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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-784/S-001

CONTENTS

Reviews / Information Included in this ANDA Review.

Approval Letter(s)	X
Tentative Approval Letter(s)	
Final Printed Labeling	X
CSO Labeling Review(s)	
Medical Officer Review(s)	
Chemistry Review(s)	X
Microbiology Review(s)	
Bioequivalence Review(s)	
Administrative Document(s)	
Correspondence	X

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APPLICATION NUMBER:

80-784/S-001

APPROVAL LETTER

NDA 80-784/S-001
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.

Sincerely yours,

Marvin Seife 1/16/73

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

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

JRCarr/JLMeyer/RJWolters JLMeyer 1/16/73
JRCarr 1/16/73
cc: Purepac Pharmaceutical
R/D init. by MClark/JMeyer/1-12-73
Final typing/kim/1-15-73
Approved
RJW 1-16-73

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-784/S-001

FINAL PRINTED LABELING

PUREPAC

FOLIC ACID

TABLETS U.S.P.

1mg.

APPROVED JAN 17 1973

NDC-228-2F10-10

CAUTION: Federal law pro-hibits dispensing without prescription.

1000 TABLETS

USUAL DOSE:

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.

APPROVED JAN 17 1973

NDC-228-2F10-10

CAUTION: Federal law pro-hibits dispensing without prescription.

100 TABLETS

USUAL DOSE:

SEE PACKAGE INSERT

LOT NO.

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-784/S-001

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 1,0000 Tablets

DATE OF SUBMISSION: 11-17-72

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

CLINICAL EVALUATION:

1. Review of Studies: None submitted

2. Review of Labeling:

a. Container label: Satisfactory

b. Pakcage 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-99
JRCarr, D.D.S./kim/12-8-72

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-784/S-001

CORRESPONDENCE

orig

NDA NO. 80-784 REF. NO. 5001

NDA SUPPL FOR Dist Purepac Pharm.

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 Sk[illegible] Vice-President
Rondex Laboratories, Inc.

NS:pm
Enclosures

RECEIVED
NOV 21 1972
BUREAU OF DRUGS