CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-421

APPROVAL LETTER

ANDA 40-421

JUN 21 2001

Able Laboratories, Inc.
Attention: Shashikant Shah
6 Hollywood Court
South Plainfield, NJ 07080-4295

Dear Sir:

This is in reference to your abbreviated new drug application dated October 6, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Carisoprodol Tablets USP, 350 mg.

Reference is also made to your amendments dated January 16, April 20, and May 17, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Carisoprodol Tablets USP, 350 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Soma® Tablets, 350 mg, of Wallace Laboratories). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print.

Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler 6/21/01
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA **40-421** APPROVAL SUMMARY (Pending EES)

PRODUCT: Carisoprodol Tablets, USP
FIRM: Able Laboratories, Inc.
DOSAGE FORM: Tablet
STRENGTHS: 350 mg
cGMP STATEMENT/EIR UPDATE STATUS: **Pending**
BIO STUDY: APPROVE, Bio Review Dated 11/30/00
VALIDATION: N/A (DS and DP are compendial)

STABILITY: Three months accelerated stability data, 40 ± 2°C/75% ± 5% RH, and twelve months long-term room temperature data, 25 ± 2°C/60% ± 5% RH, for both 100 and 1000 container/closure system is submitted for the demonstration batch #TB-059 (100's: #TB-059A, 1000's: #TB-059C). The container/closure system used for the stability study is equivalent to the system proposed for commercial use. All reported data are within specifications as listed. Thus, a 24 month expiration date is justified.

Tests and specifications for the drug product on stability include: Description (White to off-white round tablets debossed "A266"on one side and plain on the other side); Physical Evaluation (Organoleptic); Assay of Label Claim); Dissolution (Q) dissolved in 60 minutes); Related Compounds
e: , Individual Unknown Impurity:
Total Impurities:

LABELING: Acceptable 5/25/2001

STERILIZATION VALIDATION: N/A

SIZE OF BIO BATCH: Tablets (Batch #TB-059)

SIZE OF STABILITY BATCHES: The stability batch is the same as the bio-batch. The 100's container/closure designates the batch as #TB-059A, and the 1000's container/closure designates the batch as #TB-059C.

PROPOSED PRODUCTION BATCHES: The proposed maximum production batch size is Tablets. The manufacturing process for production batches remains the same as that for the test batch.

CHEMIST: John D. Franolic, Ph.D. John D. Franolic DATE: 05/07/01 6/8/01

SUPERVISOR: D. Gill, Ph.D. DSGill 6-8-01 DATE: 05/08/01

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-421

APPROVED DRAFT LABELING

Rx Only

NDC 53265-266-11

ABLE LABORATORIES INC.

CARISOPRODOL TABLETS, USP

350 mg

1000 TABLETS

JUN 21 2001 APPROVED

EACH TABLET CONTAINS:
Carisoprodol, USP ..... 350 mg

USUAL ADULT DOSAGE: 1 tablet three times daily and at bedtime.

DISPENSE in a tight container as defined in the USP, with a child-resistant closure (as required).

See accompanying descriptive literature.

STORE at controlled room temperature 15°-30°C (59°-86°F) [see USP].

Mfg. by: ABLE LABORATORIES, INC.
SOUTH PLAINFIELD, NJ 07080

LB10146/01
05/01

Manufacturer's Code
53265

N 3 53265-266-11 8

LOT NO.:

EXP. DATE:

Rx Only

NDC 53265-266-10

ABLE LABORATORIES INC.

CARISOPRODOL TABLETS, USP

350 mg

100 TABLETS

JUN 21 2001 APPROVED

EACH TABLET CONTAINS:
Carisoprodol, USP ..... 350 mg

USUAL ADULT DOSAGE: 1 tablet three times daily and at bedtime.

DISPENSE in a tight container as defined in the USP, with a child-resistant closure (as required).

See accompanying descriptive literature.

STORE at controlled room temperature 15° - 30°C (59° - 86°F) [see USP].

