DEC 6 1982

NDA 87-805

Camall Company
Attention: Eugene M. Schmall
60950 Van Dyke Avenue
Washington, Michigan 48094

Dear Mr. Schmall:

Reference is made to your abbreviated new drug application dated December 21, 1981, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phentermine Hydrochloride Tablets, 37.5 mg. Yellow.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application requires an approved supplemental application before the change may be made except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is being deferred at the present time. However, our action in approving this application is based upon an understanding that if this requirement is reinstated you will perform the appropriate procedures.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate 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 Advertising and Labeling (HFN-240). Also, please do not use Form FD-2253 for this submission.

For Subsequent Campaigns. We call your attention to Regulation 21 CFR 310.300(b)(3) which requires that all material for any subsequent advertising or promotional campaigns at the time of their initial use be submitted to our Division of Drug Advertising and Labeling (HFN-240) with a completed Form FD-2253. A copy of Form FD-2253 is enclosed for your convenience.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

Marvin Seife 12/6/82

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of The Associate Director
for Drug Monographs
Office of Drugs
National Center for Drugs and Biologics

Enclosures:
Conditions of Approval of a New Drug Application
Records & Reports Requirements
Form FD 2253

cc: DET-DO
HFN-5
HFN-313
HFN-530
HFN-534 (H. Zell)
HZell/LDavidson
R/D INITIAL HZell/MSeife
mstephens: 12/3/82 (8806A)
Approval

12/3/82

12/3/82

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 87-805

DATE APPROVAL LETTER ISSUED: DEC 6 1982

TO: Press Relations Staff (HFI-40)

FROM:
- [XX] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [XX] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [XX] HUMAN
- [ ] VETERINA

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG

Phentermine Hydrochloride

DOSAGE FORM

Tablet 37.5 mg. Yellow ORIGINAL APPROVED

HOW DISPENSED
- [XX] RX
- [ ] OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s). If amount is declared on label.)

Phentermine Hydrochloride, 37.5 mg.

NAME OF APPLICANT (Include City and State)

Camall Company
60950 Van Dyke Avenue
Washington, Michigan 48094

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

Anorectic

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: Lynn Davidson

DATE: December 3, 1982

FORM APPROVED BY

NAME: Howard C. Zell, Ph.D.

DATE: 12/3/82

FORM FD 1642 (2/78) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

CHEMIST'S REVIEW NDA 87-805

3. NAME AND ADDRESS OF APPLICANT
Camall Company
Washington, Michigan 48094

4. AF NUMBER
DESI 5378
FR 8/8/70

5. SUPPLEMENT(s)
Original (12/21/81)

6. NAME OF DRUG
Phentermine Hydrochloride

8. SUPPLEMENT(s) PROVIDE(s) FOR:
Original submission (amended)

9. AMENDMENTS AND OTHER DATES:
Correspondence History
FIRM
9/29/82 Amendment dated 9/20/82 - Reply to 6/29/82 letter
FDA
6/28/82 Review (Davidson) - Not approvable
6/29/82 Letter sent (Davidson) - Not approvable, request DMF, special procedures, systems suitability, methods, synthesis, labeling, stability
10/13/82 Methods Validation Request sent to DET-DO
12/1/82 Lab Report received from DET-DO (Schneider)

10. PHARMACOLOGICAL CATEGORY
Anorectic

11. HOW DISPENSED
RX

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Tablet

14. POTENCY
37.5 mg. Yellow

15. CHEMICAL NAME AND STRUCTURE
$C_{10}H_{15}N \cdot HCl$, M.W. 185.7

17. COMMENTS
All remaining deficiencies were sufficiently answered in the amendment dated 9/20/82.

18. CONCLUSIONS AND RECOMMENDATIONS
Approval letter should issue. A separate labeling letter should issue later with the suggested revisions from the 10/4/82 medical review. Methods validation was completed and is satisfactory.

19. REVIEWER:

DATE COMPLETED:
December 3, 1982

NDA 87-805

JUN 29 1982

Camall Company
Attention: Eugene M. Schmall
60950 Van Dyke Avenue
Washington, Michigan 48094

Gentlemen:

Please refer to your abbreviated new drug application dated December 21, 1981, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for the preparation Phentermine Hydrochloride Tablets, 37.5 mg. Yellow.

