

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

Approval Package for:

APPLICATION NUMBER:

80-784

Generic Name: Folic Acid 1mg Tablets

Sponsor: Rondex Laboratories, Inc.

Approval Date: November 2, 1972

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-784

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Reviews / Information Included in this ANDA Review.

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Chemistry Review(s)	X
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Bioequivalence Review(s)	
Administrative Document(s)	X
Correspondence	X

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

80-784

APPROVAL LETTER

MA 80-784

AF 32-746

Rendex Laboratories, Inc.
Attention: Mr. Nathan Skop
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

NOV 2 1972

Gentlemen:

Reference is made to your abbreviated new drug application dated November 29, 1971, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Folic Acid Tablets, 1 mg.

We acknowledge the receipt of your communication dated October 10, 1972, enclosing manufacturing information.

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 130.9 of the new drug regulations.

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

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

Your application provides for distributors (names listed in a separate enclosure). We are enclosing, with the copy of this letter to the distributors, the conditions pertaining to the approval of this application.

cc:

- NWK-DO
- Dup
- BD-69
- BD-66
- BD-106
- BD-242
- BD-100
- BD-310
- JRCarr/JLMeyer/RJWolters

Enclosures:

- Records and Reports Requirement
- Conditions of Approval of a New Drug Application
- List of Distributors

R/D init. by MClark/10-26-72

Final typing/kim/10-26-72

Approval

Sincerely yours,

Paul A. Bryan, M.D. 12/1/72

Paul A. Bryan, M.D.
Director
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs

M. Seife 10/1/72

M. Clark init 11/1/72
RJ Wolters 10-26-72

The application provides for you to label the drug in 100 and 1,000 tablet containers with labels showing the distributors to be:

Approved Pharmaceutical Corporation
Syracuse, New York 13201

Berry Withington Company
Cambridge, Massachusetts 02140

Bioline Laboratories
Brooklyn, New York 11203

Columbia Medical Company
New York, New York 10003

It also provides for you to label the drug in 1,000 tablet containers with labels showing the distributor to be:

Gotham Pharmaceutical Company, Inc.
Brooklyn, New York 11223

APPEARS THIS WAY
ON ORIGINAL

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

80-784

FINAL PRINTED LABELING

FOLIC ACID

ORAL

DESCRIPTION: Folic Acid, $C_{10}H_{16}N_2O_6$, is a yellow or yellowish orange, odorless, crystalline powder, very slightly soluble in water.

ACTION: Folic acid is rapidly but preferentially absorbed from the small intestine. It is almost completely absorbed orally, even in the presence of the malabsorption associated with tropical sprue. Folic acid (pteroylglutamic acid) is not active as such in the human organism. Rather it is enzymatically reduced in the body to tetrahydrofolic acid, the coenzyme which is concerned with nearly all, or possibly all, mammalian metabolic systems in which there is a transfer of a one carbon unit, viz., $-CH_2-CHO$, $-CH=NH$.

INDICATIONS: Folic acid is effective in the treatment of megaloblastic anemias due to a deficiency of folic acid as may be seen in tropical or non-tropical sprue, in anemias of nutritional origin, pregnancy, infancy, or childhood.

WARNINGS: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient.

PRECAUTIONS: Folic acid especially in doses above 1.0 mg. daily may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION

Oral administration: Folic acid is well absorbed and may be administered orally with satisfactory results except in severe instances of intestinal malabsorption.

Usual therapeutic dosage: In adults: 0.25 mg. to 1.0 mg. daily. In children (regardless of age): 0.25 to 1.0 mg. daily. Resistant cases may require larger doses.

Maintenance dosage: When clinical symptoms have subsided and the blood picture has become normal, a maintenance dose of 0.1 mg. to 0.25 mg. daily should be used, but never less than 0.1 mg. per day. Patients should be kept under close supervision and adjustment of the maintenance dose made if relapse appears imminent.

In the presence of alcoholism, pregnancy, hemolytic anemia, anticonvulsant therapy, or chronic infection, the maintenance dose should be at least doubled.

HOW SUPPLIED: Folic Acid 1 mg. Tablets in bottles of 100 and 1,000.

CAUTION: Federal law prohibits dispensing without prescription.

May 1972

Handwritten:
6-15-15
20784 3-7-72
P. 1000

FOLIC ACID
1 mg.
U.S.P.

Control No. _____

SEE PACKAGE INSERT

Caution: Federal law prohibits dispensing without prescription.

1000 Tablets — 1 mg. each

Distributed By:
GOTTMAN PHARMACEUTICAL CO., INC.
Brooklyn, New York 11223

SEE PACKAGE INSERT

ORIGINAL
NO. 30-784
DATE 6-7-72
BY [Signature]
[Signature]

SEE PACKAGE INSERT

FOLIC ACID
1 mg. U.S.P.

CAUTION: Federal law prohibits dispensing without prescription.

100 TABLETS - 1 MG. EACH

Distributed By
BERRY WITHINGTON CO.
Cambridge, Mass. 02140

SEE PACKAGE INSERT

Control No.

SEE PACKAGE INSERT

FOLIC ACID *fw*
1 mg.

U.S.P.

Caution: Federal law prohibits dispensing without prescription.

1000 Tablets - 1 mg. Each

Distributed By
BERRY WITHINGTON CO.
Cambridge, Mass. 02140

SEE PACKAGE INSERT

Control No.

Imprinted: ORIGINAL
MMA No. 80-789 R. 8-7-75
Reviewed by: R/M/H
10-16-75

FOLIC ACID
1 mg. U.S.P.

CAUTION: Federal law prohibits dispensing without prescription.

100 TABLETS - 1 MG. EACH

Distributed By
APPROVED
PHARMACEUTICAL CORPORATION
Syracuse, New York 13201

SEE PACKAGE INSERT

SEE PACKAGE INSERT

Control No.

FOLIC ACID
1 mg. U.S.P.

CAUTION: Federal law prohibits dispensing without prescription.

1000 TABLETS - 1 MG. EACH

Distributed By
APPROVED
PHARMACEUTICAL CORPORATION
Syracuse, New York 13201

SEE PACKAGE INSERT

SEE PACKAGE INSERT

Control No.

