CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

83-564

CORRESPONDENCE

Orig

Delco CHEMICAL COMPANY, INC.

RESUBMISSION
NDA ORIG AMENDMENT

7 MacQUESTEN PARKWAY NORTH, MOUNT VERNON, NEW YORK 10550 914-664-8348

October 20, 1975

Marvin Seife, M.D., Director
Division of Generic Drug Monographs
Office of Drug Monographs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland, 28052

Re: Amendment to N.D.A. 83-564
Delcobese Capsules, 5 mg.,
10 mg., 15 mg., 20 mg.

Dear Dr. Seife:

Reference is made to your letter of October 17, 1975, referring to our amendment to our abbreviated new drug application #83-564, dated April 14, 1975, for Delcobese Capsules, 5 mg., 10 mg., 15 mg. and 20 mg.

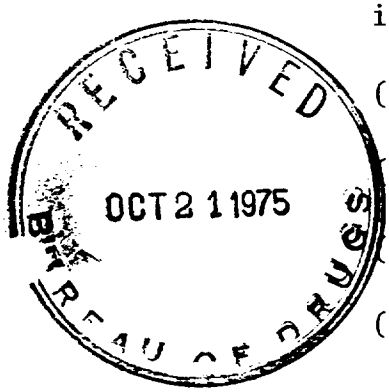
We are herewith submitting the following updated and revised information as it relates to the adequate assurance of the identity, strength, quality and purity of components and final dosage forms as requested in your above dated letter.

I. Active ingredients.

A. Page 39 of the submission - added the upper limit to the purity of the active ingredient Dextroamphetamine Sulfate not to exceed (See revised page 39 enclosed.)

B. Pages 40 and 41 of the submission - the monograph for the active ingredient d, l Amphetamine Adipate is revised to include:

(1) consolidation of pages 40 & 41 (i.e. specific rotation listed with other tests).
(2) molecular weight to read 281.34.
(3) purity limits between
(4) the addition of the specific color change in the assay titration end point to read "
(5) the addition of a Residue on Ignition test.



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CHEMICAL COMPANY, Inc.
7 MacQUESTEN PARKWAY NORTH, MOUNT VERNON, NEW YORK 10550 914-664-8348

(6) identification tests for d, l amphetamine and adipate.
(See revised pages 40 and 41 enclosed.)

C. Pages 42 and 43 of the submission - the monograph for the active ingredient Dextroamphetamine Adipate is revised to include:

(1) consolidation of pages 42 and 43 (i.e. specific rotation listed with other tests).
(2) molecular weight to read 281.34.
(3) purity limits between
(4) the addition of the specific color change in the assay titration end point to read "
(5) the addition of a Residue on Ignition test.
(6) identification tests for Dextroamphetamine and Adipate.
(7) the change in Specific Rotation readings.

(See revised pages 42 and 43 enclosed.)

II. Final dosage forms.

Pages 48 and 49 of the submission - the monograph for the finished dosage form, Delcobese Capsules, is revised to include:

A. a statement of the total amphetamine base content for each dosage form.

B. the purity limits between of the labeled amount of the mixed salts or as equivalent to the amphetamine base.

C. disintegration time limits.

D. Content Uniformity test.

E. A colorimetric assay procedure using the

Delco
CHEMICAL COMPANY, Inc.
7 MacQUESTEN PARKWAY NORTH, MOUNT VERNON, NEW YORK 10550 914-664-8348

he

III. Inactive Ingredients.

A. Empty Gelatin Capsules - We are submitting a specification monograph for empty Gelatin Capsules which contain statements as to its weight, identification, composition, solubility, and which also includes a statement from the capsule supplier, _____ certifying as to the capsule composition and specifications. (See Gelatin Capsules monograph and Elanco Products' letter of certification enclosed.)

The applicant has noted your request for a current description of the facilities, personnel, and standard operating procedures in use by our contract manufacturer. We refer you to pages 24 through 33 of the submitted amended application whereby the contract manufacturer, namely Inwood Laboratories, Inc., has described some current operations as it relates to Delcobese products. We have notified _____, Inc. of your suggestion to immediately review their and update those sections that require updating and will have them forward these revisions to you.