Reference is also made to your amendments dated February 22, 1982 and to your correspondence dated May 21, 1982.

The application is deficient and therefore not approvable under Section 505(b) of the Act as follows:

1. It fails to conform to the enclosed FDA guidelines for in vitro dissolution testing for phentermine hydrochloride as required by the Federal Register notice of November 7, 1980. Specific sampling times may be substituted for the dissolution profile.

2. It fails to provide a description of the special procedures and precautions used in handling controlled drug substances as required.

3. It fails to provide systems suitability tests required for the These tests include specifications for

precision of replicates,
etc. Clarification is also required of the composition of the

4. It fails to provide detailed, stepwise methodology for the assay of the raw active ingredient. A complete description of the preparation of the samples and standards is required.

5. It fails to provide the correct DMF reference for is an incorrect reference. Information on the facilities, equipment, and CGMP compliance is still required for directly or by DMF reference.

6. It fails to provide information on the synthesis of the active ingredient by directly or by DMF reference. This information is required as part of the full manufacturing and controls required for this product by the Federal Register notice dated July 19, 1974.

7. Drug Master Files are required to be updated annually in accord with the published Administrative Guidelines (HEW Publication No. FDA 79-3072). The information in

all

requires updating and is therefore unsatisfactory. Letters of authorization are also required for the following referenced DMFs:

8. It fails to include a commitment to recall batches which fail stability testing.

9. It fails to provide for the addition of the lot number to the container labeling.

10. It fails to conform to 21 CFR 201.100(e) and 21 CFR 201.56(e) which require that:

a) The name and place of business of one of the following must appear on the package insert: manufacturer, packager, distributor, or dispenser.

b) The date of the most recent revision must be paced after the last section of the package insert.

At the time of next printing, or within 180 days, whichever is sooner, the package insert must be so revised.

The file is now closed. If you wish to reopen it, the submission should be in the form of an amendment to this application, adequately organized, which represents the information necessary to remove all deficiencies we have outlined.

If you do not agree with our conclusions, you may make a written request to file the application over protest, as authorized by 21 CFR 314.110(d). If you do so, the application shall be re-evaluated and within 90 days of the date of receipt of such request (or additional period as we may agree upon), the application shall be approved or you shall be given a written notice of opportunity for a hearing on the question of whether the application is approvable.

Sincerely yours,

Marvin Seife 6/29/82

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drugs
Bureaus of Drugs and Biologics

cc: DET-DO
HFD-616
HFD-530
HFD-534 (H. Zell)
HZell/LDavidson
R/D INTIAL HZell/MSeife
mstephens: 6/25/82(7995A)
Not Approvable

6/28/82

6/28/82

Enclosure: Dissolution Guidelines

REVIEW OF PROFESSIONAL LABELING
Original Amendment
FPL

ANDA #: 87-805 FIRM: Camall Company

NAME OF DRUG: Phentermine HCl

DATE OF SUBMISSION: February 22, 1982

COMMENTS:

Container: Satisfactory

Insert: Missing - date of most recent revision is to be prominently placed immediately after the last section of the labeling 21 CFR 201.56(e).

RECOMMENDATIONS:
1. Container labeling - satisfactory
2. Incorporate above noted item onto package insert (overstamp is permissible until new printing).

Kent Johnson

cc:
KJ/wh/6-22-82

CHEMIST'S REVIEW NDA 87-805

3. NAME AND ADDRESS OF APPLICANT
Camall Company
Washington, Michigan 48094

4. AF NUMBER
DESI 5378
FR 3/6/70

5. SUPPLEMENT(s)
Original (12/21/81)

6. NAME OF DRUG
Phentermine Hydrochloride

8. SUPPLEMENT(s) PROVIDE(s) FOR:
Original Submission and Amendment

9. AMENDMENTS AND OTHER DATES:
Correspondence History

Firm

12/29/81	Original ANDA submission dated 12/21/81
3/1/82	Amendment dated 2/22/82 - Samples
3/1/82	Amendment dated 2/22/82 - FPL
5/24/82	Correspondence dated 5/21/82 - Stability Data