ORIGINAL
80-764-1082-22
R/11/11
11-26-72

SEE PACKAGE INSERT

FOLIC ACID
1 mg. U.S.P. *M*

CAUTION: Federal law prohibits dispensing without prescription.

100 TABLETS - 1 MG. EACH

RONDEX LABORATORIES, INC.
Guttenberg, N. J. 07093

SEE PACKAGE INSERT

Control No.

SEE PACKAGE INSERT

FOLIC ACID
1 mg. U.S.P. *M*

CAUTION: Federal law prohibits dispensing without prescription.

100 TABLETS - 1 MG. EACH

Distributed By
BIOLINE LABORATORIES, Inc.
Brooklyn, N. Y. 11203

SEE PACKAGE INSERT

Control No.

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

80-784

CHEMISTRY REVIEW(S)

REVIEW OF ANDA

DATE COMPLETED: 1/12/72

ANDA #: 80-784

F.R. Date: 4/9/71
Rondex Laboratories, Inc.
68# Sixty Ninth Street
Guttenberg, New Jersey

NAME OF DRUG: Trade & Generic: Folic Acid Tablets, 1 mg.

DATE OF SUBMISSION: 11/29/71

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: Content uniformity and dissolution tests submitted to be evaluated by the chemist.
2. Review of Labeling:
 - a. Container Label: 1 mg tablets in bottles of 100 and 1000. The following revisions are required: (1) Delete, _____
(2) Add lot or control number.
 - b. Package Insert: Revise as follows: Delete the paragraph in the DOSAGE AND ADMINISTRATION section entitled _____, as this product is in tablet form only.

CONCLUSIONS: (1) Chemist to review.
(2) Labeling requires above stated revisions.

RECOMMENDATION: Request firm to submit FPL with revisions noted above.

Margaret A. Clark MD

Margaret A. Clark, M.D.

cc:
Dup.
BD-69
MAClark/mc/1/12/72

REVIEW OF AMENDMENT

DATE COMPLETED: 5/22/72

ANDA # 80-784

F.R. Date: 4/9/71
Rondex Laboratories, Inc.
68 Sixty Ninth Street
Guttenberg, New Jersey

NAME OF DRUG: Trade & Generic: Folic Acid Tablets, 1 mg.

DATE OF SUBMISSION: 5/12/72

TYPE OF SUBMISSION: Amendment for distributor: Approved Pharmaceutical Corp.
Syracuse, New York 13201

CLINICAL EVALUATION:

1. Review of Labeling: The labeling has the same errors noted in the Rondex labeling which were communicated to the firm in our letter of 1/27/72. The firm should be told that distributor labeling should not be submitted unless the appropriate corrections have been made. In addition, the labeling for Approved Pharmaceutical Corp. states that tablets are available in strengths of 0.1 mg., 0.25 mg. and 1 mg. The ANDA submitted by Rondex is for 1 mg. only and hence distributors may have only this strength.

CONCLUSIONS: Labeling should have corrections noted in our letter of 1/27/72.

Only the 1 mg. strength is acceptable under this application.

RECOMMENDATION: Firm should be instructed not to submit labeling which is known to be incorrect.



Margaret A. Clark, M.D.

cc:
Dup.
BD-69
MAClark/mc/5/22/72

REVIEW OF RESUBMISSION

DATE COMPLETED: 8-31-72

ANDA #: 80-784

F.R. DATE: 4-9-71

CO. NAME: Rondex Laboratories, Inc.
68 Sixty Ninth Street
Guttenberg, N.J. 07093

NAME OF DRUG: Trade & Generic: Folic Acid Tablets, 1 mg.
Bottles of 100 and 1000 tablets

DATE OF SUBMISSION: 7-27-72 Received for review 8-31-72

TYPE OF SUBMISSION: Resubmission for Rondex Laboratories, Inc.
Guttenberg, N.J. 07093

and distributors: Bioline Laboratories
Brooklyn, N.Y. 11203

and

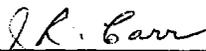
Columbia Medical Co.
New York, N.Y. 10003

CLINICAL EVALUATION:

1. Review of Studies: None submitted
2. Review of Labeling:
 - a) Container labels: Satisfactory
 - b) Rackage insert: Satisfactory

CONCLUSION: The labeling for this product is acceptable.

RECOMMENDATIONS: The company is to be notified of the aforementioned conclusion.



J.R. Carr, D.D.S.

cc:
Dup
BD-69
JRCarr/wlb/8-31-72

REVIEW OF AMENDMENT

DATE COMPLETED: 8-31-72

ANDA #: 80-784

F.R. DATE: 4-9-71

CO. NAME: Rondex Labs., Inc.
68 Sixty Ninth Street
Guttenberg, N.J. 07093

NAME OF DRUG: Trade & Generic: Folic Acid, 1 mg. Tablets
Bottles of 100 and 1000 tablets

DATE OF SUBMISSION: 8-1-72 Received for review 8-31-72

TYPE OF SUBMISSION: Amendment for distributors: Approved Pharmaceutical Corp.
Syracuse, N.Y. 13201

Berry Withington Co.
Cambridge, Mass. 02140

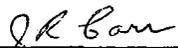
Gotham Pharmaceutical Co. Inc.
Brooklyn, N.Y. 11223
(bottles of 1000 tabs only)

CLINICAL EVALUATION:

1. Review of Studies: None submitted.
2. Review of Labeling:
 - a) Container labels: Satisfactory. However, Gotham Pharmaceutical should submit a label for the 100 tablet size if they plan to market this size.
 - b) Package insert: Satisfactory. If Gotham Pharmaceutical does not plan to market the 100 tablet size, this should be deleted from their insert.

CONCLUSION: The labeling is acceptable. Note above concerning Gotham Pharmaceutical.

RECOMMENDATIONS: The company is to be notified of the aforementioned conclusion.



J.R. Carr, D.D.S.

cc:
Dup
BD-69
JRCarr/wlb/8-31-72

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date
4-9-71

ORIGINAL
11-29-71
SUPPLEMENT

Name & Address of Applicant (City & State)
Roddex Laboratories, Inc.
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

NDA Number
80-784
Supplement Date and Number

Name of Drug

Nonproprietary Name
Folic Acid

Amendment Date(s)

Purpose of Supplement

Other Date(s)

Pharmacological Category

Vitamin

How Dispensed

R_x

O.T.C.