Mfg. by: ABLE LABORATORIES, INC.
SOUTH PLAINFIELD, NJ 07080

LB10132/01
05/01

Manufacturer's Code
53265

N 3 53265-266-10 1

LOT NO.:

EXP. DATE:

CARISOPRODOL TABLETS, USP

350 mg

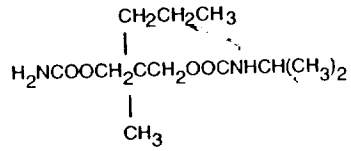
JUN 21 2001

APPROVED

Final Insert # 10

Rx only

DESCRIPTION - Carisoprodol Tablets, USP are available as 350 mg round, white tablets. Chemically, carisoprodol is N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate. Carisoprodol is a white, crystalline powder, having a mild, characteristic odor and a bitter taste. It is very slightly soluble in water; freely soluble in alcohol, in chloroform, and in acetone. The molecular formula is $C_{12}H_{24}N_2O_4$, with a molecular weight of 260.33. The structural formula is:



Each carisoprodol tablet intended for oral administration contains 350 mg of carisoprodol USP. In addition, it also contains the following inactive ingredients: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, and starch.

Actions - Carisoprodol produces muscle relaxation in animals by blocking interneuronal activity in the descending reticular formation and spinal cord. The onset of action is rapid and effects last four to six hours.

Indications - Carisoprodol is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Carisoprodol does not directly relax tense skeletal muscles in man.

Contraindications - Acute intermittent porphyria as well as allergic or idiosyncratic reactions to carisoprodol or related compounds such as meprobamate, mebutamate, or tybamate.

Warnings

Idiosyncratic Reactions - On very rare occasions, the first dose of carisoprodol has been followed by idiosyncratic symptoms appearing within minutes or hours. Symptoms reported include: extreme weakness, transient quadriplegia, dizziness, ataxia, temporary loss of vision, diplopia, mydriasis, dysarthria, agitation, euphoria, confusion, and disorientation. Symptoms usually subside over the course of the next several hours. Supportive and symptomatic therapy, including hospitalization, may be necessary.

Usage in Pregnancy and Lactation - Safe usage of this drug in pregnancy or lactation has not been established. Therefore, use of this drug in pregnancy, in nursing mothers, or in women of childbearing potential requires that the potential benefits of the drug be weighed against the potential hazards to mother and child. Carisoprodol is present in breast milk of lactating mothers at concentrations two to four times that of maternal plasma. This factor should be taken into account when use of the drug is contemplated in breast-feeding patients.

Usage in Children - Because of limited clinical experience, carisoprodol tablets are not recommended for use in patients under 12 years of age.

Potentially Hazardous Tasks - Patients should be warned that this drug may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a motor vehicle or operating machinery.

Additive Effects - Since the effects of carisoprodol and alcohol or carisoprodol and other CNS depressants or psychotropic drugs may be additive, appropriate caution should be exercised with patients who take more than one of these agents simultaneously.

Drug Dependence - In dogs, no withdrawal symptoms occurred after abrupt cessation of carisoprodol from dosages as high as 1 gm/kg/day. In a study in man, abrupt cessation of 100 mg/kg/day (about five times the recommended daily adult dosage) was followed in some subjects by mild withdrawal symptoms such as abdominal cramps, insomnia, chilliness, headache, and nausea. Delirium and convulsions did not occur. In clinical use, psychological dependence and abuse have been rare, and there have been no reports of significant abstinence signs. Nevertheless, the drug should be used with caution in addiction-prone individuals.

Precautions - Carisoprodol is metabolized in the liver and excreted by the kidney; to avoid its excess accumulation, caution should be exercised in administration to patients with compromised liver or kidney function.

Adverse Reactions - *Central Nervous System* - Drowsiness and other CNS effects may require dosage reduction. Also observed: dizziness, vertigo, ataxia, tremor, agitation, irritability, headache, depressive reactions, syncope, and insomnia. (See also Idiosyncratic Reactions under "Warnings.")

Allergic or Idiosyncratic - Allergic or idiosyncratic reactions occasionally develop. They are usually seen within the period of the first to fourth dose in patients having had no previous contact with the drug. Skin rash, erythema multiforme, pruritus, eosinophilia, and fixed drug eruption with cross reaction to meprobamate have been reported with carisoprodol. Severe reactions have been manifested by asthmatic episodes, fever, weakness, dizziness, angioneurotic edema, smarting eyes, hypotension, and anaphylactoid shock. (See also Idiosyncratic Reactions under "Warnings.")

In case of allergic or idiosyncratic reactions to carisoprodol, discontinue the drug and initiate appropriate symptomatic therapy, which may include epinephrine, antihistamines, and in severe cases corticosteroids. In evaluating possible allergic reactions, also consider allergy to excipients (information on excipients is available to physicians on request).