FDA

1/7/82	Inspection Request (Rosen) - Camall,
1/8/82	Memo from HFD-322 (Fishman) - Camall, in CGMP compliance
1/11/82	Acknowledgement of ANDA submission

10. PHARMACOLOGICAL CATEGORY
Anorectic

11. HOW DISPENSED
RX

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Tablet

14. POTENCY
37.5 mg Yellow

15. CHEMICAL NAME AND STRUCTURE
α,α-dimethyl phenethylamine, $C_{10}H_{15}N$

17. COMMENTS
See Attached

18. CONCLUSIONS AND RECOMMENDATIONS
A not approvable letter should issue as detailed in review section 17 above. Methods validation required. BIO is not required. Full manufacturing and controls required as per Federal Notice of 7/19/74.

19. REVIEWER:

DATE COMPLETED: 6/28/82

6/28/82

DIVISION OF BIOPHARMACEUTICS

GUIDELINES FOR IN VITRO DISSOLUTION TESTING

FOR PHENTERAMINE HYDROCHLORIDE (FAST DISSOLVING)

For a product that is formulated to be fast dissolving (not formulated as a cationic resin complex or utilizing any other slow release mechanism): the dissolution testing should be conducted in 900 ml of 0.1N hydrochloric acid at 37°C using USP Method II, paddle speed being maintained at 50 revolution per minute. Samples should be collected at 15, 30 and 60 minutes to generate a dissolution profile for the drug product. A total of twelve (12) individual dosage units should be tested for dissolution and ten (10) dosage units for content uniformity. Dissolution of the tablet or capsule should be not less than 80% of the labeled phenteramine HCl in 60 minutes.

To: Lynn A. Davidson (HFD-534)

From: Sal Pinella (HFO-610) March 5, 1982.

Subject: ANDA 87-605 - Phentermine HCl Tabs, Cansell Co.

The following information is needed for validation of the methods:

A.

3. System suitability parameters have not been provided.

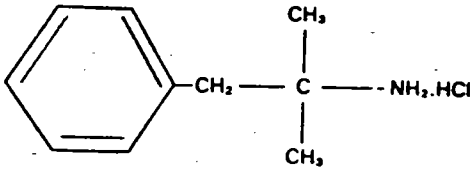
Dissolution. Is the entire profile necessary or will 30 & 60 min (the usual dissolution time limits) suffice?

It can followed "cook book" style, [redacted] Complete description of samples, stds values spiked etc. should be provided.

Phentermine HCl C IV

Each tablet contains:
Phentermine HCl 37.5 mg.

Phentermine hydrochloride is designated chemically as phenyl-tert-butylamine hydrochloride. It is a white crystalline powder that is odorless or has a faint characteristic odor, is very soluble in water and alcohol and melts at about 203°.



Actions: Phentermine hydrochloride is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, the amphetamines. Actions include central nervous system stimulation and elevation of blood pressure. Tachyphylaxis and tolerance have been demonstrated with all drugs of this class in which these phenomena have been looked for.

Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics." It has been established, however, that the action of such drugs in treating obesity is primarily one of appetite suppression. Other central nervous system actions, or metabolic effects, may be involved, for example.

Adult obese subjects instructed in dietary management and treated with "anorectic" drugs, lose more weight on the average than those treated with placebo and diet, as determined in relatively short-term clinical trials. The magnitude of increased weight loss of drug-treated patients over placebo-treated patients is only a fraction of a pound a week. The rate of weight loss is greatest in the first weeks of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The possible origins of the increased weight loss due to the various drug effects are not established. The amount of weight loss associated with the use of an "anorectic" drug varies from trial to trial, and the increased weight loss appears to be related in part to variables other than the drug prescribed, such as the physician-investigator, the population treated, and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

The natural history of obesity is measured in years, whereas, the studies cited are restricted to a few weeks duration; thus, the total impact of drug-induced weight loss over that of diet alone must be considered clinically limited.