AF Number

32-746

Related IND/NDA/ME(s)

Dosage Form(s)

Tablet

Potency (ies)

1 mg.

Satisfactory

Labeling

Date Due Request FPL with minor revisions (MClark)

Satisfactory

Components, Composition, Manufacturing and Controls

Date Due See below

Satisfactory

Biologic Availability

Date Due NA

Is data on current

formulation? YES NO

**APPEARS THIS WAY
ON ORIGINAL**

Satisfactory

Probably or Possibly Effective Indications
(if in labeling)

Date Data Due _____

Establishment Inspection

Satisfactory 6-12-71

Recalls

If relabeling of drug in commercial channels required?

YES

NO

If so, what level:

Remarks

Request: FPL

for _____ and assay specifications for Folic
acid. Clarify omission of above.

Conclusions

rev w/f

RJWalters

RJWalters

REVIEWER:

SIGNATURE:

DATE:

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date
4-9-71

NDA Number
80-784

Name & Address of Applicant (City & State)

Rondex Laboratories, Inc.
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

Original _____

Amendment 5-12-72

Supplement _____

Name of Drug

Nonproprietary Name

Folic Acid

Other _____

Purpose of Supplement

Distributor labeling

Date(s) of Submission(s)

Pharmacological Category

Vitamin

How Dispensed

R_x

O.T.C.

AF Number 32-746

Related NDA & MF

Dosage Form(s)

Tablet

Potency (ies)

1 mg.

Satisfactory

Labeling

Date Due

To be revised.

Satisfactory

Components, Composition, Manufacturing and Controls

Date Due

See previous Chem Rev.

Satisfactory

Biologic Availability

Date Due

NA

Is data on current

formulation?

YES

NO

APPEARS THIS WAY
ON ORIGINAL

Satisfactory

Probably or Possibly Effective Indications

(if in labeling)

Date Data Due

Establishment Inspection

Satisfactory 6-12-71

Recalls

If relabeling of drug in commercial channels required?

YES

NO

If so, what level:

Remarks

Request: Revise the labeling in accord with our letter of 1-27-72.
Clarify the additional potencies.
Information requested in our letter of 1-27-72.

Conclusions

rev w/f

RJWalters
RJWalters

REVIEWER:

SIGNATURE:

DATE:

RJWalters 6-16-72

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date
4-9-71

NDA Number
80-784

Name and Address of Applicant (City & State)
Rondex Laboratories, Inc.
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

Original _____
Amendment 10-10-72
Supplement _____
Other _____

Name of Drug
Proprietary Name
Folic Acid

Date(s) of Submission(s)

Purpose of Supplement
Manufacturing information

AF Number 32-746

Pharmacological Category
Vitamin
How Dispensed
R_x O.T.C.

Related NDA & MF

Dosage Form(s)
Tablets
Potency (ies)
1 mg.

Satisfactory Labeling
 Date Due Satisfactory (JRCarr)

Satisfactory Components, Composition, Manufacturing and Controls
 Date Due Active ingredient and drug dosage form comply with USP specs.

Satisfactory Biologic Availability
 Date Due NA
Is data on current formulation? YES NO

Satisfactory Probably or Possibly Effective Indications
 (if in labeling)
Date Data Due _____

Establishment Inspection
Rondex Satisfactory TWX dated 12-9-71
ADS Satisfactory 7-20-72

Recalls

If relabeling of drug in commercial channels required? YES NO
If so, what level:

Remarks

APPEARS THIS WAY
ON ORIGINAL

Conclusions **Approval**
RJWalters
RJWalters 10-26-72

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date
4-9-71

NDA Number
80-784

Name & Address of Applicant (City & State)

Rondex Laboratories, Inc.
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

Original _____

Amendment ~~7-27-72~~
8-1-72

Supplement _____

Other _____

Name of Drug

Nonproprietary Name

Folic Acid

Date(s) of Submission(s)

Purpose of Supplement

Revised labeling and manufacturing information.

AF Number 32-746

Related NDA & MF

Pharmacological Category

Vitamin

How Dispensed

R_x

O.T.C.

Dosage Form(s)

Tablet

Potency (ies)

1 mg.

Satisfactory

Labeling

Date Due

Satisfactory (JRCarr)

Satisfactory

Components, Composition, Manufacturing and Controls

Date Due

See below

Satisfactory

Biologic Availability NA

Date Due

Is data on current

formulation? YES NO

APPEARS THIS WAY
ON ORIGINAL

Satisfactory

Probably or Possibly Effective Indications

(if in labeling)

Date Data Due

Establishment Inspection

Satisfactory TWX dated 12-9-71

Recalls

If relabeling of drug in commercial channels required?

YES

NO

If so, what level:

Remarks

Request the _____ and _____

Firm states that it will not market the 100 tablet container size for
Gotham unless ~~ix~~ the labels are submitted for review prior to marketing.

Conclusions

rev w/f

RJWalters

RJWalters 9-5-72

REVIEWER:

SIGNATURE:

DATE:

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT		Federal Register Statement Date 4-9-71	NDA Number 80-784
Name and Address of Applicant (City and State) Rondex Laboratories, Inc. 68 Sixty-Ninth Street Guttenberg, New Jersey 07093			Original _____ Amendment _____ Supplement 11-17-72 S-001
Name of Drug	Nonproprietary Name Folic Acid		Other _____
Purpose of Supplement Distributor Purepac			Date(s) of Submission(s) _____
Pharmacological Category Vitamin	How Dispensed R _x <input checked="" type="checkbox"/> O.T.C. <input type="checkbox"/>		AF Number 32-746
Dosage Form(s) Tablet	Potency (ies) 1 mg.		Related IND/NDA/MF

Satisfactory Labeling Date Due Satisfactory (JRCarr) Revise insert at next printing.

Satisfactory Components, Composition, Manufacturing and Controls Date Due NA

Satisfactory Biologic Availability Date Due NA
Is data on current formulation? YES NO

Satisfactory Probably or Possibly Effective Indications (if in labeling) Date data Due _____

Establishment Inspection NA	Recalls
------------------------------------	---------

Is relabeling of drug in commercial channels required? YES No
If so, what level?

Remarks
Request a revise insert to conform to new labeling guidelines.

