CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 84-472

Name: Folic Acid Tablets 1 mg

Sponsor: Premo Pharmaceutical Laboratories, Inc.

Approval Date: June 16, 1976

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 84-472

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 84-472

APPROVAL LETTER

NDA 84-472

JUN 16 1976

Premo Pharmaceuticals Laboratories, Inc.
Attention: Mr. Ashok Patel
111 Leuning Street
South Hackensack, NJ 07606

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 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.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

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

Sincerely yours,

Marvin Seife 6/16/76

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

NWK-DO
Dup
HFD-614,HFD-616
RBarzilai/JLMeyer/JMRoss
R/D init. JMeyer/MSeife 6-14-76
ft/cjb/6-14-76
approve

JMR/Marvin Seife, MD 6/15/76

Enclosures:
Conditions of Approval of a New Drug Application
Records and Reports Requirements

RB/Marvin Seife, M.D. 6/15/76

JMeyer 6/16/76

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 84-472

LABELING

FOLIC ACID TABLETS

JUN 16 1976

APPROVED

DESCRIPTION: Folic Acid, $C_{19}H_{19}N_7O_6$, 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 mammalian organism. Rather it is enzymatically reduced in the body to tetrahydorfolic acid, the coenzyme of which is concerned with nearly all, or possibly all, mammalian metabolic systems in which there is a transfer of a one carbon unit, viz., $-CH_3$, -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 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.

Parenteral 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, hemolytic anemia, anticonvulsant therapy or chronic infection, the maintenance dose should be at least doubled.

HOW SUPPLIED: Available as 1 mg. tablets in bottles of 100 and 1000.

CAUTION: Federal law prohibits dispensing without prescription

November, 1973

NDC 0331-0843-10

FOLIC ACID TABLETS, U.S.P.

1 mg.

JUN 1 6 1976

Caution: Federal law prohibits dispensing without prescription.

APPROVED

sual Dose: 1 tablet
ee package insert.

1000 TABLETS premo

Omega Medical Systems, Inc.
Premo Pharmaceutical Division, distributor
South Hackensack, N.J., U.S.A. 07606

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 84-472

CHEMISTRY REVIEWS

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date: 4-9-71, 10-16-73, & 12-10-73

NDA Number 84-472

AF Number

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Name and Address of Applicant (City and State)

Premo Pharmaceutical Lab. Inc.
Div of Omega Medical Systems
111 Leuning Street
So. Hackensack, NJ 07606

Date(s) of Submission(s)

Purpose of Amendment/Supplement

New Application

Pharmacological Category	Name Of Drug	How Dispensed
Vitamin	Folic Acid	Rx [x] OTC [ ]
Dosage Form(s): tablet	Potency: 1 mg.	
Environmental Impact Analysis Report: submitted	Samples	Related IND/NDA/MF(s): 84-158, 80-816, 83-526

Labeling

Container labels: Satisfactory(OMCarroll)
Package insert: " " "

Biologic Availability

Deferred

Establishment Inspection

Premo Pharm. Labs. Inc. EIR Requested 10-18-74
[redacted] (b) (4) " " "
[redacted] (b) (4) EIR Requested 10/18/74
" " "
" " "

Components, Composition, Manufacturing and Controls

active ingredient, excipients , finished dosage form are tested according to U SP specs.

Remarks

Requested: 1. clarify absence of control no. on container label and absence of container labels for 100 tablet container.
2. clarify the source or reference for the tests and specifications performed on [redacted] (b) (4)

Conclusion: rev w/f

Reviewer: J.M.Ross

J.M. Ross
11-11-74

Date:

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date
4-9-71, 10-16-73, 12-10-73

NDA Number 84-472

AF Number

Original
Amendment X
Supplement
Resubmission
Correspondance
Report
Other

Name and Address of Applicant (City and State)

Premo Pharmaceutical Lab. Inc.
Div of Omega Medical Systems
111 Leuning Street
So. Hackensack, NJ 07606

Date(s) of Submission(s)

3-25-75

Purpose of Amendment/Supplement

submission of additional manufacturing information

Pharmacological Category	Name Of Drug	How Dispensed
Vitamin	Folic Acid	Rx [x] OTC [ ]
Dosage Form(s)	Potency	
tablet	1 mg.	
Environmental Impact Analysis Report	Samples	Related IND/NDA/MF(s)
submitted		84-158 80-816 83-626