Cardiovascular - Tachycardia, postural hypotension, and facial flushing.

Gastrointestinal - Nausea, vomiting, hiccup, and epigastric distress.

Hematologic - Leukopenia, in which other drugs or viral infection may have been responsible, and pancytopenia, attributed to phenylbutazone, have been reported. No serious blood dyscrasias have been attributed to carisoprodol.

Dosage and Administration - The usual adult dosage of Carisoprodol Tablets, USP is one 350 mg tablet, three times daily and at bedtime. Usage in patients under age 12 is not recommended.

Overdosage - Overdosage of carisoprodol has produced stupor, coma, shock, respiratory depression, and, very rarely, death. The effects of an overdosage of carisoprodol and alcohol or other CNS depressants or psychotropic agents can be additive even when one of the drugs has been taken in the usual recommended dosage. Any drug remaining in the stomach should be removed and symptomatic therapy given. Should respiration or blood pressure become compromised, respiratory assistance, central nervous system stimulants, and pressor agents should be administered cautiously as indicated. Carisoprodol is metabolized in the liver and excreted by the kidney. Although carisoprodol overdosage experience is limited, the following types of treatment have been used successfully with the related drug meprobamate: diuresis, osmotic (mannitol) diuresis, peritoneal dialysis, and hemodialysis (carisoprodol is dialyzable). Careful monitoring of urinary output is necessary and caution should be taken to avoid overhydration. Observe for possible relapse due to incomplete gastric emptying and delayed absorption. Carisoprodol can be measured in biological fluids by gas chromatography (Douglas, J. F., et al.: *J Pharm Sci* 58: 145, 1969).

How Supplied - Carisoprodol Tablets, USP 350 mg are available as white to off-white, round tablets, debossed "A266" on one side and plain on the other side.
Bottles of 100
Bottles of 1000

Store at controlled room temperature 15°-30°C (59°-86°F). [see USP.]

IN16020/01 05/01 VC8126

Dispense in a tight container as defined in the USP, with a child-resistant closure (as required).

Manufacturer's code 53265

Manufactured by:
ABLE LABORATORIES, INC.
6 Hollywood Court, CN 1013,
South Plainfield, NJ 07080-4295

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-421

CHEMISTRY REVIEW(S)

MAR 15 2001

38. CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 40-421 **APPLICANT:** Able Laboratories, Inc.

DRUG PRODUCT: Carisoprodol Tablets, USP 350 mg

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:

1. for Carisoprodol drug substance was found inadequate. The DMF holder has been notified of the deficiencies. Please provide notification in your response that the DMF holder has responded to these deficiencies.

2. Please do not delete the test for Organic Volatile Impurities (OVIs) from the drug substance specifications as it is a monograph requirement. Testing, however, will not be required so long as the vendor's certification (that there is no potential for the OVIs to be present in the drug substance) remains in effect.

3. The batch number listed on the Raw Material Specification and Release Report for Starch, (Able Lot #99E005, MFG's Lot No. KGGMY), does not match that shown on the manufacturer's certificate of analysis atch No. KGIHA). Please provide the correct manufacturer's certificate of analysis for Able Lot #99E005.

4. The report of analysis submitted for Colloidal Silicon Dioxide from the outside testing laboratory, is not for the above component. Please provide the correct report.

5. Please provide instructions for packaging of the drug product in the master batch record.

6. Please provide yield limits for each stage of the manufacturing and packaging process in the master batch record.

7. Please provide the time limits that the drug product will be held prior to packaging in the master batch record.

8. The executed batch record for batch #TB-059 erroneously lists a net gain of in step #21 of the manufacturing process. The actual data shows a net loss of . Please correct.

9. Please provide yield limits for each stage of the manufacturing and packaging process in the executed batch summary.

10. Please explain the net gain of tablets tablets from

TB-059A + tablets from TB-059C) obtained during the packaging process. Please provide a process deviation report.

11. Please provide a completed bottle specification and release report for the 150 cc and 950 cc bottles.

12. Please provide a second test for identification in the Product Specification and Release Report for the drug product.

13. Please rename the "absorptivity factors" as relative response factors in the method validation of assay and related compounds for the drug substance and drug product. The term "absorptivity factor" is not accurate since the peak area data is obtained with a refractive index detector.