The stability program is an ongoing one and is being monitored with the proposed expiration date in mind. Any pertinent accumulated data will be submitted when available.

We trust these revisions to the specifications submitted will complete the necessary information required whereby we may be favored with an approval of the submitted application.

Sincerely yours,
DELCO CHEMICAL COMPANY, INC.

Louis Cohen
President

LC/ME

ORIG E

Delco

NDA ORIG AMENDMENT.

CHEMICAL COMPANY, Inc. FPL

7 MacQUESTEN PARKWAY NORTH, MOUNT VERNON, NEW YORK 10550 914-664-8348

April 14, 1975

Marvin Seife, M. D., Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs
Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Amendment to NDA 83-564
Delcobese Capsules, 5 mg., 10 mg.,
15 mg., & 20 mg.

Dear Dr. Seife:

Reference is made to our letter of February 7, 1975 advising you that of January 3, 1975 [illegible] Incorporated, [illegible] St., [illegible], [illegible] 11696 will be the new manufacturer for the above listed capsules and that an amended application will be forthcoming as soon as the necessary data became available.

We are herewith submitting this Amendment to our abbreviated new drug application #83-564 as set forth in paragraph 314.6 of Title 21 of the Code of Federal Regulations. This Amendment is submitted in compliance with the Federal Register notice of July 19, 1974, pages 26459/26462, reference "Drugs for Human Use - Drug Efficacy Study Implementation Certain Single Entity Oral Anorectic Drugs in Conventional or Controlled Release Dosage Forms".

Since this Amendment is substantive, the previous submission may be considered to be withdrawn and this amended application be considered resubmitted.

We trust you will find this Amendment in order.

Sincerely yours,

DELCO CHEMICAL COMPANY, Inc.

Louis Cohen

Louis Cohen, President

LC-em.

Delco

CHEMICAL COMPANY, Inc.

7 MacQUESTEN PARKWAY NORTH, MOUNT VERNON, NEW YORK 10550 914-664-8348

October 24, 1975

Marvin Seife, M.D., Director
Division of Generic Drug Monographs
Office of Drug Monographs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland, 28052

Re: Amendment to N.D.A. 83-564
Delcobese Capsules, 5 mg.,
10 mg., 15 mg., 20 mg.

Dear Dr. Seife:

Reference is made to our letter of October 20, 1975. In response to your letter of October 17, 1975, referring to our amendment to our abbreviated new drug application #83-564, dated April 14, 1975, for Delcobese capsules 5 mg., 10 mg., 15 mg. and 20 mg.

In our letter of October 20, 1975, we had revised the monograph for the finished dosage form, Delcobese capsules in which the assay described therein was a colorimetric procedure using the color reaction whereby a

nt
ally

We are enclosing herewith the description of the method we used to validate this analytical procedure and trust you will find it satisfactory.

Sincerely yours,

DELCO CHEMICAL COMPANY, INC.

Louis Cohen

Louis Cohen
President

LC/MF/nc

Specializing In Obesity Products For Over 25 Years

NDA 83-564

OCT 17 1975

AF 9-389

Delco Chemical Company, Inc.
Attention: Louis Cohen
7 MacQuesten Parkway North
Mount Vernon, NY 10550

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delcobese Capsules, 5 mg., 10 mg., 20 mg.

We acknowledge your communications dated August 15, 1973, July 10, 1974 and February 7, 1975 relating to the application.

Reference is also made to your amendment dated April 14, 1975 which replaces , with Incorporated as the contract manufacturer, processor, packager and labeler of the drug dosage forms.

The application is inadequate under sections 505(b)(3) and (4) of the Act in that it fails to contain the following information required in an application:

A quantitative statement of composition of the gelatin capsules in use.
A current description of the facilities, personnel, and standard operating procedures in use by your contract manufacturer. We suggest a review of updating as necessary.

Adequate assurance of the identity, strength, quality and purity of components and final dosage forms. In this regard for:

I. Active ingredients:
   A. Dextroamphetamine sulfate: Provide for an upper purity limit as per U.S.P. standards (re: page 39, insert "....and not more than percent...."