APPEARS THIS WAY
ON ORIGINAL

Conclusions Approved

R. J. Walters H1673
R. Walters

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

80-784

**ADMINISTRATIVE
DOCUMENTS**

[DESI 5897; Docket No. FDC-D-265; NDA 5-897, etc.]

FOLIC ACID PREPARATIONS, ORAL AND PARENTERAL FOR THERAPEUTIC USE

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following folic acid preparations:

1. a. Folvite Elixir; 5 mg. folic acid per 5 cc.;
- b. Folvite Tablets; 5 mg. and 20 mg. folic acid per tablet; and
- c. Folvite Parenteral Solution; sodium folate equivalent to 15 mg. folic acid per cc.; marketed by Lederle Laboratories, Pearl River, New York 10965 (NDA 5-897).
2. Folic Acid Tablets; 5 mg. per tablet; marketed by Eli Lilly and Co., Box 618, Indianapolis, Indiana 46206 (NDA 6-135).
3. Folic Acid Injection; 15 mg. folic acid, as the sodium salt, per cc.; marketed by S. F. Durst and Co., Inc., 5317 North Third Street, Philadelphia, Pennsylvania 19120 (NDA 6-338).

In addition to the above products, folic acid preparations for therapeutic use are marketed by other firms. A partial list of other suppliers of folic acid preparations limited to prescription dispensing, as indicated in readily available reference sources, is as follows:

ABA Pharmaceutical Co., Division of Bergher Distributing Co.
 American Pharmaceutical Co.
 American Drug Products.
 American Quinine Co.
 Approved Pharmaceutical Corp.
 Arcum Pharmaceutical Corp.
 Associated Labs., Inc.
 Barre Drug Co., Inc., The.
 Barry-Martin Pharmaceuticals, Inc.
 Bell Pharmacal Co.
 Carroll Chemical Co., The.
 Columbia Medical Co.
 Consolidated Midland Corp., CMC Research Division.
 Corvit Pharmaceuticals.
 Daniels, Robert and Co., Inc.
 DuMont Pharmacal Co.
 Evron Pharmaceutical Co., Inc.
 Faraday Laboratories, Inc.
 Gold Leaf Pharmacal Co., Inc.
 Gotham Pharmaceutical Co., Inc.
 Halsey Drug Co., Inc.
 Harvey Labs., Inc.
 Jan Labs.
 Kirkman Labs., Inc.
 Lannett Co., Inc.
 Lit Drug Co.
 Lustgarten Laboratories, Inc.
 Mifflin, McCambridge Co., Inc.
 Penhurst Pharmacal Co.
 Pharmex, Inc.
 Preston Franklin Pharmacal Co.
 Richlyn Labs.
 Robinson Laboratory, Inc.
 Spencer-Mead, Inc.
 Stanlabs, Inc.
 Supreme Pharmaceutical Co., Inc.
 Thompson, Wm. T., Co.
 Towne, Paulson and Co., Inc.
 Vitamin Research Corp.
 Vita-Fore Products Co.

West-Ward, Inc.
 Williams Chemical Co.
 Winsale Drug Co.

The drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new-drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new-drug application is required from any person marketing such drugs without approval.

The Food and Drug Administration is prepared to approve new-drug applications and supplements to previously approved new-drug applications under conditions described in this announcement.

A. Effectiveness classification. The Food and Drug Administration has considered the Academy reports, as well as other available evidence, and concludes that:

1. Folic acid is effective for the treatment of megaloblastic anemias of tropical and nontropical sprue, nutritional origin, pregnancy, infancy, and childhood.

2. There is a lack of substantial evidence that folic acid is effective for the following labeled indications: "macrocytic anemias associated with pellagra and similar deficiency states" and such vague, unspecific conditions as "macrocytic anemia of gastrointestinal origin" and "megaloblastic anemias other than pernicious anemia."

The Food and Drug Administration also concludes that there is no evidence that doses of folic acid greater than 1 mg. daily have greater efficacy than do those of 1 mg. Further, the usual therapeutic dose, oral or parenteral, should be 0.25 mg. to 1.0 mg. daily, and the maintenance dose should ordinarily be 0.1 to 0.25 mg. daily. Administration of higher doses greatly increases the possibility of masking vitamin B-12 deficiencies and the insidious development of or precipitation of neurological manifestations and/or lesions.

Preparations supplying no more than 0.1 mg. folic acid daily continue to be regarded as dietary supplements (21 CFR 3.42) and may be prescribed when a maintenance dose of 0.1 mg. a day is indicated.

B. Form of drug. Folic acid preparations are in (1) tablet form suitable for oral administration and contain no less than 0.15 mg. and no more than 1.0 mg. folic acid per tablet or (2) solution form suitable for parenteral administration in the dosages recommended in the labeling guidelines below.

C. Labeling conditions. 1. The label bears the statement "**CAUTION: Federal law prohibits dispensing without prescription.**"

2. The drug is labeled to comply with all requirements of the Act and regulations promulgated thereunder, and those parts of its labeling indicated below are substantially as follows: (Optional additional information, applicable to the drug, may be proposed under other appropriate paragraph headings and should follow the information set forth below.)

FOLIC ACID

DESCRIPTION

(To be supplied by the manufacturer. This is to be confined to an appropriate description of the physical and chemical properties of the drug, and the formulation.)

ACTIONS

(To be supplied by the manufacturer. This is to be confined to an appropriate statement of the demonstrated pharmacologic/physiologic actions of the active ingredients of the drug in humans. When the mode of action has not been determined, this should be clearly indicated.)

INDICATIONS

Folic acid is effective in the treatment of megaloblastic anemias due to a deficiency of folic acid as may be seen in tropical or nontropical sprue, in anemias of nutritional origin, pregnancy, infancy, or childhood.

WARNINGS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient.

PRECAUTIONS

Folic acid especially in doses above 1.0 mg. daily may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION

Oral administration. Folic acid is well absorbed and may be administered orally with satisfactory results except in severe instances of intestinal malabsorption.

Parental administration: Intramuscular, intravenous, and subcutaneous routes may be used if the disease is exceptionally severe, or if gastrointestinal absorption may be, or is known to be, impaired.

Usual therapeutic dosage: In adults: 0.25 mg. to 1.0 mg. daily. In Children (regardless of age): 0.25 to 1.0 mg. daily. Resistant cases may require larger doses.