Labeling

Container label: Satisfactory (OMCarroll)
Package insert: " " see below Remarks

Biologic Availability

Deferred

Establishment Inspection

EI requested for ALL 10-18-74

[redacted] (b) (4) [redacted] (b) (4) [redacted] (b) (4)

Components, Composition, Manufacturing and Controls

active ingredient, excipients, and finished dosage form are tested according to USP spec

Remarks

Requested:
1. delete 100 tablet size container from HOW SUPPLIED section of package insert
2. Applicant told - CGMP- currently being evaluated

Conclusion rev w/f

Reviewer: J.M.Ross J.M. Ross 6-5-75 Date:

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date
4-9-71,10-16-73,12-10-73

NDA Number 84-472

AF Number

Original
Amendment x
Supplement
Resubmission
Correspondance
Report
Other

Name and Address of Applicant (City and State)

Premo Pharmaceutical Lab, Inc.
111 Leuning Street
So. Hackensack,NJ. 07606

Date(s) of Submission(s)

6/27/75

Purpose of Amendment/Supplement

submission of printed package inserts

Pharmacological Category	Name Of Drug	
Vitamin	Folic Acid	
Dosage Form(s)	Potency	How Dispensed
tablet	1 mg.	Rx ☒ OTC ☐
Environmental Impact Analysis Report	Samples	Related IND/NDA/MF(s)
submitted		

Labeling

Container label: Satisfactory(OMCarroll)
package insert: " " see remarks

Biologic Availability

Deferred

Establishment Inspection

(b) (4)

[redacted] requested EI 11/75

Components,Composition, Manufacturing and Controls

active ingredient, excipienta finished dosage form are tested according to USP specs.

Remarks

1. Designate what each testing lab does

Conclusion rev w/f

Reviewer: J.M.Ross J.M. Ross 2/19/76

Date:

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date
4-9-71, 10-16-73, 12-10-73

NDA Number 84-472

AF Number

Original
Amendment X
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Report
Other

Name and Address of Applicant (City and State)
Premo Pharm. Labs. Inc.
So. Hackendack, NJ 07606

Date(s) of Submission(s)
2/25/76

Purpose of Amendment/Supplement
designating the part or test perfomed aby each testing lab.

Pharmacological Category	Name Of Drug	How Dispensed
Vitamine	Folic Acid	Rx [X] OTC [ ]
Dosage Form(s)	Potency	
tablet	1 mg.	
Environmental Impact Analysis Report NA	Samples	Related IND/NDA/MF(s)

Labeling NA

Biologic Availability
Deferred

Establishment Inspection [redacted] (b) (4) EI Requestd... 4/5/76

Components, Composition, Manufacturing and Controls
active ingredient, excipients and finished dosage form are tested according to USP specs.

Remarks
Satisfactory Insepection report.

Conclusion rev w/f J.M. Ross 4/6/76

Reviewer: J.M. Ross Date:

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date
4-9-71, 10-16-73, 12-10-73

NDA Number 84-472

AF Number

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Name and Address of Applicant (City and State)
Premo-Pharm.Labs. Inc
South Hackensack, NJ
07606

Date(s) of Submission(s)

Purpose of Amendment/Supplement

Pharmacological Category	Name Of Drug	How Dispensed
vitamin	Folic Acid	Rx [X] OTC [ ]
Dosage Form(s)	Potency	
tablet	1 mg.	
Environmental Impact Analysis Report	Samples	Related IND/NDA/MF(s)
submitted		

Labeling
Container label: Satisfactory(Barzilai)
Package insert: " "

Biologic Availability
Deferred

Establishment Inspection
[redacted] (b) (4)
in compiance 6/7/76
" " "
" " "

Components, Composition, Manufacturing and Controls
active ingredient, excipients and finished dosage form are tested according to USP specs.

Remarks
Requested ; Delete [redacted] (b) (4) as agreed in telephone conversation 6/10/76
7 additional container labels

Conclusion
Approved J.M.Ross 6/16/76

Reviewer: J.M.Ross
Date:

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 84-472

MEDICAL REVIEWS

R

REVIEW OF ANDA

DATE COMPLETED: 10-21-74

ANDA #: 84-472

F.R. DATE: 12-10-73

CO. NAME: Premo Pharmaceutical
Div. of Omega Medical Systems
111 Leuning St.
South Hackensack, NJ
07606

NAME OF DRUG: Folic Acid Tablets, 1 mg.

