JUN 12 1981

NDA 87-301

Lemmon Company
Attention: Stanley Scheindlin
P.O. Box 30
Sellersville, PA 18960

Gentlemen:

Reference is made to your abbreviated new drug application dated March 19, 1980 submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Phentermine Hydrochloride Capsules, 15 mg., Grey and Yellow.

Reference is also made to your amendment dated June 11, 1981.

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.

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 both copies and a completed form FD-2253, together with a copy of the Final Printed Labeling, to the Division of Drug Advertising (HFD-170). A copy of Form FD-2253 is enclosed for your convenience.

We call your attention to regulation 21 CFR 310.300(b)(3) [or 431.60(b)(3) if Form 6] which requires that material for any subsequent advertising or promotional campaigns, at the time of their initial use, be submitted to our Division of Drug Advertising (HFD-170) with a completed form FD-2253.

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

Sincerely yours,

Marvin Seife 6/12/81

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

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

cc:
cc:
PHI-DO
DUP
HFD-530
HFD-614
HFD-313
HFD-5
MSeife/JMeyer/MAJarski
r/d/ init. JMeyer/MSeife 6-11-81
f/t/wh/6-11-81
approved

6/12/81

6/12/81

ATTACHMENT

. For compendial ingredients, specifications and tests are to be in accord with currently official compendia.

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 87-301

DATE APPROVAL LETTER ISSUED: JUN 12 1981

TO: Press Relations Staff (HFI-40)

FROM:
- [X] 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
- [X] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY:
- [X] HUMAN
- [ ] VETERINARY

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

Phentermine HCl

DOSAGE FORM:

Capsule gray & yellow ORIGINAL ABBREVIATED

HOW DISPENSED:
- [X] 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 HCl 15 mg.

NAME OF APPLICANT (Include City and State)

Lemmon Company
Sellersville, PA 18960

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: Mary Ann Jarski

DATE: 6/12/81

FORM APPROVED BY

NAME: Jack L. Meyer

DATE:

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

REVIEW OF ANDA

DATE COMPLETED: 4-21-80

ANDA#: 87-301

CO. NAME: Lemmon Company
ADDRESS: Sellersville, PA 18960

NAME OF DRUG: Phentermine HCl Capsules 15 mg. (Gray & Yellow)

DATE OF SUBMISSION: 3-25-80

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies:
   Pertinent Data is to be reviewed by the chemist
   Bioavailability Requirement: Not Required
   To be marketed under the Label of Drummer Laboratories
   which is a marketing Division of Lemmon Company

2. Review of Labels:
   a) Container Labels: Satisfactory CIV
      Drummer Laboratories 15 mg. capsules Bottles of 1,000

   b) Insert Labeling: Satisfactory
      Date: 12-79

CONCLUSION: Insert Labeling is satisfactory
Container Labels are satisfactory
*Does not state Prolonged, Slow; Delayed; Controlled; Resin Base,
But does state: one capsule after breakfast (1)

RECOMMENDATIONS: The firm is to be so notified,

V.V Karusaitis, M.D.

cc:
DUP
VVKarusaitis/pb/5/1/80

MEMORANDUM

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

TO : Division of Drug Manufacturing, HFD-320 DATE: April 9, 1980

FROM : Division of Generic Drugs, HFD- 530

Requester's Name: W.F. Kochert 34040 Phone: _____

SUBJECT: GMP EVALUATION REQUEST

NDA,ANDA, and SUPPLEMENT NUMBER: ANDA 87-301

DRUG Trade Name: Phentermine HCl Cap, 15 mg.(Gray & Yellow)

DRUG Non-Proprietary Name: _____

DRUG CLASSIFICATION: ___ A or B ___ 1C x Other

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

180 DAY DATE: Sept. 25, 1980

APPLICANT'S NAME: Lemmon Company

ADDRESS: Sellersville, Pa. 18960

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

Lemmon Pharmacal Co. Cathill and Lonely Roads, West Rock Hill Township, Bucks County, Pa.

Manufacture, control and label the finished drug.

/FOR HFD-320 USE ONLY/

Date Received: _____ Date Completed: _____

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

Rec 4/10/80

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE: June 11, 1981

NDA NUMBER:

IND NUMBER:

TELECON/MEETING

INITIATED BY: ☐ APPLICANT/SPONSOR ☐ FDA

MADE: ☐ BY TELEPHONE ☐ IN PERSON

PRODUCT NAME: Phentermine Hydrochloride

FIRM NAME: Lemmon Company, Sellersville, PA 18960

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: Dr. Stanley Scheindlin, Director of Technical Affairs

TELEPHONE NO.: 215-723-5544

87-190	Yellow	30 mg.
87-202	Red & Yellow	30 mg.
87-200	Red & Black	30 mg.
87-223	Black	30 mg.
87-301	Grey & Black	15 mg.