14. Please provide the tests that will be performed at each station in the accelerated and long-term controlled room temperature (CRT) stability protocol.

15. Please revise your stability results summary data sheets (accelerated and long-term) to include the following changes:

    (a) Provide the limits for temperature and relative humidity (i.e., 25°C /60% RH and 40°C/75% RH should be 25°C ± 2°C/60% ± 5% RH and 40°C ± 2°C/75% ± 5% RH, respectively).

    (b) Inclusion of all the stations that will be tested in the study (i.e., for the long-term CRT study, show the 24 and 36 month stations).

    (c) Inclusion of the organoleptic test data.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

1. You are advised that the use of in-house analytical methods for testing the drug substance and drug product does not relieve you from meeting the compendial standards. In the event of a dispute, the official USP methods will prevail.

2. Please submit all available room temperature stability data.

3. Please provide cGMP certification for the drug substance manufacturer,

4. A satisfactory cGMP compliance evaluation for the firms referenced in the ANDA is required for approval. We have requested an evaluation from the Division of Manufacturing and Product Quality.

5. A review of the labels and labeling is pending. Any deficiencies found will be sent to you under separate cover.

Sincerely yours,

M Smela for

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. **CHEMIST'S REVIEW NO.# 2**

2. **ANDA #** 40-421 (Carisoprodol Tablets USP, 350 mg)

3. **NAME AND ADDRESS OF APPLICANT:**
Able Laboratories, Inc.
Att. Mr. Shashikant Shah, R.Ph.
6 Hollywood Court CN1013
South Plainfield, NJ 07080-4295

4. **LEGAL BASIS OF SUBMISSION:**
Reference Listed Drug: **SOMA® (Carisoprodol Tablets, USP 350 mg)**
Manufacturer: Wallace Laboratories, Inc.
NDA # 11-792

The applicant has certified that in their opinion and to the best of their knowledge, there is no patent that claims the listed drug referred to in the application, or if there are patents, they are expired.
According to information published in the list of Approved Drug Products 20th edition, SOMA® (Carisoprodol Tablets, USP 350 mg) is not entitled to marketing exclusivity under section 505(j)(5)(D) of the Act.

5. **SUPPLEMENT(s):** N/A

6. **PROPRIETARY NAME:** N/A

7. **NONPROPRIETARY NAME:** Carisoprodol, USP

8. **SUPPLEMENT(s) PROVIDE(s) FOR:** N/A

9. **AMENDMENTS AND OTHER DATES:**

Firm:

10-06-2000	Original submission date
01-16-2001	New correspondence - withdrawal of Scientech Laboratories as an outside contract testing laboratory
04-20-2001	Minor amendment -Response to CMC deficiencies

FDA:

11-16-2000	Acknowledge of receipt
11-30-00	Bioequivalence waiver
03-15-2001	Deficiency Letter (MINOR)

10. **PHARMACOLOGICAL CATEGORY:** Muscle relaxant

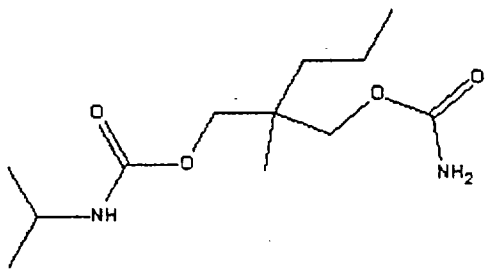
11. **Rx or OTC**: Rx

12. **RELATED IND/NDA/DMF(s)**: Approved NDA # 11-792 for innovator; DMFs: see DMF checklist

13. **DOSAGE FORM**: Tablet

14. **STRENGTH**: 350 mg

15. **CHEMICAL NAME, STRUCTURE AND PHYSICAL PROPERTIES**:
Carisoprodol. (±)-2-Methyl-2-propyl-1,3-propanediol carbamate isopropylcarbamate. $C_{12}H_{24}N_2O_4$. 260.33. [78-44-4]. Muscle relaxant.



16. **COMMENTS**:
Both the bulk drug substance and the drug product have USP monographs. Type II or the bulk drug substance was reviewed in connection with this submission, and was found deficient last review cycle. It has been found adequate this review cycle.

The bioequivalence review was completed on 11/30/00 and 3/15/01. The labeling review is pending. EER is pending 4/23/01.