Indications: Phentermine hydrochloride is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

The limited usefulness of agents of this class (see ACTIONS) should be measured against possible risk factors in their use such as those described below.

Contraindications: Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma.

Agitated states.

Patients with a history of drug abuse.

During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crisis may result).

Warnings: Tolerance to the anorectic effect usually develops within a few weeks. When this occurs, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Phentermine hydrochloride may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly.

Drug Dependence: Phentermine hydrochloride is related chemically and pharmacologically to the amphetamines. Amphetamines and related stimulant drugs have been extensively abused, and the possibility of abuse of phentermine hydrochloride should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with intense psychological dependence and severe social dysfunction. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia.

Usage in Pregnancy: No reproduction studies or teratology studies of phentermine hydrochloride, in animals or humans, have been published. Therefore, use of phentermine hydrochloride by women who are or may become pregnant, requires that the potential benefit be weighed against the possible hazard to mother and infant.

Usage, In Children: Phentermine hydrochloride is not recommended for use in children under 12 years of age.

Precautions: Caution is to be exercised in prescribing phentermine hydrochloride for patients with even mild hypertension.

Insulin requirements in diabetes mellitus may be altered in association with the use of phentermine hydrochloride and the concomitant dietary regimen.

Phentermine hydrochloride may decrease the hypotensive effect of guanethidine.

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.

Adverse Reactions:
Cardiovascular: Palpitation, tachycardia, elevation of blood pressure.
Central Nervous System: Overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache; rarely psychotic episodes at recommended doses.
Gastrointestinal: Dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances.
Allergic: Urticaria.
Endocrine: Impotence, changes in libido.

Dosage and Administration: The usual adult dose is one tablet daily, administered before breakfast. Dosage may be adjusted to the patient's need.

Phentermine hydrochloride is not recommended for use in children under 12 years of age.

Overdosage: Manifestations of acute overdosage with phentermine hydrochloride include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultive behavior, hallucinations, panic states.

Fatigue and depression usually follow the central stimulation.

Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. In fatal poisoning, death is usually preceded by convulsions and coma.

Management of acute phentermine hydrochloride intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequest to permit recommendation in this regard. Acidification of the urine increases phentermine hydrochloride excretion. Intravenous phentolamine (Regitine) has been suggested for possible acute, severe hypertension, if this complicates phentermine hydrochloride overdosage.

How Supplied:
Bottles of 100's, 500's, and 1000's. Yellow oblong tablets 0.225 X 0.550 creased

CAUTION: Federal law prohibits dispensing without a prescription.