B. d,l Amphetamine adipate:
   (1) Consolidate pages 40 and 41 (i.e. include specific rotation with other tests)
   (2) Change the molecular weight to 281.34
   (3) Change the purity limits to "....percent...."
   (4) Specify the color of the endpoint in the assay (i.e. emerald green)
   (5) Add:
      a) identification testing for the amphetamine and adipate portions of the molecule
      b) residue on ignition testing

C. Dextroamphetamine adipate:
   Appropriate comments as applied to d,l Amphetamine adipate

II. Final dosage forms:

A. Include a statement of total amine content for each dosage form.
B. Include purity specifications of not less than not more than the total established amine content.
C. Specify the disintegration time.
D. Add:
   1) identification testing for amphetamine
   2) content uniformity (total amines)

We note that stability data submitted with the application is for a period less than the proposed expiration date. Possibly you may have accumulated longer term data by this time.

Please let us have your response promptly.

Sincerely yours,

Larry Dewe 10/17/75

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

mks 10/16/75

cc:

Enter evaluation or comments for each item. If necessary, continue on 8" x 10½" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

NDA NUMBER 83-564

25. COMPONENTS AND COMPOSITION (6, 7)

quantitative statement of composition for the gelatin capsules formulates with [illegible] of active ingredients

26. FACILITIES AND PERSONNEL (8a,b)

provided in

27. SYNTHESIS (8c)

provided in

28. RAW MATERIAL CONTROLS (8d,e)

a. NEW DRUG SUBSTANCE

inadequate for active ingredients as per issuing letter

b. OTHER INGREDIENTS

29. OTHER FIRM(s) (8i)

product is manufactured, processed, packaged and labeled by

30. MANUFACTURING AND PROCESSING (8g,h,j,k)

peovided in

31. CONTAINER (8i)

information included

32. PACKAGING AND LABELING (8l,m)

provided in

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

inadequate for finished dosage form

34. STABILITY (8p)

additional data requested - firm provides for a 3 yr. expiration date and makes commitment to continue testing and withdraw lots that may become substandard.

35. CONTROL NUMBERS (8c)

provided in

36. SAMPLES AND RESULTS (9)

a. VALIDATION not required b. MARKET PACKAGE

37. LABELING (4)

38. ESTABLISHMENT INSPECTION

39. RECALLS

ORIG NEW CORRES

ORIG

E

Delco CHEMICAL COMPANY, Inc.

7 MacQUESTEN PARKWAY NORTH, MOUNT VERNON, NEW YORK 10550 914-664-8348

February 7, 1975

See FDA letter 10-17-75

Marvin Seife, M.D., Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs
Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Re: NDA 83-564
Delcobese Capsules, 5mg., 10mg., 15mg., and 20mg.

Dear Dr. Seife,

Reference is made to our abbreviated new drug application dated February 23, 1973, submitted pursuant to Section (505(b) of the Federal Food, Drug and Cosmetic Act for Delcobese Capsules, 5mg., 10mg., 15mg., and 20mg.

Please be advised that as of January 3, 1975
Incorporated,
will be the new manufacturer for the above listed capsules.

We are currently collecting the necessary data required for the filing an amendment to the above numbered abbreviated new drug application and should have this necessary data available for this amendment within the next 60 days.

We trust you will find the above in order, we are

RECEIVED 1 COPY
PHOTOSTATS MADE
FOR DUP 1 TRIP 1

Sincerely yours,

DELCO CHEMICAL CO., INC.

Louis Cohen

Louis Cohen, President

RECEIVED FEB 14 1975 BUREAU OF DRUGS

LC/gf
cc: MF

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ORIG NEW CORRES

Delco CHEMICAL COMPANY, INC.

Specializing In Obesity Products For Over 25 Years

7 MacQUESTEN PARKWAY NORTH • MOUNT VERNON, NEW YORK 10550 • MOunt Vernon 4-8348

July 10, 1974

Marvin Seife, M.D., Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Ref: NDA 83-564
Product: Delcobese 5mg., 10mg., 15mg., and 20 mg. capsules
"Annual Report"

Dear Doctor Seife:

There has been no significant change in our production or analytical control for our products referred to above.

We are at this time submitting our stability data for the respective dosage forms.

Respectfully submitted,
Delco Chemical Co., Inc.