17. **CONCLUSIONS AND RECOMMENDATIONS**:
The application is approvable (~~and~~ pending EES).

18. **RECORDS AND REPORTS**: N/A

19. **REVIEWER**: John D. Franolic, Ph.D. **DATE COMPLETED**: 05/07/2001
Endorsed by D. Gill, Ph.D.

Page(s) 20

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

chem Rev. 2

5/7/01

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-421

Bioequivalence Review(s)

BIOEQUIVALENCY COMMENTS

ANDA: 40-421 APPLICANT: Able Laboratories, Inc.

DRUG PRODUCT: Carisoprodol Tablets, USP 350 mg

The Division of Bioequivalence has completed its review and has no further questions at this time.

We acknowledge that the dissolution testing will be incorporated into your stability and quality control programs as specified in USP 24.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. Conner

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

Carisoprodol Tablets, USP
350 mg Tablets
ANDA #40-421
Reviewer: James Chaney
V:\FIRMSAM\ABLE\LTRS&REV\40421dw.O00

Able Laboratories, Inc.
South Plainfield, NJ
Submission Date:
October 6, 2000

Review of Dissolution Data and a Waiver Request

Able Laboratories has submitted comparative dissolution data on its drug product, Carisoprodol Tables, USP, 350 mg comparing it to the reference, Wallace's Soma®, 350 mg tablet, in support of a request for waiver of *in vivo* bioequivalence requirements.

Carisoprodol produces muscle relaxation and is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions. The usual adult dose is one 350-mg tablet, three times daily and at bed time.

Comments:

1. The dissolution method used was correct and satisfactory content uniformity data were submitted for the lot used in the dissolution testing.

2. The comparative dissolution testing data on the test and reference products meet the USP dissolution specifications. The data, method and specifications are shown in Table 1.

3. The test product does not contain any inactive ingredients that may cause a bioequivalence problem. All the inactive ingredients in the tablet are present in amounts that fall within the ranges given in the IIG for this dosage form. The reference product contains the following inactive ingredients: alginic acid, magnesium stearate, potassium sorbate, starch, and tribasic calcium phosphate. The formulation of the test product is:

Ingredient	Weight/Tablet
Carisoprodol	350.0 mg
Crospovidone,	
Polyethylene Glycol,	
Povidone	
Colloidal Silicon Dioxide,	
Starch, NF	
Microcrystalline Cellulose,	
Magnesium Stearate,	
Total tablet weight	

4. The reference product, Wallace's Soma®, 350 mg tablet (carisoprodol tablet, USP, 350 mg) is classified AA in Approved Drug Products with Therapeutic Equivalence Evaluations. Therefore, since the dissolution testing is acceptable there would be no need to conduct an *in vivo* bioequivalence study.

Recommendations:

1. The dissolution testing conducted by Able Laboratories on its drug product, carisoprodol tablets, 350 mg, lot #TB-059, has been found acceptable.

2. The dissolution testing should be incorporated into the firm's manufacturing controls and stability program. The dissolution testing should be conducted in 900 mL 0.05M phosphate buffer pH 6.9 containing 5 units at 37°C using USP apparatus 2 at 75 rpm. The test product should meet the following specifications:

   Not less than of the labeled amount of the drug in the dosage form is dissolved in 60 minutes.

3. The Division of Bioequivalence agrees that the information submitted by Able Laboratories demonstrates that its carisoprodol tablet, 350 mg strength, falls under 21 CFR 320.22 (c) of the Bioavailability/Bioequivalence Regulations. The waiver of an *in vivo* bioequivalence study for the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test product to be bioequivalent to the reference product, Soma® Tablets, 350 mg strength, manufactured by Wallace Laboratories.

The firm should be informed of the recommendations.