Maintenance dosage: When clinical symptoms have subsided and the blood picture has become normal, a maintenance dose of 0.1 mg. to 0.25 mg. daily should be used, but never less than 0.1 mg. per day. Patients should be kept under close supervision and adjustment of the maintenance dose made if relapse appears imminent.

In the presence of alcoholism, pregnancy, hemolytic anemia, anticonvulsant therapy, or chronic infection, the maintenance dose should be at least doubled.

D. Previously approved applications.

1. Each holder of a "deemed approved" new-drug application (i.e., an application which became effective on the basis of safety prior to October 10, 1962) for such drug is requested to seek approval of the claims of effectiveness and bring the application into conformance by submitting supplements containing:

a. Revised labeling as needed to conform to the labeling conditions described herein for the drug, and complete current container labeling, unless recently submitted.

b. Updating information as needed to provide for an oral dosage form containing no less than 0.15 mg. and no more than 1.0 mg. folic acid per tablet or a

015

parenteral dosage form containing an amount appropriate for administration as described herein, and to make the application current in regard to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of the new-drug application form FD-356H to the extent described for abbreviated new-drug applications, § 130.4(f), published in the FEDERAL REGISTER April 24, 1970 (35 F.R. 6574). (One supplement may contain all the information described in this paragraph.)

2. Such supplements should be submitted within the following time periods after the date of publication of this notice in the FEDERAL REGISTER:

a. 60 days for revised labeling; or, for those products which must be reformulated, 180 days for revised labeling fully in accord with this announcement, provided claims for which substantial evidence of effectiveness is lacking are deleted within 60 days. The supplements should be submitted under the provisions of § 130.9 (d) and (e) of the new-drug regulations (21 CFR 130.9) which permit certain changes to be put into effect at the earliest possible time.

b. 180 days for updating information.

3. Marketing of the drug may continue until the supplemental applications submitted in accord with the preceding subparagraphs 1 and 2 are acted upon, provided that the labeling of the preparation shipped within the jurisdiction of the Act is in accord with the labeling conditions described in this announcement within the time periods described in subparagraph 2a.

E. *New applications.* 1. Any person who distributes or intends to distribute such drug which is intended for the conditions of use for which it has been shown to be effective, as described under A1 above, should submit an abbreviated new-drug application meeting the conditions specified in § 130.4(f) (1) and (2), published in the FEDERAL REGISTER April 24, 1970 (35 F.R. 6574). Such applications should include proposed labeling which is in accord with the labeling conditions described herein.

2. Distribution of any such preparation currently on the market without an approved new-drug application may be continued provided that:

a. Within 60 days from the date of publication of this announcement in the FEDERAL REGISTER, the labeling of such preparation shipped within the jurisdiction of the Act is in accord with the labeling conditions described herein, except that if the preparation must be reformulated, 180 days will be allowed for the dosage recommendations to be in accord with this announcement.

b. The manufacturer, packer, or distributor of such drug submits, within 180 days from the date of this publication, a new-drug application to the Food and Drug Administration.

c. The applicant submits within a reasonable time additional information that may be required for the approval of the application as specified in a written communication from the Food and Drug Administration.

d. The application has not been ruled incomplete or unapprovable.

F. *Opportunity for a hearing.* 1. The Commissioner of Food and Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of all new-drug applications and all amendments and supplements thereto providing for the indications for which substantial evidence of effectiveness is lacking as described in paragraph A2 of this announcement. An order withdrawing approval of the applications will not issue if such applications are supplemented, in accord with this notice, to delete such indications. Promulgation of the proposed order would cause any such drug for human use offered for the indications for which substantial evidence of effectiveness is lacking, to be a new drug for which an approved new-drug application is not in effect. Any such drug then on the market would be subject to regulatory proceedings.

2. In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the holders of any such applications, and any interested person who would be adversely affected by such an order, an opportunity for a hearing to show why such indications should not be deleted from labeling. A request for a hearing must be filed within 30 days after the date of publication of this notice in the FEDERAL REGISTER. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that a genuine and substantial issue of fact requires a hearing, together with a well-organized and full-factual analysis of the clinical and other investigational data the objector is prepared to prove in a hearing. Any data submitted in response to this notice must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety. If a hearing is requested and justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue a written notice of the time and place at which the hearing will commence.

G. *Unapproved use or form of drug.* 1. If the article is labeled or advertised for use in any condition other than those provided for in this announcement, it may be regarded as an unapproved new drug subject to regulatory proceedings until such recommended use is approved in a new-drug application, or is otherwise in accord with this announcement.

2. If the article is proposed for marketing in another form or for use other than

the use provided for in this announcement, appropriate additional information as described in § 130.4 or § 130.9 of the regulations (21 CFR 130.4, 130.9) may be required, including results of animal and clinical tests intended to show whether the drug is safe and effective.

Representatives of the Administration are willing to meet with any interested person who desires to have a conference concerning proposed changes in the labeling set forth herein. Requests for such meetings should be made to the Office of Scientific Evaluation at the address given below, within 30 days after the publication of this notice in the FEDERAL REGISTER.

A copy of the NAS-NRC report has been furnished to each firm referred to above. Any other interested person may obtain a copy by request to the appropriate office named below.

Communications forwarded in response to this announcement should be identified with the reference number DESI 5897, directed to the attention of the following appropriate office, and addressed (unless otherwise specified) to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852:

Supplements (identify with NDA number):
Office of Scientific Evaluation (BD-100),
Bureau of Drugs.

Original abbreviated new-drug applications (identify as such): Drug Efficacy Study Implementation Project Office (BD-5), Bureau of Drugs.

Request for Hearing (identify with Docket number): Hearing Clerk, Office of General Counsel (GC-1), Room 6-62, Parklawn. All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-5), Bureau of Drugs.

Requests for NAS-NRC report: Press Relations Office (CE-200), 200 C Street SW, Washington, D.C. 20204.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: March 19, 1971.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.71-4952 Filed 4-8-71; 8:46 am]

[DESI 10423]

LEVALLORPHAN TARTRATE INJECTION

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drug for intravenous use:

Lorfan Injection, containing levallorphan tartrate; Roche Laboratories, Division of Hoffman-LaRoche, Inc., 340 Kingsland Street, Nutley, New Jersey 07110 (NDA 10-423).

- NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER
80-784

DATE APPROVAL LETTER ISSUED
NOV 2 1972

TO:
Press Relations Staff (CE-300)

FROM:
 Bureau of Drugs
 Bureau of Veterinary Medicine

ATTENTION
Forward original of this form for publication only after approval letter has been issued and the name of the drug has been entered above.
APPROVAL OF ORIGINAL ABBREVIATED NDA

TYPE OF APPLICATION
 ORIGINAL NDA ABBREVIATED ORIGINAL NDA SUPPLEMENT TO NDA
CATEGORY
 HUMAN VETERINARY

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

DOSAGE FORM: Tablet
HOW-DISPENSED
 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.)

Folic Acid 1 mg.

NAME OF APPLICANT (Include City and State)

Rondex Laboratories, Inc.
Guttenberg, New Jersey 07093

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

Vitamin

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

APPEARS THIS WAY
ON ORIGINAL

FORM PREPARED BY

NAME
R.J. Wolters

DATE

FORM APPROVED BY

NAME
J.L. Meyer

DATE

OR16

NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT		NDA NUMBER 80-784
		DATE APPROVAL LETTER ISSUED JAN 17 1973
TO: Press Relations Staff (CE-300)	FROM: <input checked="" type="checkbox"/> Bureau of ^{Drugs} Medicine <input type="checkbox"/> Bureau of Veterinary Medicine	
APPROVAL OF SUPPLEMENT TO ABBREVIATED NDA <small>Forward original of this form for publication on later approval letter has been issued and the date of approval has been entered above.</small>		
TYPE OF APPLICATION <input type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> ABBREVIATED ORIGINAL NDA <input checked="" type="checkbox"/> SUPPLEMENT TO Abbreviated NDA		CATEGORY <input checked="" type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY
TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG Folic Acid		
DOSAGE FORM Tablet	HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> 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.) Folic Acid 1 mg.		
NAME OF APPLICANT (Include City and State) Rondex Laboratories, Inc. Guttenberg, New Jersey 07093		
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY Vitamin		
COMPLETE FOR VETERINARY ONLY		
ANIMAL SPECIES FOR WHICH APPROVED		
COMPLETE FOR SUPPLEMENT ONLY		
CHANGE APPROVED TO PROVIDE FOR Distributor		
APPEARS THIS WAY ON ORIGINAL		
FORM PREPARED BY		
NAME R.J. Wolters	DATE	
FORM APPROVED BY		
NAME J.L. Meyer	DATE	

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

80-784

CORRESPONDENCE

COLUMBIA MEDICAL COMPANY

Quality Pharmaceuticals

FDA #24-11012

COLUMBIA

38 EAST 19th STREET • NEW YORK, N.Y. 10003 • TEL. 212 OR 3-7320

November 15, 1971

Drug Efficacy Study Implementation
Project Office
Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
Rockville, Maryland 20852

Re: Abbreviated New Drug Application
Folic Acid 1 mg. Tablets, U.S.P.

Gentlemen:

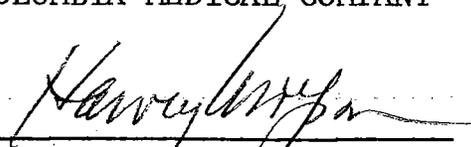
The undersigned, regularly and lawfully engaged in the distribution or dispensing of prescription drugs (FDA Registration No. 24-11012) hereby agrees to use only the labeling text which is included in the Rondex Laboratories, Inc. Abbreviated New Drug Application for Folic Acid 1 mg. Tablets, U.S.P.

It is further agreed that no changes will be made in such labeling or any other printed materail used in connection with the distribution of the drug other than that set forth in such Abbreviated New Drug Application. In the event that any changes are proposed in such labeling, they will first be submitted as a supplement to the said effective Abbrevuated New Drug Application and will not be used or otherwise distributed until or unless the supplement shall have been' approved.

We, the undersigned, understand that we are permitted to distribute the drug only under the labeling provided for in the Abbreviated New Drug Application; that any other labeling or advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling provided for in this application.

Respectfully,

COLUMBIA MEDICAL COMPANY


Harvey Wolfson, President

Page 28

NOV 17 1971

The BIOLINE Laboratories, Inc.

Distributors of Intravenous, Intramuscular, Glandular, Chemotherapeutic Preparations
Tablets, Liquids, Ointments, Physicians and Hospital Supplies



NOV 2

NOV 22 1971

1353 UTICA AVE • BROOKLYN 3, N.

Telephone NA 9-1313

NOVEMBER 18, 1971

DRUG EFFICACY STUDY IMPLEMENTATION
PROJECT OFFICE
BUREAU OF DRUGS
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

RE: ABBREVIATED NEW DRUG APPLICATION
FOLIC ACID 1 MG. TABLETS, U.S.P.

GENTLEMEN:

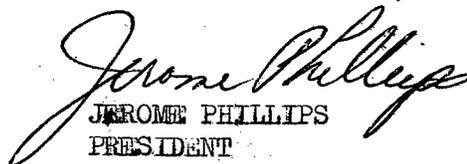
THE UNDERSIGNED, REGULARLY AND LAWFULLY ENGAGED IN THE DISTRIBUTION OR DISPENSING OF PRESCRIPTION DRUGS (FDA REGISTRATION NO. 24-12153) HEREBY AGREES TO USE ONLY THE LABELING TEXT WHICH IS INCLUDED IN THE RONDEX LABORATORIES, INC. ABBREVIATED NEW DRUG APPLICATION FOR FOLIC ACID 1 MG. TABLETS, U.S.P.

IT IS FURTHER AGREED THAT NO CHANGES WILL BE MADE IN SUCH LABELING OR ANY OTHER PRINTED MATERIAL USED IN CONNECTION WITH THE DISTRIBUTION OF THE DRUG OTHER THAN THAT SET FORTH IN SUCH ABBREVIATED NEW DRUG APPLICATION. IN THE EVENT THAT ANY CHANGES ARE PROPOSED IN SUCH LABELING, THEY WILL FIRST BE SUBMITTED AS A SUPPLEMENT TO THE SAID EFFECTIVE ABBREVIATED NEW DRUG APPLICATION AND WILL NOT BE USED OR OTHERWISE DISTRIBUTED UNTIL OR UNLESS THE SUPPLEMENT SHALL HAVE BEEN APPROVED.