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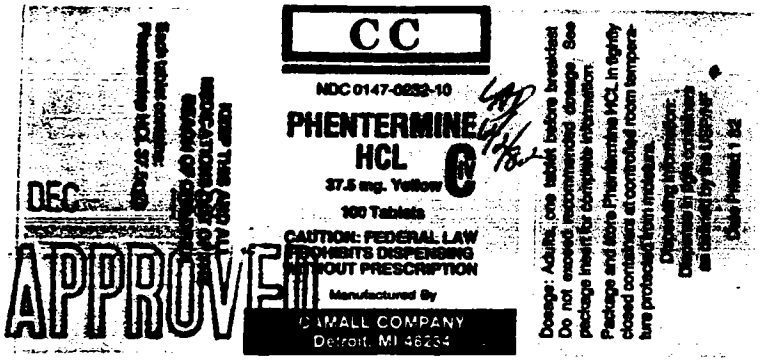
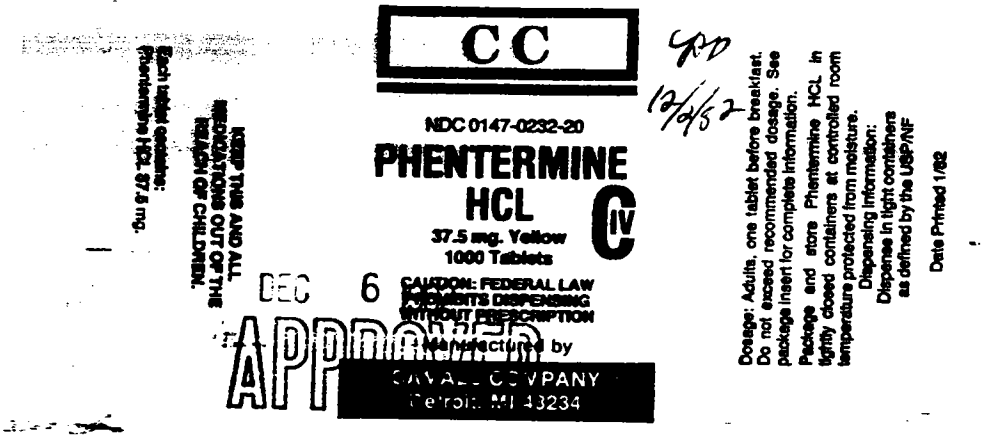
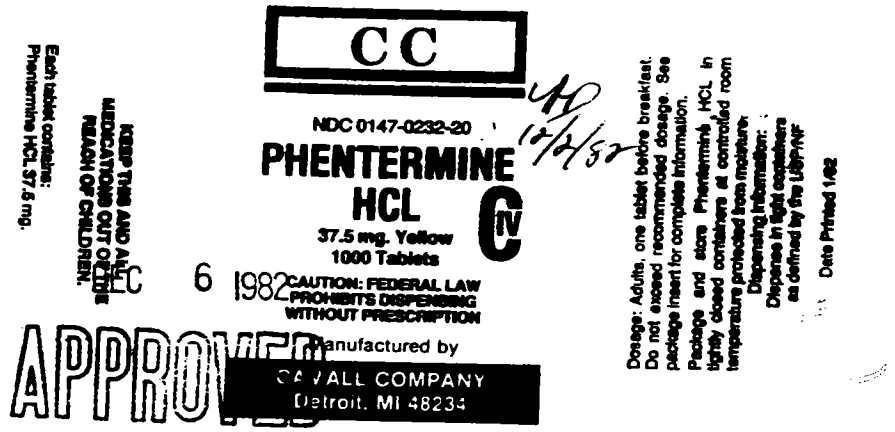
CAUTION: Federal law prohibits dispensing with-


CC
NDC 0147-0232-10
PHENTERMINE HCL
37.5 mg. Yellow
100 Tablets
CIV
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION
Manufactured By
CAMALL COMPANY
Detroit, MI 48234
DEC
APPROVED
Dosage: Adults, one tablet before breakfast. Do not exceed recommended dosage. See package insert for complete information.
Package and store Phentermine HCL in tightly closed containers at controlled room temperature protected from moisture.
Dispensing Information:
Dispense in tight containers as defined by the USP/NF
Date Printed 1/82


CC
NDC 0147-0232-20
PHENTERMINE HCL
37.5 mg. Yellow
1000 Tablets
CIV
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION
Manufactured by
CAMALL COMPANY
Detroit, MI 48234
DEC 6
APPROVED
12/6/82
Each tablet contains: Phentermine HCL 37.5 mg.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Dosage: Adults, one tablet before breakfast. Do not exceed recommended dosage. See package insert for complete information.
Package and store Phentermine HCL in tightly closed containers at controlled room temperature protected from moisture.
Dispensing Information:
Dispense in tight containers as defined by the USP/NF
Date Printed 1/82


CC
NDC 0147-0232-20
PHENTERMINE HCL
37.5 mg. Yellow
1000 Tablets
CIV
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION
Manufactured by
CAMALL COMPANY
Detroit, MI 48234
DEC 6 1982
APPROVED
12/6/82
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Dispensing Information:
Dispense in tight containers as defined by the USP/NF
Date Printed 1/82

JAN 11 1982

NDA 87-805

Camall Company
Attention: Eugene M. Schmall
60950 Van Dyke Avenue
Washington, MI 48094

Gentlemen:

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

NAME OF DRUG: Phentermine Hydrochloride Tablets, 37.5 mg.