James E. Chaney

James E. Chaney, Ph.D.
Division of Bioequivalence
Review Branch I

RD INITIALED YCHuang
FT INITIALED YCHuang

Date 11/30/2000

Concur: Dale P. Conner Date 11/30/00
Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence

Table 1. In Vitro Dissolution Testing

Drug (Generic Name): Carisoprodol Tablets, USP
Dose Strength: 350 mg
ANDA No.: 40-421
Firm: Able Laboratories, Inc.
Submission Date: 10/06/00
File Name: 40421.dw.O00

I. Conditions for Dissolution Testing:

USP Basket: Paddle: X RPM: 75
No. Units Tested: 12
Medium: 0.05M Phosphate Buffer pH 6.9 containing 5 units α-amylase per mL
Volume: 900 mL
Specifications: in 60 min
Reference Drug: Wallace's Soma®, 350 mg tablet
Assay Methodology:

II. Results of In Vitro Dissolution Testing:

Sampling Times (Minutes)	TestProduct Lot # TB-059 Strength(mg) 350			ReferenceProduct Lot # 81 1069A Strength(mg) 350		
	Mean%	Range	%CV	Mean%	Range	%CV
15	87.9		2.6	73.1		2.3
30	99.4		2.4	89.5		2.1
45	100.6		1.7	95.1		1.8
60	101.5		1.8	98.1		1.6

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40-421

CORRESPONDENCE

ABLE
LABORATORIES
INC. Subsidiary of DynaGen, Inc.

May 17, 2001

Dr. Gary Buehler
Acting Director
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

ORIG AMENDMENT
N/AF

LABELING AMENDMENT
ABBREVIATED NEW DRUG APPLICATION
ANDA # 40-421
Carisoprodol Tablets, USP
350 mg

Dear Dr. Buehler:

Pursuant to facsimile correspondence received by Able Laboratories, Inc. on May 11, 2001, the firm is herewith submitting a LABELING AMENDMENT to the original ANDA Application #40-421 for Carisoprodol Tablets, USP 350 mg., as described in 21CFR 314.120.

We have submitted a true copy of this amendment to the Field.

If you should require additional information or have any questions regarding this amendment to Abbreviated New Drug Application #40-421 for Carisoprodol Tablets, USP 350 mg., please do not hesitate to contact me directly by phone at (908) 754-2253, ext. 505 or by facsimile at (908) 753-9383.

Sincerely,

Mr. Shashikant Shah, R.Ph.
V.P. Quality/Regulatory Affairs
Cc:

CENTER FOR DRUG
RECD
MAY 18 2001
OGD
EVALUATION AND RESEARCH

Volumes Submitted:

Archival - 1
Desk Copy-1
Field Copy - 1

6 Hollywood Court ◢ South Plainfield ◢ New Jersey 07080
Telephone: 908-754-2253 ◢ Fax: 908-754-2476

ABLE
LABORATORIES
INC. Subsidiary of DynaGen, Inc.

April 20, 2001

Dr. Gary Buehler
Acting Director
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

ORIG AMENDMENT

Ref.:

ABBREVIATED NEW DRUG APPLICATION
ANDA # 40-421
Carisoprodol Tablets, USP
350 mg

Dear Dr. Buehler:

Pursuant to facsimile correspondence received by Able Laboratories, Inc. on March 15, 2001, the firm is herewith submitting a MINOR AMENDMENT to the original ANDA Application #40-421 for Carisoprodol Tablets, USP 350 mg., as described in 21CFR 314.120.

We have submitted a true copy of this amendment to the Field.

If you should require additional information or have any questions regarding this amendment to Abbreviated New Drug Application #40-421 for Carisoprodol Tablets, USP 350 mg., please do not hesitate to contact me directly by phone at (908) 754-2253, ext. 505 or by facsimile at (908) 753-9383.

Sincerely,

Mr. Shashikant Shah, R.Ph.
V.P. Quality/Regulatory Affairs
Cc:

Volumes Submitted:

Archival - 1
Field Copy - 1

4-26-01

6 Hollywood Court ◢ South Plainfield ◢ New Jersey 07080
Telephone: 908-754-2253 ◢ Fax: 908-754-2476

ABLE
LABORATORIES
INC. Subsidiary of DynaGen, Inc.

January 16, 2001

NEW CORRESP
μC

Dr. Gary Buehler
Acting Director
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

Ref.:

ABBREVIATED NEW DRUG APPLICATION
ANDA # 40-421
Carisoprodol Tablets, USP
350 mg

Dear Dr. Buehler:

Pursuant to a telephone conversation between Mr. Shashikant Shah and Mrs. Iva Klemick of ABLE Laboratories, Inc., and Mr. Jeen Min of FDA, on Monday, October 30, 2000, and a subsequent telephone conversation with Mr. Joseph McGinnis, District Compliance Officer on October 31, 2000, the firm is herewith submitting a formal withdrawal of Scientech an outside contract testing laboratory, from our original ANDA Application # 40-421 for Carisoprodol Tablets, USP 350 mg.