I called Dr. Scheindlin to discuss the information necessary for completing his (Lemmon Company) remaining Phentermine HCl applications (note 86-911 and 87-126 are approved).

1. Qualifying the DRUMMER labeling in accord with the Federal Register notice of April 15, 1980 "Requirements for Designating Manufacturer's Name on a Drug Product's Label" Effective April 10, 1981

Dr. Scheindlin made the commitment to use only labeling that contained the statement:

Drummer Laboratories
Division of Lemmon Co.
Sellersville, PA 18960

He said a written statement containing this commitment would be sent by a communication dated June 11, 1981

2. Only draft container labels were sent to application 87-223.

Dr. Scheindlin made the commitment to submit final printed labels per a communication dated June 11, 1981.

3. Not all applications contained complete Composition, Manufacturing and Controls and Stability data. I asked for permission to cross-reference the applications for this information.

Dr. Scheindlin granted that permission.

4. Raw material controls were to be up-dated in accord with currently official compendia. I indicated this would be handled as an attachment to the approval.

Dr. Scheindlin agreed.

5. Finished product specification sheets in some of the applications were not updated to provide for dissolution (although test methods were included) I indicated this would be handled as an attachment to the approval.

Dr. Scheindlin agreed

SIGNATURE

DIVISION

FORM FD 2587 (11/77)

ORIGINAL IND/NDA

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION	2. NDA NUMBER
HFD-530	87-301

3. NAME AND ADDRESS OF APPLICANT *(City and State)*

Lemmon Pharmacal Company/Drummer
Sellersville, PA 18960

4. AF NUMBER

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)

6. NAME OF DRUG

7. NONPROPRIETARY NAME

Phentermine HCl

8. SUPPLEMENT(S) PROVIDES FOR:

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES

orig: 3-19-80

10. PHARMACOLOGICAL CATEGORY

Anorectic

11. HOW DISPENSED

☒ Rx ☐ OTC

12. RELATED IND/NDA/DMF(S)

see attached

13. DOSAGE FORM (S)

capsule gray & yellow

14. POTENCY *(Iee)*

15 mg.

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS

CURRENT ☐ YES ☐ NO

REVIEWED ☐ YES ☐ NO

17. COMMENTS

see record of telephone conversation of 6-11-81

18. CONCLUSIONS AND RECOMMENDATIONS

approval

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Mary Ann Jarski		6-11-81

DISTRIBUTION ☐ ORIGINAL JACKET ☑ REVIEWER ☐ DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

LEMMON - PHENTERMINE HYDROCHLORIDE CAPSULES

86-811	Adipex-P	Blue and White	30 mg.
87-125	Pulletized		30 mg.
87-190	Yellow		30 mg.
87-202	Red and Yellow		30 mg.
87-208	Red and Black		30 mg.
87-223	Black		30 mg.
87-301	Grey and Black		15 mg.

CHEMIST'S REVIEW, Page 2

Enter evaluation or comments for each item. If necessary, continue on 8½" x 10½" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

NDA NUMBER 87-301

20. COMPONENTS AND COMPOSITION (6, 7)

see attached

21. FACILITIES AND PERSONNEL (8a,b)

included

22. SYNTHESIS (8c)

see chemist's review for

23. RAW MATERIAL CONTROLS (8d,e)

a. NEW DRUG SUBSTANCE

see chemist's review for 87-208

Note: specifications and tests for compendial items are to be updated in accord with currently official compendia

b. OTHER INGREDIENTS

24. OTHER FIRM(s) (8i)

None

25. MANUFACTURING AND PROCESSING (8f,h,j,k)

see attached

26. CONTAINER (8i)

see chemist's review for 87-208

27. PACKAGING AND LABELING (8l,m)

included

28. LABORATORY CONTROLS (In-Process and Finished Dosage Form) (8n)

see attached and chemist's review for 87-208

29. STABILITY (8p)

data not included for this drug dosage form- see chemist's revie for for 87-208

30. CONTROL NUMBERS (8c)

included

31. SAMPLES AND RESULTS (9)

no results are included for this drug dosage form - see chemist's review for 87-208

a. VALIDATION

b. MARKET PACKAGE

32. LABELING (8)

see attached

33. ESTABLISHMENT INSPECTION

not on alert list of 6-5-81

34. RECALLS

MEMORANDUM

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

TO : Seymour Fishman, HFD-322

DATE: May 20, 1980

FROM : Assistant Chief, Foreign Inspection Staff
HFO-503

SUBJECT: Foreign Inspection Information

Firm:

Applicant: Lemmon Pharm.
Sellersville, PA
NDA #87-301

A copy of the report of the most recent inspection of the subject firm is attached. The investigator did not observe any objectionable conditions or practices and no FD 483 was issued. That inspection covered

The previous inspection covered Some minor deviations were noted and no FD 483 was issued. Before that, the firm was inspected for phentermine HCL bulk in There was no FD 483 issued and the investigator noted that the firm was operating at a high level of compliance. At that time, the firm had been manufacturing phentermine HCL since 1963.