DATE OF APPLICATION: December 21, 1981

DATE OF RECEIPT: December 29, 1981

We will correspond with you further after we have had the opportunity to review this application. However, in the interim, please submit the following:

1. Samples of the finished dosage form and raw material(s) - (active ingredients.)

2. Analytical methods for the drug product and active ingredients.

3. Any reference material which may be needed to complete the analysis of the dosage form.

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

Sincerely yours,

Marvin Seife 1/11/82

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
Dup
HFD-530
HFD-614
DRosen/MSeife/wh/1-7-82
ack

ANDA ADMINISTRATIVE CONTROL RECORD

Applicant CAMALL COMPANY P No._____

ANDA # 87-805 12-29-81

Trade Name Phentermine HCL RX ✓ OTC__ Date Recd._____

Generic Name/Dosage Form/Strength: Phentermine HCL

DESI Drug ✓ DESI No._____ DESI Date(FR)_____

Similar or Related_____ Name of DESI Drug_____

Applicant Manufactuer: Yes ✓ No_____.

If No: Name of Manufacturer _____

ANDA #_____ (Approved:_____ Pending_____ Same Formulation____

Application Complete (See Pg. 2): YES ✓ NO_____
Application Acceptable: YES ✓ NO_____
REMARKS:

Letter to Firm: Acknowledgement 2263P 6 Samples Not-acceptable_____ Date 1-11-82

CSO: D Roan Date 1-7-82

BIO Review Required: Yes_____ NO ✓ In Vitro_____ In Vivo_____
Date Fwd:_____

Medical Officer Dr Seife ~~Dr Zell~~ Reveiw Completed_____ R.R____

Chemist L. DAVIDSON Reveiw Completed_____ R.R.____

Inspection Request to HFD 320(date): 1-7-82 Reply Rec.(date)_____

Letter to Firm: Labeling Review (date)_____ Response(date)_____

Chemistry: 1)(date) _____ Response_____
2)(date) _____ Response_____

Approvable Date_____

Withdrawal Date_____

Special Instructions/Actions:

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Division of Drug Manufacturing, HFD-320 DATE: 1-7-82

FROM ~~: Division of~~ Generic Drugs, HFD- 530

Requester's Name: David L. Rosen Phone: 443-4040

SUBJECT: GMP EVALUATION REQUEST

~~NDA,ANDA, and~~ SUPPLEMENT NUMBER: 87-805

~~DRUG Trade Name~~: Phentermine HCL

~~DRUG Non-Proprietary Name~~:

DRUG CLASSIFICATION: ___ A or B ___ IC ___ Other

PRODUCT CODE: TCM (description of dosage form, e.g., compressed tablet;coated tablet; soft gelatin capsule;liquid;See Table)

180 DAY DATE: 6-29-82

APPLICANT'S NAME: Camall Company

ADDRESS: 60950 Van Dyke Ave., Washington, MI 48094

FACILITIES TO BE EVALUATED: (Name, Address, and Responsibility)

1. Applicant

FOR HFD-320 USE ONLY

Date Received: Date Completed:

cc:
HFD-320 (Orig)
HFD- (2 Copies)

2.1

VOLUME 9

NEW DRUG APPLICATION

NDA No. 87-805

NAME OF APPLICANT

Camall Company

NAME OF NEW DRUG

Phentermine HCL 37.5mg Labs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 87-215/S-013, Phentermine Hydrochloride Capsules, 30 mg (Black)
87-805/S-009, Phentermine Hydrochloride Tablets, 37.5 mg (Yellow)
87-915/S-006, Phentermine Hydrochloride Capsules, 37.5 mg (Yellow)
87-918/S-007, Phentermine Hydrochloride Capsules, 37.5 mg (Black)
87-930/S-006, Phentermine Hydrochloride Capsules, 37.5 mg (Brown/Clear)
86-732/S-015, Phentermine Hydrochloride Capsules, 30 mg (Blue/Clear)
86-735/S-011, Phentermine Hydrochloride Capsules, 15 mg (Gray/Yellow)
87-226/S-013, Phentermine Hydrochloride Capsules, 30 mg (Brown/Clear)
83-923/S-035, Phentermine Hydrochloride Tablets, 8 mg (Orange)
85-319/S-027, Phentermine Hydrochloride Tablets, 8 mg (Green)
85-417/S-016, Phentermine Hydrochloride Capsules, 30 mg (Yellow)
85-411/S-011, Phentermine Hydrochloride Capsules, 30 mg (Green/Clear)
88-576/S-005, Phentermine Hydrochloride Capsules, 18.75 mg (Gray/Yellow)
88-596/S-007, Phentermine Hydrochloride Tablets, 37.5 mg (White/Blue Specks)
88-610/S-003, Phentermine Hydrochloride Capsules, 37.5 mg (Black/Yellow)
88-611/S-003, Phentermine Hydrochloride Capsules, 37.5 mg (Red/Black)
88-625/S-005, Phentermine Hydrochloride Capsules, 37.5 mg (Green/Clear)