The firm will no longer utilize Scientech in any capacity. Testing performed by Scientech, referenced in Section X.1 and X.2 of the ANDA submission, will be performed by either ABLE or Scientech, when certain specialized testing is not available in-house, or in case of an overload in the analytical laboratory.

We have submitted a true copy of this amendment to the Field.

If you should require additional information or have any questions regarding the withdrawal of Scientech laboratories from Abbreviated New Drug Application for Carisoprodol Tablets, USP 350 mg., please do not hesitate to contact me directly by phone at (908) 754-2253, ext. 505 or by facsimile at (908) 753-9383.

Sincerely,

Mr. Shashikant Shah, R.P.h.
V.P. Quality/Regulatory Affairs
Cc:

Volumes Submitted:

Archival - 2
Field Copy - 1

CENTER FOR DRUG EVALUATION AND RESEARCH
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6 Hollywood Court ◢ South Plainfield ◢ New Jersey 07080
Telephone: 908-754-2253 ◢ Fax: 908-754-2476

ANDA 40-421

Able Laboratories, Inc.
Attention: Shashikant Shah
6 Hollywood Court CN1013
South Plainfield, NJ 07080-4295

NOV 16 2000

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Carisoprodol Tablets USP, 350 mg

DATE OF APPLICATION: October 6, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: October 10, 2000

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Ruby Yu
Project Manager
(301) 827-5848

Sincerely yours,

Gregory S. Davis for

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ABLE
LABORATORIES
INC. Subsidiary of DynaGen, Inc.

40-421

October 6, 2000

505(j)(2)(A) OK
16-NOV-2000

FEDERAL EXPRESS
Director
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, Maryland 20855

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
OCT 10 2000
OGD

ABBREVIATED NEW DRUG APPLICATION
Carisoprodol Tablets, USP
350 mg

Dear Director:

Pursuant to Section 505(j)(1) of the Federal Food, Drug and Cosmetic Act, ABLE LABORATORIES, INC., herewith submits an original Abbreviated New Drug Application (ANDA) for Carisoprodol Tablets, USP 350 mg.

The Carisoprodol Tablets, USP 350 mg drug product for which this ANDA is submitted is identical to SOMA®, USP 350 mg. previously approved by the Food and Drug Administration under New Drug Application 011792.

It is the opinion of ABLE LABORATORIES, INC., and to the best of our knowledge, with respect to each patent which claims the listed drug or which claims a use for such listed drug for which we are seeking approval that such patent(s), if filed, have expired and therefore will not be infringed by the manufacture, use, or sale of the drug for which this Abbreviated New Drug Application is being submitted.

ABLE LABORATORIES, INC., is hereby requesting a waiver from the requirement for submission of evidence demonstrating the *in vivo* bioequivalence of the drug product which is the subject of this application. This request is made pursuant to the provisions of 21 CFR §320.22(c) which permits a waiver for a solid oral dosage form of a drug product determined to be effective for at least one indication in the Drug Efficacy Study Implementation (DESI Notice, *Federal Register* of July 8, 1972; 37 F.R. 13488-13497).

Furthermore, SOMA®, USP 350 mg referenced product is coded "AA" in the 20th Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations*. Products coded as "AA" are not regarded as presenting either actual or potential bioequivalence problems, drug quality or standards issues.

6 Hollywood Court ◢ South Plainfield ◢ New Jersey 07080
Telephone: 908-754-2253 ◢ Fax: 908-754-2476

ABLE
LABORATORIES
INC. Subsidiary of DynaGen, Inc.

We are requesting a two (2) year expiration dating period for this product based on accelerated stability data provided herein. We trust that this Abbreviated New Drug Application for Carisoprodol Tablets, USP 350 mg meets all requirements.

If you should require additional information or have any questions regarding this Abbreviated New Drug Application, please do not hesitate to contact me directly by phone at (908) 754-2253, ext. 505 or by facsimile at (908) 754-2476.

We have submitted a true copy of the chemistry section to the field .

Thank you.

Sincerely,

ABLE LABORATORIES, INC.

Mr. Shashikant Shah, R.Ph.
V.P. Quality/Regulatory

Volumes Submitted:
Archival - 4
Field Copy - 4
Chemistry - 4