based on the stability data enclosed herein. At the request of the Agency, we will provide samples of the bulk drug substance and finished dosage form.

We trust that this submission is complete and this new drug application can be expeditiously approved. Please contact me if you have any questions or need additional information concerning this submission.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

cacinda.doc/5
Attachment



Hospital Products Division

Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

January 14, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF METABOLIC AND ENDOCRINE
DRUG PRODUCTS, HFD #510
Attn: DOCUMENT CONTROL ROOM #14B-19
5600 Fishers Lane
Rockville, Maryland 20857

ATTENTION: John K. Jenkin, M.D.
Acting Director

VIA FAX (301) 443-9282

Re: NDA 21-117 10% Calcium Chloride Injection, USP in Plastic Syringe

MINOR AMENDMENT - SAFETY UPDATE

Abbott Laboratories hereby amends the above-referenced new drug application for the subject drug. This letter is in response to a telephone conversation between Mr. Steve McCort of FDA and Dr. Jessie Lee of Abbott Laboratories on January 14, 2000 requesting the safety update of the 10% Calcium Chloride Injection.

We conducted safety search of the 10% Calcium Chloride Injection on March 1, 1999. No reports regarding the safety issue of the above-referenced drug product were found. The search covered from March 1, 1999 back to 1995.

We trust that this submission is complete. If there are any further questions, please contact me.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

G:\1-2000\da.jyl\7

MEMO TO THE FILE

RE: Safety Update

DATE: 01/21/00

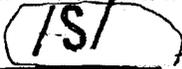
NDA: 21-117

DRUG: Calcium Chloride Injection in Plastic

APPEARS THIS WAY
ON ORIGINAL

The company conducted a literature search to satisfy the requirements of a safety update for the above referenced NDA. This search covered the time period 1995-March 1, 1999. No relevant reports were found.

This information is sufficient.

 1/24/00
Eric Colman, MD
Acting Team Leader

APPEARS THIS WAY
ON ORIGINAL

ABBOTT

ORIGINAL

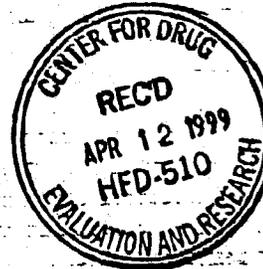
BL

Hospital Products Division
Abbott Laboratories
One Abbott Park Road
Abbott Park, Illinois 60064-3500

NDA ORIG AMENDMENT
SUPPL NEW CORRESP

April 9, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF METABOLIC AND ENDOCRINE
DRUG PRODUCTS, HFD #510
Attn: DOCUMENT CONTROL ROOM #14B-19
5600 Fishers Lane
Rockville, Maryland 20857



4/22/99

Noted

ATTENTION: Solomon Sobel, M.D.
Director

RE: NDA 21-117 10% Calcium Chloride Injection, USP, Plastic Syringe

GENERAL CORRESPONDENCE

Abbott Laboratories hereby provides additional labeling information concerning the New Drug Application for the subject drug to provide for 10% Calcium Chloride Injection, USP, 10 mL Plastic Syringe, in accordance with Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. This is in response to a phone conversation between Mr. Steve McCort of FDA and Dr. Jessie Lee of Abbott Laboratories on April 6, 1999 requesting additional labeling information. The subject drug is an

The proposed labeling for the 10% Calcium Chloride Injection, USP, 10 mL Plastic Syringe was similar to the same drug solution packaged in a glass syringe. Abbott Laboratories currently markets the 10% Calcium Chloride Injection in an Abboject® glass syringe. The labeling of these two drug products are identical with the exception in their NDC numbers, drug brand names, needle vs. non-needle systems and other editorial changes. A side-by-side comparison of the labeling between the Abboject® glass container and the plastic syringe is provided in EXHIBIT I.

We trust that this submission is complete. Please contact me if you have any questions or need additional information concerning this submission.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

| | |
|---------------------------------|---|
| REVIEWS COMPLETED | |
| CSO ACTION: | |
| <input type="checkbox"/> LETTER | <input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO |
| CSO INITIALS | DATE |

JYL:jl

G:\4-99\da.jyl\9
attachment