Based upon this firm's inspection history, it appears that the firm could be approved as a source of phentermine HCL. The firm is drug-listed for that product. I have made a note that phentermine HCL should be covered during our next biennial reinspection (ca. 2/81).

If you have any questions please call me at X31855.

Richard J. DeRisio

Attachment

cc: HFD-530 (Kochert)

APR 2 1980

NDA 87-301

Lemmon Company
Attention: Stanley Scheindlin, D.Sc.
P.O. Box 30
Sellersville, PA 18960

Gentlemen:

We acknowledge the 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 Capsules, 15 mg. (Gray & Yellow)

DATE OF APPLICATION March 19, 1980

DATE OF RECEIPT: March 25, 1980

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 NDA number shown above.

Sincerely yours,

/S/

James C. Morrison
Acting Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

PHI-DO DUP HFD-614
JCMorrison/mlb/3-31-80
ack

PHENTERMINE HYDROCHLORIDE CAPSULES 15 mg. (IV)

APPROVED

JUN 12 1981

DESCRIPTION

Each gray and yellow capsule contains:

Phentermine hydrochloride ..... 15 mg.
(Equivalent to 12 mg. of Phentermine base.)

Phentermine hydrochloride is designated chemically as phenyl-tert- butylamine hydrochloride. It is a white crystalline powder, very soluble in water and alcohol.

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 not 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 inherent 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 crises 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 disfunction. 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.

USING 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.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

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 capsule daily, administered approximately 2 hours after 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 inadequate 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 1000 capsules.

CAUTION

Federal law prohibits dispensing without prescription.

Printed in U.S.A.
12/79

Item 4

Copies of the label and all other labeling to be used for the drug.

LABELS

[redacted]

Usual Adult Dosage: One capsule daily, administered approximately 2 hours after breakfast. If necessary dose may be increased to two capsules daily. See package insert for full prescribing information.

Contains color additives including FD&C Yellow No. 5 (Tartrazine)

Each gray & yellow capsule contains:
Phentermine Hydrochloride 15 mg. (equivalent to 12 mg. of Phentermine base)

Caution: Federal law prohibits dispensing without prescription.

1000 CAPSULES

Dispense in tight containers protected from moisture.

Store at controlled room temperature.

JUN 12 1981

APPROVED

[redacted] USA

[redacted]

Usual Adult Dosage: One capsule daily, administered approximately 2 hours after breakfast. If necessary dose may be increased to two capsules daily. See package insert for full prescribing information.

Contains color additives including FD&C Yellow No. 5 (Tartrazine)

Each gray & yellow capsule contains:
Phentermine Hydrochloride 15 mg. (equivalent to 12 mg. of Phentermine base)

Caution: Federal law prohibits dispensing without prescription.

1000 CAPSULES

Dispense in tight containers protected from moisture.

Store at controlled room temperature.

JUN 12 1981

APPROVED

VOLUME 1.1

NEW DRUG APPLICATION

NDA No. 87-301

NAME OF APPLICANT

LEMMON Co.

NAME OF NEW DRUG

PHENTERMINE HCl

CAPSULES 15 mg.

(GRAY + YELLOW)

NEW DRUG APPLICATION

87-301

Approved 6-12-81
by Vote

ANDA 87-301/S-014

Eon Labs
Attention: Yau-Kit Lam
227-15 N. Conduit Avenue
Laurelton, NY 11413

DEC 19 1994

Dear Sir:

This is in reference to your supplemental new drug application dated July 23, 1990, submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug application for Phentermine Hydrochloride Capsules, 15 mg (Grey/Yellow).

The supplemental application provides for the addition of as a contract facility for microbiological and analytical testing.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

Florence S. Fang
Acting Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 87-301/S-014

NAME AND ADDRESS OF APPLICANT:
Eon Labs
227-15 N. Conduit Avenue
Laurelton, NY 11413

PURPOSE OF SUPPLEMENT
Addition of contract facility.

DATE(S) OF SUBMISSION(S)
July 23, 1990.