Louis Cohen

Louis Cohen, Pres.

RECEIVED
JUL 16 1974
BUREAU OF DRUGS

RESUBMISSION

NDA ORIG AMENDMENT

Delco CHEMICAL COMPANY, INC.

Specializing In Obesity Products For Over 25 Years

7 MacQUESTEN PARKWAY NORTH • MOUNT VERNON, NEW YORK 10550 • MOunt Vernon 4-8348

August 15, 1973

Marvin Seife, M.D., Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Ref: NDA 83-564
Product: Delcobese 5mg., 10mg., 15mg., and 20mg. Capsules

Dear Doctor Seife:

Reference is made to your communication dated August 7, 1973 - we will endeavor, herewith, to submit and clarify the requirements of the application.

I. Form 356-H-Paragraph 7. - A full statement of the composition of the drug.

a) The statement included in our submission does set forth the name and amount of each ingredient, whether active or not, contained in a stated quantity of the drug in the form it is to be distributed-see page 1.20 of NDA.

b) The batch formulae representative of that to be employed for the manufacture of the finished dosage forms appear on Pages 1.55, 1.56, 1.57 and 1.58 of the NDA.

II. Paragraph 8 (Form 356-H)

A. "Pertaining to your role in the operations.:

[illegible] and Dextroamphetamine

[illegible] an Dextroamphetamine Adipate

III. "A more complete description of, and the data derived from studies of the stability of the drug dosage form."

Answer: We are submitting herewith stability data re the drug dosage form.

IV. "Samples of the finished capsules"

Answer: We are submitting herewith samples of the finished capsules, as per your request.

V. "Revised (1) container labels on which the statement "central stimulant short-term appetite depressant" is deleted and (2) package insert, as per the accompanying labeling guidelines and with information in the "Supplied in....." section transferred to the How Supplied section."

Answer: We are herewith submitting new labels deleting the statement "central stimulant short-term appetite depressant."

However, as to the insert guidelines you forwarded dated "Draft 1/29/73" it is not consistent with the guidelines published in the Federal Register Vol. 38 No. 28, dated Monday, February 12, 1973 which is after the Draft which you forwarded; please clarify.

Too, the "How supplied in" relates to the description of the composition of the dosage form - and we would appreciate your review of your comments in your missive dated August 7, 1973.

VI. "It is also requested that you clarify operations performed by you in connection with this application"

Answer: Delco Chemical Co., Inc. is the sole distributor of Delcobese

products and as aforementioned is in control of the synthesis of the Adipate salts of Amphetamine and Dextroamphetamine. It is under our specifications that subcontractors synthesize same.

Production for 'Delco' at is conducted under the supervision of Delco's Quality Assurance Director - Andrée R. Barresi.

[illegible] Adipate and Dextroamphetamine Adipate on pages 1-31

[illegible] sing and packing of Amphet[illegible]

[illegible] 30 [illegible] dosage form enclosed with this submission.

We would appreciate your amending our NDA accordingly, and awaiting your reply with regard to the package insert, we remain

Very truly yours,
Delco Chemical Co., Inc.

Louis Cohen

Louis Cohen, President

enc.

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper.)

1. ORGANIZATION: bd-69

2. NDA NUMBER: 83-

3. NAME AND ADDRESS OF APPLICANT (City and State)
delco chemical co., inc.
mt. vernon, ny 10550

4. DATE NDA APPROVED

5. IF PRIOR TO ... DATE APPROVED FOR EFFICACY

6. NAME OF DRUG: delcobese

7. NONPROPRIETARY NAME: adipate & sulfate salts of amphetamine + d-amphetamine

8. SUPPLEMENT NUMBER / DATE

9. PURPOSE OF SUPPLEMENT

10. AMENDMENT DATE(s): 4/6/73

11. OTHER DATE (Report)

12. PHARMACOLOGICAL CATEGORY: anorexic

13. AF NUMBER: 9-389
rexar 3-550

16. RELATED IND. NDA/M...: 83-564 = tablets

14. DOSAGE FORM: capsules

15. HOW DISPENSED: XX Rx ☐ OTC

17. POTENCY (Use): 5,10,15,20 mg.

18. NAS/NRC: ☐ UNDER REVIEW ☒ REVIEWED

19. CHEMICAL NAME

20. RECORDS AND REPORTS
CURRENT: ☐ YES ☐ NO
REVIEWED: ☐ YES ☐

21. CHEMICAL FORMULA

22. REMARKS

NOTE: 1. bioavailability deferred, as per bio committee 1/8/73
2. designation to be INADEQUATE
3. response to be requested within 120 days