DATE OF SUBMISSION: 9-19-74

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: None submitted. Bioavailability deferred.

2. Review of Labeling:

   Container labels for bottle labels for 100 and 1000 tablets are satisfactory.

   Package insert is satisfactory.

3. Controls and environmental impact statement will be reviewed by the chemist.

CONCLUSIONS: Labelings are satisfactory.
Controls and environmental impact statement will be reviewed by the chemist.

RECOMMENDATIONS: See conclusions.

O.M. Carroll, M.D.

cc:
Dup
HFD-107
OMCarroll/wlb/10-23-74

R

REVIEW OF AMENDMENT

DATE COMPLETED: 7-24-75

ANDA #: 84-472

F.R. DATE: 12-10-73

CO. NAME: Premo Pharmaceutical
Div. of Omega Medical Systems
South Hackensack, NJ 07606

NAME OF DRUG: Folic Acid Tablets, 1 mg.

CLINICAL EVALUATION:

1. Review of Studies: None submitted.

2. Review of Labeling:

   Container labels for bottles of 100 and 1000 tablets are satisfactory.

   Package insert: Satisfactory.

3. Controls and environmental impact statement to be reviewed by the chemist.

CONCLUSIONS: Labelings are satisfactory.

RECOMMENDATIONS: Recommend ANDA be approved.

O.M. Carroll, M.D.

cc:
Dup
HFD-530
OMCarroll/wlb/7-28-75

Note labeling revisions of containers requested in our 11/14/75 letter. (see firm's letter of 3/25/75, RA

R. Bagdan 3/31/76

2/3/76

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 84-472

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

premo

"Pioneers in Generics"

Premo Pharmaceutical Laboratories, Inc.

(Division of Omega Medical Systems)

111 Leuning St., So. Hackensack, N.J. 07606 / (201) 343-5000

September 17, 1974

ABBREVIATED NEW DRUG APPLICATION

84-472

Food and Drug Administration
Bureau of Drugs
5600 Fisher Lane
Rockville, Maryland 20852

Gentlemen:

Reference: ANDA FOLIC ACID TABLETS, U.S.P., 1 mg.

Enclosed is our Abbreviated New Drug Application, in triplicate, for the above drug, in accordance with the notice published in the Federal Register.

If additional information is required by the Food and Drug Administration, such information will be supplied in a reasonable length of time.

Sincerely yours,

PREMO PHARMACEUTICAL LABORATORIES, INC.

Ashok Patel.

Ashok Patel
Director of Laboratories

AP:ms

Enc.

RECEIVED 1 COPY PHOTOSTATS OF COVER LETTER MADE FOR DUP TRIP

RECEIVED SEP 19 1974 BUREAU OF DRUGS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

Form Approved
OMB No. 57-R0003

NEW DRUG APPLICATION *(DRUGS FOR HUMAN USE)*

(Title 21, Code of Federal Regulations, § 130.4)

Name of applicant PREMO PHARMACEUTICAL LABORATORIES, INC.
Division of Omega Medical Systems, Inc.

Address 111 Leuning Street, South Hackensack, New Jersey 07606

Date July 31, 1974

Name of new drug ANDA FOLIC ACID TABLETS USP 1 mg.

- [X] Original application (regulation § 130.4).
- [ ] Amendment to original, unapproved application (regulation § 130.7).
- [ ] Abbreviated application (regulation § 130.4(f)).
- [ ] Amendment to abbreviated, unapproved application (regulation § 130.7).
- [ ] Supplement to an approved application (regulation § 130.9).
- [ ] Amendment to supplement to an approved application.

The undersigned submits this application for a new drug pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act. It is understood that when this application is approved, the labeling and advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application; and if the article is a prescription drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the drug will contain the same information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant warnings, hazards, contraindications, side effects, and precautions, as that contained in the labeling which is part of this application in accord with §1.106(b) (21 CFR 1.106(b)). It is understood that all representations in this application apply to the drug produced until an approved supplement to the application provides for a change or the change is made in conformance with other provisions of §130.9 of the new-drug regulations.

Attached hereto, submitted in the form described in §130.4(e) of the new-drug regulations, and constituting a part of this application are the following:

1. Table of contents. The table of contents should specify the volume number and the page number in which the complete and detailed item is located and the volume number and the page number in which the summary of that item is located (if any).