PHARMACOLOGICAL CATEGORY	TRADE NAME	NONPROPRIETARY NAME
Anorexiant	NA	Phentermine HCl

DOSAGE FORM	POTENCY	RX OR OTC
Capsule (Grey/Yellow)	15 mg	Rx

SAMPLES	RELATED IND/NDA/DMF	STERILIZATION
NA	NA	NA

LABELING
NA

BIOEQUIVALENCY STATUS
NA

ESTABLISHMENT INSPECTION
Satisfactory. CGMP compliance status-acceptable, 12/5/94.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS
The purpose of the supplement is to add the following contract facility:

The contract lab will conduct microbiological testing on the components of the drug product in addition to analytical testing.

PACKAGING
NA

STABILITY
NA

REMARKS AND CONCLUSION
Approvable.

RECALLS

Reviewer
Andrew J. Langowski

Date Completed
12/9/94

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date March 21, 1990

From R M. Patel, Ph.D. Supervisory Chemist

Subject ANDA 87-301/soll of Vitarine; Phentermine HCl Capsules, 15mg

To Mr. Paul Vogel, Chief, Non-Sterile Drug Branch

Attached is a cover letter from the applicant that describes information, probably conveyed by Compliance to the firm, during the meeting dated July 7, 1989.

All we have is their version. Therefore, it would help the review chemist if (a) the minutes of the meeting is filed in the ANDA, and (b) some input is provided by Compliance concerning their cover letter, especially for their last paragraph (pages 2 and 3).

It is understood that the firm is still on the Alert list and we need a clearance from your office prior to considering whether this submission should be recommended for approval. Please be advised that the review chemist (Dr. Dwyer) has not yet started on this project, except that he is raising a question - what to do.

Please call us (443-1390) and/or send us some information so that we made the RIGHT job.

Raz Patel, Ph.D. 3/21/90

To Jackie 3/21/90

cc: Dr. S. Dwyer

ANDA 87-190/S-013 (Yellow - 30 mg)
87-208/S-013 (Red/Black - 30 mg)
87-223/S-013 (Black - 30 mg)
87-301/S-012 (Grey/Yellow - 15 mg)

Vitarine Pharmaceuticals, Inc.
Attention: Andrea Garrity
227-15 N. Conduit Avenue
Springfield Gardens, NY 11413

Dear Madam:

Reference is made to your supplemental new drug applications submitted pursuant to Section 314.70 of the Regulations, dated September 19, 1989, regarding your abbreviated new drug applications for Phentermine Hydrochloride Capsules, USP.

The supplemental applications provide for revised package insert labeling.

We have completed the review of these supplemental applications and they are approved. Our letters of June 12, 1981 detailed the conditions relating to the approval of these abbreviated applications.

The material submitted is being retained in our files.

Sincerely yours,

Acting Director
Division of Generic Drugs
Center for Drug Evaluation and Research

cc: HFD-238
HFD-83
JPhillips/KJohnson/sb/9/28/89
8384A pg: 5 /APPROVAL

VOLUME 3.1

NEW DRUG APPLICATION

NDA No. 87-301

NAME OF APPLICANT

Eon LABS

NAME OF NEW DRUG

Phentermine HCL Capsules 15.

ARCHIVAL COPY

Gray & yellow

1 1

VOLUME 2.1

NEW DRUG APPLICATION

NDA No. 87-301

NAME OF APPLICANT

Vitarine

NAME OF NEW DRUG

Phentermine HCl Caps.,
15 mg (Gray/Yellow)

ARCHIVAL COPY

FDA 2626 (7/84)

THIS SUBMISSION: VOL_____ OF _____ VOLS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 87-301

Vitarine Pharmaceuticals, Inc.
Attention: Gail Prince
227-15 N. Conduit Avenue
Springfield Gardens, NY 11413

OCT 29 1986

Dear Madam:

Reference is made to the dissolution data you submitted on September 11, 1986 for Phentermine Hydrochloride Capsules, 15 mg.

The data have been reviewed by our Division of Bioequivalence and they have the following comments:

"1. The dissolution testing conducted by the firm on its Phentermine HCl 15 mg Capsules, lot #860703, manufactured at Springfield Gardens, NY, is acceptable.

2. The dissolution testing should be incorporated into your manufacturing controls and stability program. Dissolution testing should be conducted in 500 ml of water using USP XXI apparatus II (paddle) at 50 rpm. The test product should meet the following specification:

Not less than of the labeled amount of phentermine HCl in the capsule is dissolved in 45 minutes.

3. From the bioequivalence point of view, the firm has met the bioequivalence requirements and the firm's Phentermine HCl 15 mg Capsules manufactured at Springfield Gardens, NY, lot #860703, are deemed bioequivalent to the firm's Phentermine HCl 15 mg Capsules manufactured at South Hackensack, NY, lot #A52128."

Sincerely yours,

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