WE, THE UNDERSIGNED, UNDERSTAND THAT WE ARE PERMITTED TO DISTRIBUTE THE DRUG ONLY UNDER THE LABELING PROVIDED FOR IN THE ABBREVIATED NEW DRUG APPLICATION; THAT ANY OTHER LABELING OR ADVERTISING FOR THE DRUG WILL PRESCRIBE, RECOMMEND, OR SUGGEST ITS USE ONLY UNDER THE CONDITIONS STATED IN THE LABELING PROVIDED FOR IN THIS APPLICATION.

RESPECTFULLY,

BIOLINE LABORATORIES, INC.


JEROME PHILLIPS
PRESIDENT

APPEARS THIS WAY
ON ORIGINAL

ABBREVIATED
NEW DRUG APPLICATION



80-784

RONDEX LABORATORIES, Inc.

"THE HOME OF FINE PHARMACEUTICALS"

68 SIXTY NINTH STREET, GUTTENBERG, NEW JERSEY

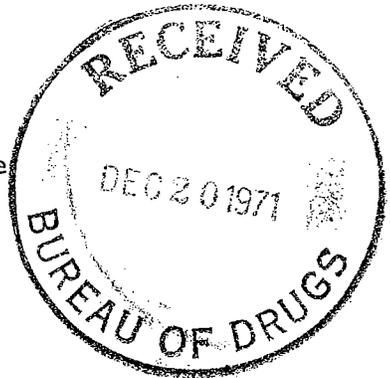
TEL. NEW JERSEY: 868-5400

NEW YORK DIRECT: 594-0913

CABLE - RONDEX, GUTTENBERG N J

November 29, 1971

Drug Efficacy Study Implementation Project Office
Bureau of Drugs
Department of Health, Education, and Welfare
Food and Drug Administration
Rockville, Maryland 20852



Gentlemen:

Rondex Laboratories, Inc., FDA Registration # 24-10563, is herewith submitting an Abbreviated New Drug Application for Folic Acid 1 mg. Tablets, U.S.P., pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act, and Section 130.4(f)(1) and (2) of the Code of Federal Regulations.

Enclosed you will find an original and two copies of the required information arranged in the order outlined in 21 CFR Part 130, Abbreviated Applications.

Thank you for your attention to this matter.

Respectfully submitted,

RONDEX LABORATORIES, INC.

Edward Plymack, President

EP:va
Enclosures

NDA 80-784

AF 32-746

JAN 03 1972

Rondex Laboratories, Inc.
Attention: Mr. Edward Plymack
69 Sixty Ninth Street
Guttenberg, New Jersey 07093

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: Folic Acid Tablets, 1 mg.

DATE of APPLICATION: November 29, 1971

DATE of RECEIPT: December 20, 1971

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,

Oree M. Carroll, M.D. 12/30/71

Oree M. Carroll, M.D.
Director
Division of Actions Implementation
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs

cc:

NYK-DO

Dup

BD-69

BD-67

BD-22

BD-310

JLMeyer/bhy 12/23/71

Ack.

orig inculed

NDA 80-784

AF 32-746

JAN 27 1972

Rondek Laboratories, Inc.
Attention: Mr. Edward Flynnack
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

Gentlemen:

Reference is made to your abbreviated new drug application dated November 29, 1971, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Folic Acid Tablets, 1 mg.

The application provides for you to market the drug under your own label. It also provides for you to label the drug with a label showing the distributors to be:

Bioline Laboratories, Inc.
Brooklyn, New York 11203

Columbia Medical Company
New York, New York 10003

We have completed the review of this abbreviated new drug application as submitted with draft labeling. However, before the application may be approved, it will be necessary for you to submit final printed labeling. The labeling should be identical in content to the draft copy, except for the following revisions:

1. Delete the term: _____ from the container labels.
2. In the DOSAGE and ADMINISTRATION section of the package insert, delete the section entitled _____, as your product is a tablet.

Please submit twelve copies of the revised labels and labeling.

In addition, the absence of an identifying lot or control number is noted. Please clarify.

Additional information required by Section 130.4(f) of the regulations:

Procedures that assure that the drug dosage form and components will comply with the specifications and tests described in an official compendium if such article is recognized therein, or, if not listed or if the article differs from the compendium drug, that the specifications and tests applied to the drug and its components are adequate to assure their identity, strength, quality, and purity.

- a) Clarify the omission of the _____
the _____
and the specifications for _____
- b) It is noted that the active ingredient, Folic Acid does not meet the U.S.P. XVIII assay specification. Please clarify.
- c) Since the U.S.P. XVIII does not include a dissolution test for Folic Acid Tablets, the material submitted will not be reviewed.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife 1/26/72

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

cc:

NYK-DO

Dup

BD-69

BD-67

BD-22

BD-242

MAClark/JLMeyer/RJWolters 1-13-72

R/D init. by MClark/JLMeyer/MSeife 1-24-72

Final typing/wlb/1-25-72

Rev w/f

RJ Wolters 1-25-72
JMeyer 1/25/72
MClark MD 1/26/72



RONDEX LABORATORIES, Inc.

"THE HOME OF FINE PHARMACEUTICALS"

68 SIXTY NINTH STREET, GUTTENBERG, NEW JERSEY

TEL. NEW JERSEY: 868-5400

NEW YORK DIRECT: 594-0913

CABLE - RONDEX, GUTTENBERG N J

ORIG

May 12, 1972

NDA 80-784

Director
 Drug Efficacy Study Implementation
 Project Office
 Bureau of Drugs
 Food and Drug Administration
 Department of Health, Education, and Welfare
 Rockville, Maryland 20852

Dear Sir,

Rondex Laboratories, Inc., is herewith submitting in triplicate an amendment to our Unapproved Abbreviated New Drug Application for

Folic Acid 1 mg. Tablets, U.S.P., NDA 80-784
 pursuant to Section 505(b) of the Federal Food Drug and Cosmetic Act.
 This supplement provides for the distribution of the drug in bottles of
 100 and 1000 Tablets by:

Approved Pharmaceutical Corporation
 Syracuse, New York 13201

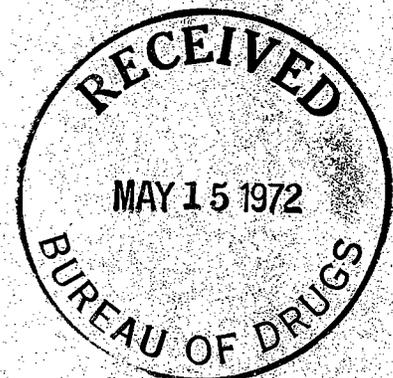
Thank you for your attention to this matter.