2. Summary. A summary demonstrating that the application is well-organized, adequately tabulated, statistically analyzed (where appropriate), and coherent and that it presents a sound basis for the approval requested. The summary should include the following information: (In lieu of the outline described below and the evaluation described in Item 3, an expanded summary and evaluation as outlined in §130.4(d) of the new-drug regulations may be submitted to facilitate the review of this application.)

a. Chemistry.

i. Chemical structural formula or description for any new-drug substance.

ii. Relationship to other chemically or pharmacologically related drugs.

iii. Description of dosage form and quantitative composition.

b. Scientific rationale and purpose the drug is to serve.

c. Reference number of the investigational drug notice(s) under which this drug was investigated and of any notice, new-drug application, or master file of which any contents are being incorporated by reference to support this application.

d. Preclinical studies. (Present all findings including all adverse experiences which may be interpreted as incidental or not drug-related. Refer to date and page number of the investigational drug notice(s) or the volume and page number of this application where complete data and reports appear.)

i. Pharmacology (pharmacodynamics, endocrinology, metabolism, etc.).

ii. Toxicology and pathology: Acute toxicity studies; subacute and chronic toxicity studies; reproduction and teratology studies; miscellaneous studies.

e. Clinical studies. (All material should refer specifically to each clinical investigator and to the volume and page number in the application and any documents incorporated by reference where the complete data and reports may be found.)

i. Special studies not described elsewhere.

ii. Dose-range studies.

iii. Controlled clinical studies.

iv. Other clinical studies (for example, uncontrolled or incompletely controlled studies).

v. Clinical laboratory studies related to effectiveness.

vi. Clinical laboratory studies related to safety.

vii. Summary of literature and unpublished reports available to the applicant.

3. Evaluation of safety and effectiveness. a. Summarize separately the favorable and unfavorable evidence for each claim in the package labeling. Include references to the volume and page number in the application and in any documents incorporated by reference where the complete data and reports may be found.

b. Include tabulation of all side effects or adverse experience, by age, sex, and dosage formulation, whether or not considered to be significant, showing whether administration of the drug was stopped and showing the investigator's name with a reference to the volume and page number in the application and any documents incorporated by reference where the complete data and reports may be found. Indicate those side effects or adverse experiences considered to be drug-related.

4. Copies of the label and all other labeling to be used for the drug (a total of 12 copies if in final printed form, 4 copies if in draft form):

a. Each label, or other labeling, should be clearly identified to show its position on, or the manner in which it accompanies, the market package.

b. If the drug is to be offered over the counter, labeling on or within the retail package should include adequate directions for use by the layman under all the conditions for which the drug is intended for lay use or is to be prescribed, recommended, or suggested in any labeling or advertising sponsored by or on behalf of the applicant and directed to the layman. If the drug is intended or offered for uses under the professional supervision of a practitioner licensed by law to administer it, the application should also contain labeling that includes adequate information for all such uses, including all the purposes for which the over-the-counter drug is to be advertised to, or represented for use by, physicians.

c. If the drug is limited in its labeling to use under the professional supervision of a practitioner licensed by law to administer it, its labeling should bear information for use under which such practitioners can use the drug for the purposes for which it is intended, including all the purposes for which it is to be advertised or represented, in accord with §1.106(b) (21 CFR 1.106(b)). The application should include any labeling for the drug intended to be made available to the layman.

d. If no established name exists for a new-drug substance, the application shall propose a nonproprietary name for use as the established name for the substance.

e. Typewritten or other draft labeling copy may be submitted for preliminary consideration of an application. An application will not ordinarily be approved prior to the submission of the final printed label and labeling of the drug.

f. No application may be approved if the labeling is false or misleading in any particular.

(When mailing pieces, any other labeling, or advertising copy are devised for promotion of the new drug, samples shall be submitted at the time of initial dissemination of such labeling and at the time of initial placement of any such advertising for a prescription drug (see §130.13 of the new-drug regulations). Approval of a supplemental new-drug application is required prior to use of any promotional claims not covered by the approved application.)

5. A statement as to whether the drug is (or is not) limited in its labeling and by this application to use under the professional supervision of a practitioner licensed by law to administer it.