23. CONCLUSIONS

inadequate letter to issue

25. REVIEWER

NAME: gmillar

SIGNATURE: [signature] 8/3/73

DATE COMPLETED: 3

DISTRIBUTION: ☒ ORIGINAL JACKET ☐ DUPLICATE JACKET ☐ REVIEWER

FDH FORM 2268 (10/65) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable. | 83-564

25. COMPONENTS AND COMPOSITION (6, 7)

talc used = from .in #2 capsules(specs needed)
all weight 5.5 gr.

satisfactory
note: glc assay for determination of total amphetamine

26. FACILITIES AND PERSONNEL (8e,b)

needed for (a) delco. as sponsor (b) as synthesizer of 4 active ingredients &(c) as mfg of capsules

27. SYNTHESIS (8c)

as per chemical corp:llote batch formulae given for subject ; need same for (1) [illegible]

28. RAW MATERIAL CONTROLS (8d,e)

a. NEW DRUG SUBSTANCE

[illegible] amphetamine adipate = del

(need reference for it)

b. OTHER INGREDIENTS

satisfactory

29. OTHER FIRM(s) (8f)

appropriate as per #27 & 1 labs performe certifications need , as per #30 animal studies

30. MANUFACTURING AND PROCESSING (8g,h,j,k)

need special precautions + info as to quotat as per FR of 5/8/73; otherwise = satisfavtory

Note: CII drug for batches

31. CONTAINER (8i)

in bottles of 1000 + 5000
need full information

32. PACKAGING AND LABELING (8l,m)

need full information

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

need additional specs ts = (1)wt variation (2) (a)glc (b)non-aqueous titration for total amines.

34. STABILITY (8p)

needed

35. CONTROL NUMBERS (8c)

beeded

36. SAMPLES AND RESULTS (9)

a. VALIDATION ethod b. MARKET PACKAGE

37. LABELING (4)

revised, as per MO(jheilert)

38. ESTABLISHMENT INSPECTION

requested 8/1/73 for

39. RECALLS

na

FDH FORM 2266 (10/68)

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 2/1/73
FROM: gerry millar (thru Jack L. Meyer)		OFFICE BD-60
TO: Mr.C.G Broker (thru: Stan Stringer BD-100)		DIVISION BD-340

SUBJECT: Collaborative draft(s)

SUMMARY In connection with NDAs 83-563 for delcobese(4 amphetamine combo) tablets + capsules
83-564 5,10,15 & 20 mg.

The applicant: delco chemical co., inc
mt. vernon, ny 10550

AF: 9-389

We acknowledge receipt on 2/5/73

of abbr nda

dated 2/23/73

for the preparations

In accordance with the 2/27/73 directive, Office of Compliance a request is made for:

REQUESTED

XXX ◯ 1. establishment inspection report on

XX ☐ a. the applicant

XXXX ☐ b. others firm that mfg et al these preparations

582

◯ 2. evaluation of compliance with CGMPR

◯ 3. recommendation for approval/disapproval of the application/communication/supplement based on your evaluation of compliance with CGMPR

NOTE: have inspectors check rexar's quota, as per FR of 5/[illegible]/73

PLEASE INITIATE

SIGNATURE | DOCUMENT NUMBER

	5mg	10 mg	15 mg	20 mg
amphetamines	as per label contents			
corn starch lactose talc				

Original E

NDA ORIG AMENDMENT

Delco CHEMICAL COMPANY, INC. FPLI

Specializing In Obesity Products For Over 25 Years

7 MacQUESTEN PARKWAY NORTH • MOUNT VERNON, NEW YORK 10550 • MOunt Vernon 4-8348

PERSONALLY SUBMITTED BY
Joseph Bertolini
Rec'd by Bureau
4-12-73

April 6, 1973.