Camall Company
Attention: Eugene Schmall
P.O. Box 218
Washington, Michigan 48094

JUL 20 1988

Dear Sir:

Reference is made to your supplemental new drug applications submitted pursuant to Section 314.70 of the Regulations, dated June 18, 1987, regarding your abbreviated new drug applications for Phentermine Hydrochloride Products.

In order for our laboratory to ascertain that your bulk drug conforms to USP requirements, send the following materials to the address below:

Materials to be sent:

1. Bulk active ingredient, phentermine hydrochloride from
- Send three times the amount needed to perform all USP testing. Package the material in a tight, moisture-free container sealed in an outer container. Identify the manufacturer, the manufacturer's address, DMF number and lot number of the bulk sent.

2. A Certificate of Analysis (either yours or the manufacturer's) for the lot sent.

3. Standards - Reference, Impurity, and Internal - Send three times the amount required by the USP. [If you do not send the standard and St. Louis doesn't have it, the analysis will be delayed].

4. Copies of representative chromatograms and/or spectra (if applicable.)

Address:

Center for Drug Evaluation and Research
Office of Drug Research and Review
Attention: Lawrence Jones, Ph.D.
Room 1002, HFH-300
1114 Market Street
St. Louis, MO 63101

These materials must be sent within 20 days of receiving this letter. If you cannot send these materials by this date, please notify the ANDA by letter. Send copies of all correspondence regarding the samples requested to the ANDA.

We recommend that you send the samples by registered mail/return receipt requested.

Sincerely yours,

/ for

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 87-805/S-008

Camall Company
Attention: Eugene Schmall
P.O. Box 218
Washington, Michigan 48094

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Dear Sir:

Reference is made to your supplemental new drug application submitted pursuant to Section 314.70 of the Regulations, dated July 7, 1987, regarding your abbreviated new drug application for Phentermine Hydrochloride, USP, 37.5 mg, Yellow Tablets.

We acknowledge your amendment dated August 1, 1987.

The supplemental application provides for an alternate analytical laboratory facility:

We have reviewed the material submitted and have the following comments:

1. Clarify how samples will be obtained and transferred to this facility. Describe all tests to be conducted for raw materials, in-process controls, and the drug product at the "alternate Laboratory Facility." Explain the procedures to track and control the flow of samples.

2. Clarify if all instruments, gauges and recording devices are calibrated to demonstrate accuracy prior to use.

3. Please submit Certificates of Analysis on the same lot of the drug product comparing test results obtained by your laboratory at Michigan with that supplied by

4. Clarify water testing at this site.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

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VOLUME 3.1

NEW DRUG APPLICATION

NDA No. 87-805

NAME OF APPLICANT

AMALL CO

NAME OF NEW DRUG

IENTERMINE
IDROCHLORIDE TABLET
SP, 37.5 mg

ARCHIVAL COPY

FORM FDA 2626 (7/84)

THIS SUBMISSION: VOL 1 OF 1 VOLS.

NEW DRUG APPLICATION

87-805

Camall Company
60950 Van Dyke Avenue
Washington, Mi. 48094

NAME OF APPLICANT

NAME OF NEW DRUG

Phentermine Hydrochloride Tablets
37.5 mg. Yellow

Copy No. 1

Vol No. 1

THIS SUBMISSION: VOL. _____ OF ____

FORM FD 2626 (7/75)