6. A full list of the articles used as components of the drug. This list should include all substances used in the synthesis, extraction, or other method of preparation of any new-drug substance, and in the preparation of the finished dosage form, regardless of whether they undergo chemical change or are removed in the process. Each substance should be identified by its established name, if any, or complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

7. A full statement of the composition of the drug. The statement shall set forth the name and amount of each ingredient, whether active or not, contained in a stated quantity of the drug in the form in which it is to be distributed (for example, amount per tablet or per milliliter) and a batch formula representative of that to be employed for the manufacture of the finished dosage form. All components should be included in the batch formula regardless of whether they appear in the finished product. Any calculated excess of an ingredient over the label declaration should be designated as such and percent excess shown. Reasonable variations may be specified.

8. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug. Included in this description should be full information with respect to any new-drug substance and to the new-drug dosage form, as follows, in sufficient detail to permit evaluation of the adequacy of the described methods of manufacture, processing, and packing and the described facilities and controls to determine and preserve the identity, strength, quality, and purity of the drug:

a. A description of the physical facilities including building and equipment used in manufacturing, processing, packaging, labeling, storage, and control operations.

b. A description of the qualifications, including educational background and experience, of the technical and professional personnel who are responsible for assuring that the drug has the safety, identity, strength, quality, and purity it purports or is represented to possess, and a statement of their responsibilities.

c. The methods used in the synthesis, extraction, isolation, or purification of any new-drug substance. When the specifications and controls applied to such substance are inadequate in themselves to determine its identity, strength, quality, and purity, the methods should be described in sufficient detail, including quantities used, times, temperatures, pH, solvents, etc., to determine these characteristics. Alternative methods or variations in methods within reasonable limits that do not affect such characteristics of the substance may be specified.

d. Precautions to assure proper identity, strength, quality, and purity of the raw materials, whether active or not, including the specifications for acceptance and methods of testing for each lot of raw material.

e. Whether or not each lot of raw materials is given a serial number to identify it, and the use made of such numbers in subsequent plant operations.

f. If the applicant does not himself perform all the manufacturing, processing, packaging, labeling, and control operations for any new-drug substance or the new-drug dosage form, his statement identifying each person who will perform any part of such operations and designating the part; and a signed statement from each such person fully describing, directly or by reference, the methods, facilities, and controls in his part of the operation.

g. Method of preparation of the master formula records and individual batch records and manner in which these records are used.

h. The instructions used in the manufacturing, processing, packaging, and labeling of each dosage form of the new drug, including any special precautions observed in the operations.

i. Adequate information with respect to the characteristics of and the test methods employed for the container, closure, or other component parts of the drug package to assure their suitability for the intended use.

j. Number of individuals checking weight or volume of each individual ingredient entering into each batch of the drug.

k. Whether or not the total weight or volume of each batch is determined at any stage of the manufacturing process subsequent to making up a batch according to the formula card and, if so, at what stage and by whom it is done.

l. Precautions to check the actual package yield produced from a batch of the drug with the theoretical yield. This should include a description of the accounting for such items as discards, breakage, etc., and the criteria used in accepting or rejecting batches of drugs in the event of an unexplained discrepancy.

m. Precautions to assure that each lot of the drug is packaged with the proper label and labeling, including provisions for labeling storage and inventory control.

n. The analytical controls used during the various stages of the manufacturing, processing, packaging, and labeling of the drug, including a detailed description of the collection of samples and the analytical procedures to which they are subjected. The analytical procedures should be capable of determining the active components within a reasonable degree of accuracy and of assuring the identity of such components. If the article is one that is represented to be sterile, the same information with regard to the manufacturing, processing, packaging, and the collection of samples of the drug should be given for sterility controls. Include the standards used for acceptance of each lot of the finished drug.

o. An explanation of the exact significance of the batch control numbers used in the manufacturing, processing, packaging, and labeling of the drug, including the control numbers that appear on the label of the finished article. State whether these numbers enable determination of the complete manufacturing history of the product. Describe any methods used to permit determination of the distribution of any batch if its recall is required.

p. A complete description of, and data derived from, studies of the stability of the drug, including information showing the suitability of the analytical methods used. Describe any additional stability studies underway or contemplated. Stability data should be submitted for any new-drug substance, for the finished dosage form of the drug in the container in which it is to be marketed, including any proposed multiple-dose container, and if it is to be put into solution at the time of dispensing, for the solution prepared as directed. State the expiration date(s) that will be used on the label to preserve the identity, strength, quality, and purity of the drug until it is used. (If no expiration date is proposed, the applicant must justify its absence.)

q. Additional procedures employed which are designed to prevent contamination and otherwise assure proper control of the product.

