

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

Approval Package for:

APPLICATION NUMBER:

80-784/S-001

Generic Name: Folic Acid 1mg Tablets

Sponsor: Rondex Laboratories, Inc.

Approval Date: January 17, 1973

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APPLICATION NUMBER:

80-784/S-001

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Reviews / Information Included in this ANDA Review.

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Chemistry Review(s)	X
Microbiology Review(s)	
Bioequivalence Review(s)	
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APPROVAL LETTER

NDA 80-784/s-002
AF 32-746

JAN 17 1973

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

Gentlemen:

We acknowledge the receipt of your supplemental application dated November 17, 1972, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Folic Acid Tablets, 1 mg.

The supplemental application provides for you to label 100 and 1000 tablet containers of the drug with a label showing the distributor to be:

Purepac Pharmaceutical Company
Elizabeth, New Jersey 07207

We have completed the review of this supplemental application and it is approved. Our letter of November 2, 1972, detailed the conditions relating to the approval of this application.

We are enclosing with the copy of this letter to the distributor the conditions relating to the approval of this application.

At the time of the next printing or within 180 days, whichever is sooner, revise the package insert to conform to the accompanying labeling guidelines.

Please submit twelve copies of the revised insert when available.

cc:
NWK-DO

Dup

BD-69

BD-66

BD-106

BD-242

Enclosures:

Conditions of Approval of a New Drug Application
Records and Reports Requirement
Labeling Guidelines

JRCarr/JLMeyer/RJWalters

cc: Purepac Pharmaceutical

R/D init. by MClark/JMeyer/1-12-73

Final typing/kim/1-15-73

Approved

Sincerely yours,

Marvin Seife, M.D.

Director

Division of Actions Implementation

Drug Efficacy Study Implementation

Project Office

Bureau of Drugs

JRCarr
1/16/73

RJW alt 1-14-73

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FINAL PRINTED LABELING

Distributed by
PUREPAC PHARMACEUTICAL CO.
Division Elizabeth Laboratories
Elizabeth, N. J. 07207, U.S.A.

PUREPAC



FOLIC ACID

TABLETS U.S.P.
1mg

NDC-228-2F10-10

CAUTION: Federal law prohibits dispensing without prescription.
1000 TABLETS

USUAL DOSE: *m*
SEE PACKAGE INSERT

LOT NO.

Distributed by
PUREPAC PHARMACEUTICAL CO.
Division Elizabeth Laboratories
Elizabeth, N. J. 07207, U.S.A.

PUREPAC



FOLIC ACID

TABLETS U.S.P.
1mg

NDC-228-2F10-10

CAUTION: Federal law prohibits dispensing without prescription.
100 TABLETS

USUAL DOSE: *BR*
SEE PACKAGE INSERT

LOT NO.

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CHEMISTRY REVIEW(S)

REVIEW OF SUPPLEMENT

DATE COMPLETED: 12-6-72

ANDA #: 80-784/S-001

F.R. DATE: 4-9-72

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

APPROVAL DATE: 11-2-72

NAME OF DRUG: Trade & Generic: Folic Acid Tablets, U.S.P. 1 mg.
Bottles of 100 and 1,000 Tablets

DATE OF SUBMISSION: 11-17-72

TYPE OF SUBMISSION: Supplement for distributor: Purepac Pharmaceutical Co.
Elizabeth, N.J. 07207

CLINICAL EVALUATION:

1. Review of Studies: None submitted

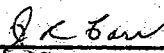
2. Review of Labeling:

a. Container label: Satisfactory

b. Package insert: Needs to be revised to conform to labeling guidelines
it conforms to FR statement of 4-9-71.

CONCLUSION: The package insert needs revision to conform to labeling
guidelines. This may be done at the time of the next
printing or within 180 days.

RECOMMENDATION: The company is to be notified of the aforementioned
conclusion and sent a copy of labeling guidelines.


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

cc:

Dup

BD-69

JRCarr, D.D.S./kim/12-8-72

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CORRESPONDENCE

NDA NO. *80-784*

REF. NO. *5001*

NDA SUPPL FOR *Purepac Pharmaceuticals*



FPL

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

November 17, 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 supplement to our Approved Abbreviated New Drug Application for Folic Acid 1 mg. Tablets, 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:

Purepac Pharmaceutical Company
200 Elmora Avenue
Elizabeth, New Jersey 07207

Thank you for your attention to this matter.

Sincerely,

Nathan Skop
Nathan Skop, Vice-President
Rondex Laboratories, Inc.

NS:pm
Enclosures