Marvin Seife, M.D., Director
Division of Actions Implementation
Drug Effecacy Study Implementation
Project Office
Bureau of Drugs, Food and Drug Administration
5600 Fishers Lane,
Rockville, Maryland 20852

Ref: NDA 83-564
Products: DELCOBESE CAPSULES, 5mg., 10 mg., 15 mg., and 20 mg.

Dear Doctor Seife:

Pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act; and in accordance to s.s. 130.7 we are amending our New Drug Application as follows:

Under Paragraph 4 (Copies of labels) Form 356-H

We have revised the package insert; and now are submitting the new copy pertaining thereto.

Enclosed are 12 copies of the new package insert.

CEIVED 1 COPY
OTOCOPIES MADE
IR DUP TAP

RECEIVED
APR 12 1973
BUREAU OF DRUGS

Respectfully submitted,
DELCO CHEMICAL CO., INC.

Louis Cohen

Louis Cohen, President

LC:g

NDA 83-564
AF 9-389

MAR 30 1973

Delco Chemical Co., Inc.
Attention: Mr. Louis Cohen
7 N. Macquesten Parkway
Mt. Vernon, New York 10550

Gentlemen:

Reference is made to your abbreviated new drug application dated February 23, 1973, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delcobese Capsules, 5 mg., 10 mg., 15 mg., and 20 mg.

Since no provision has been made for this preparation as a sustained release capsule to be filed as an abbreviated new drug application in any Federal Register notice, the application as submitted will not be reviewed at this time.

However, the material submitted is being retained in our file.

Sincerely yours,

Marvin Seife 3/30/73

Marvin Seife, M.D.
Director
Division of Antibiotic Implementation
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs

cc:
NYK-DO

3/29/73

ACK.

NDA 83-564/S-001

DEC 19 1975

Delco Chemical Company, Inc.
Attention: Louis Cohen
3 MacQuesten Parkway North
Mount Vernon, NY 10550

Gentlemen:

We acknowledge receipt on November 26, 1975, of a communication of November 14, 1975, submitted on your behalf by your manufacturing facility, [redacted] is regarded as a supplemental new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delcobese Tablets, 5 mg., 10 mg., 15 mg., and 20 mg. Capsules

The supplemental application provides for control revisions at the Facility.

We have completed the review of this supplemental application and it is approved. Our letter of October 24, 1975, detailed the conditions relating to the approval of this application.

The material submitted is being retained in the file.

Sincerely yours,

Marvin Seife 12/18/75

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

5.1 .

ANDA

83-564 Amphetamine Sulfate Capsules USP, 5 mg, 10 mg and 20 mg
83-563 Amphetamine Sulfate Tablets USP, 5 mg, 10 mg and 20 mg

Lemmon Company
Attention: Stanley Scheindlin, D.Sc.
650 Cathill Road
Sellersville, PA 18960

MAR 23 1993

Dear Sir:

We acknowledge the receipt of your communications dated February 24, 1993, requesting withdrawal of approval of your abbreviated new drug applications for the above referenced products.

In compliance with your request and in accordance with Section 314.150(c) of the Regulations under the Federal Food, Drug and Cosmetic Act, action will be taken to withdraw approval of the applications. Appropriate notice will be given by publication in the Federal Register in accordance with Section 314.152.

These withdrawals will not prejudice any future filing of the applications. You may request that the information in these applications be considered in connection with any resubmission.

Sincerely yours,

Ken Johnson for

3-21-93

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc:

LEMMON

LEMMON COMPANY
650 Cathill Road
Sellersville, PA 18960
Phone: (215) 256-8400
Fax: (215) 721-9669

Stanley Scheindlin, D.Sc.
Director, Regulatory Affairs

3.1

WITHDRAWN

February 24, 1993

Roger L. Williams, M.D.
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ANDA 83-564
AMPHETAMINE SULFATE CAPSULES (DELCOBESE), 5, 10, 15 and 20 mg

Dear Dr. Williams:

Manufacture and commercial distribution of this product have been discontinued for several years, and future production is not anticipated. We hereby request to withdraw the above-referenced Abbreviated New Drug Application without prejudice to any future filing.

Yours very truly,

Stanley Scheindlin

SS/cs

ORIGINAL