Sincerely,

Nathan Skop, Vice-President
 Rondex Laboratories, Inc.

RECEIVED / COPY
 PHOTOSTATS MADE
 FOR DUP / TRIP

NS:pm
 Enclosures



MDA 80-784
AF 32-746

JUN 21 1972

Rondex Laboratories, Inc.
Attention: Mr. Nathan Skop
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

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 Folic Acid Tablets, 1 mg.

We acknowledge the receipt of your communication dated May 12, 1972, enclosing labeling for an additional distributor.

The application as amended provides for you to label the drug with a label showing the distributor to be:

Approved Pharmaceutical Corporation
Syracuse, New York 13201

Reference is also made to our letter of January 27, 1972.

We cannot complete the review of this application however, until all submitted labeling (including that for the distributors) is revised in accord with the comments contained in our letter of January 27, 1972.

In addition, the labeling for Approved Pharmaceutical Corporation, refers to other potencies (0.1 mg. and 0.25 mg.) while the application submitted by Rondex is for the potency of 1 mg. Please clarify.

The additional information required by Section 130.4(f) of the regulations as requested on January 27, 1972, is also required.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife 6/21/72
Marvin Seife, M.D.
Director
Division of Actions Implementation
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs

RJWalters 6-16-72
MAClark/JLMeyer/RJWalters/6-13-72
R/D init. by MCLark/JMeyer/6-14-72
Final typing/kim/6-15-72
Rev w/f

cc:
NWK-DO
Dup
BD-69

Summary 6/20/72
M. Clark MD 6/20/72
BD-67 BB-106 BD-242

Rev. a/f

RESUBMISSION *E*
NDA ORIG AMENDMENT



RONDEX LABORATORIES, Inc.

"THE HOME OF FINE PHARMACEUTICALS"

68 SIXTY NINTH STREET, GUTTENBERG, NEW JERSEY

TEL. NEW JERSEY: 868-5400

NEW YORK DIRECT: 594-0913

CABLE - RONDEX, GUTTENBERG N J

*FPL
ORIG*

NDA 80-784

July 27, 1972

Director
Division of Actions Implementation
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Dear Sir,

Rondex Laboratories, Inc. is herewith submitting in triplicate Communication No. 1 to our Abbreviated New Drug Application for Folic Acid Tablets, 1 mg, NDA 80-784, to supply the information requested in your letter of January 27, 1972.

Thank you for your attention to this matter.

Sincerely,

Nathan Skop, Vice-President
Rondex Laboratories, Inc.

NS:pjm
Enclosures



Rondex**RONDEX LABORATORIES, Inc.**

"THE HOME OF FINE PHARMACEUTICALS"

68 SIXTY NINTH STREET, GUTTENBERG, NEW JERSEY

TEL. NEW JERSEY: 868-5400

NEW YORK DIRECT: 594-0913

CABLE - RONDEX, GUTTENBERG N J

FPL

ORIG

NDA 80-784

August 1, 1972

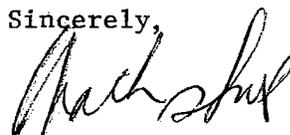
Director
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs
Food and Drug Administration
Department of Health, Education and Welfare
Rockville, Maryland 20852

Dear Sir,

Rondex Laboratories, Inc. is herewith submitting in triplicate an Amendment to our unapproved Abbreviated New Drug Application for Folic Acid 1 mg. Tablets, U.S.P., NDA 80-784. This Amendment provides for revised labeling for one distributor previously submitted, and for labeling for two additional distributors.

Thank you for your attention to this matter.

Sincerely,



Nathan Skop, Vice-President
Rondex Laboratories, Inc.

NS:pjm
Enclosures



NDA 80-784

~~AP 32-746~~

SEP 8 1972

Rondex Laboratories, Inc.
Attention: Mr. Nathan Skop
68 Sixty Ninth Street
Guttenberg, New Jersey 07093

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 Folic Acid Tablets, 1 mg.

Reference is also made to your communications dated July 27, and August 1, 1972, enclosing printed labeling and manufacturing information.

The application provides for you to market the drug under your own label. It also provides for you to label the drug with labels showing the distributors to be:

Approved Pharmaceutical Corporation
Syracuse, New York 13201

Berry Withington Company
Cambridge, Massachusetts 02140

Bioline Laboratories
Brooklyn, New York 11203

Columbia Medical Company
New York, New York 10003

Gotham Pharmaceutical Company, Inc.
Brooklyn, New York 11223

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following

additional information is necessary:

It is recommended that the _____
and the _____ be
performed by the applicant.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife 9/7/72
Marvin Seife, M.D.

Director
Division of Actions Implementation
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs

cc:

NWK-DO

Dup

BD-69

BD-66

BD-106

BD-242

JRCarr/JLMeyer/RJWalters/9-1-72

R/D init. by MClark/JMeyer/9-5-72

Final typing/kim/9-5-72

Rev w/f

JMeyer 9/6/72

*RJWalters
9-5-72*

M. Clark M.D. for Dr. Carr 9/7/72



RONDEX LABORATORIES, Inc.

"THE HOME OF FINE PHARMACEUTICALS"

68 SIXTY NINTH STREET, GUTTENBERG, NEW JERSEY

TEL. NEW JERSEY: 868-5400

NEW YORK DIRECT: 594-0913

CABLE - RONDEX, GUTTENBERG N J

NDA 80-784

October 10, 1972

Director
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs
Food and Drug Administration
Department of Health, Education, and Welfare
Rockville, Maryland 20852

Dear Sir,

Rondex Laboratories, Inc. is herewith submitting in triplicate a Communication to our Abbreviated New Drug Application for Folic Acid Tablets, 1 mg., NDA 80-784.

This Communication provides the information requested in your letter of September 8, 1972.

Thank your for your attention to this matter.

Sincerely yours,

Nathan Skop, Vice-President
Rondex Laboratories, Inc.

NS:pjm
Enclosures