(An application may be refused unless it includes adequate information showing that the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity in conformity with good manufacturing practice and identifies each establishment, showing the location of the plant conducting these operations.)

9. Samples of the drug and articles used as components, as follows: a. The following samples shall be submitted with the application or as soon thereafter as they become available. Each sample shall consist of four identical, separately packaged subdivisions, each containing at least three times the amount required to perform the laboratory test procedures described in the application to determine compliance with its control specifications for identity and assays:

i. A representative sample or samples of the finished dosage form(s) proposed in the application and employed in the clinical investigations and a representative sample or samples of each new-drug substance, as defined in §130.1(g), from the batch(es) employed in the production of such dosage form(s).

ii. A representative sample or samples of finished market packages of each dosage form of the drug prepared for initial marketing and, if any such sample is not from a commercial-scale production batch, such a sample from a representative commercial-scale production batch; and a representative sample or samples of each new-drug substance as defined in §130.1(g), from the batch(es) employed in the production of such dosage form(s).

iii. A sample or samples of any reference standard and blank used in the procedures described in the application for assaying each new-drug substance and other assayed components of the finished drug: *Provided, however,* That samples of reference standards recognized in the official U.S. Pharmacopeia or The National Formulary need not be submitted unless requested.

b. Additional samples shall be submitted on request.

c. Each of the samples submitted shall be appropriately packaged and labeled to preserve its characteristics, to identify the material and the quantity in each subdivision of the sample, and to identify each subdivision with the name of the applicant and the new-drug application to which it relates.

d. There shall be included a full list of the samples submitted pursuant to Item 9a; a statement of the additional samples that will be submitted as soon as available; and, with respect to each sample submitted, full information with respect to its identity, the origin of any new-drug substance contained therein (including in the case of new-drug substances, a statement whether it was produced on a laboratory, pilot-plant, or full-production scale) and detailed results of all laboratory tests made to determine the identity, strength, quality, and purity of the batch represented by the sample, including assays. Include for any reference standard a complete description of its preparation and the results of all laboratory tests on it. If the test methods used differed from those described in the application, full details of the methods employed in obtaining the reported results shall be submitted.

e. The requirements of Item 9a may be waived in whole or in part on request of the applicant or otherwise when any such samples are not necessary.

f. If samples of the drug are sent under separate cover, they should be addressed to the attention of the Bureau of Medicine and identified on the outside of the shipping carton with the name of the applicant and the name of the drug as shown on the application.

10. Full reports of preclinical investigations that have been made to show whether or not the drug is safe for use and effective in use. a. An application may be refused unless it contains full reports of adequate preclinical tests by all methods reasonably applicable to a determination of the safety and effectiveness of the drug under the conditions of use suggested in the proposed labeling.

b. Detailed reports of the preclinical investigations, including all studies made on laboratory animals, the methods used, and the results obtained, should be clearly set forth. Such information should include identification of the person who conducted each investigation, a statement of where the investigations were conducted, and where the underlying data are available for inspection. The animal studies may not be considered adequate unless they give proper attention to the conditions of use recommended in the proposed labeling for the drug such as, for example, whether the drug is for short- or long-term administration or whether it is to be used in infants, children, pregnant women, or women of child-bearing potential.

c. Detailed reports of any pertinent microbiological and *in vitro* studies.

d. Summarize and provide a list of literature references (if available) to all other preclinical information known to the applicant, whether published or unpublished, that is pertinent to an evaluation of the safety or effectiveness of the drug.

11. List of investigators. a. A complete list of all investigators supplied with the drug including the name and post office address of each investigator and, following each name, the volume and page references to the investigator's report(s) in this application and in any documents incorporated by reference, or the explanation of the omission of any reports.

b. The unexplained omission of any reports of investigations made with the new drug by the applicant, or

submitted to him by an investigator, or the unexplained omission of any pertinent reports of investigations or clinical experience received or otherwise obtained by the applicant from published literature or other sources, whether or not it would bias an evaluation of the safety of the drug or its effectiveness in use, may constitute grounds for the refusal or withdrawal of the approval of an application.

12. Full reports of clinical investigations that have been made to show whether or not the drug is safe for use and effective in use. a. An application may be refused unless it contains full reports of adequate tests by all methods reasonably applicable to show whether or not the drug is safe and effective for use as suggested in the labeling.

b. An application may be refused unless it includes substantial evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

c. Reports of all clinical tests sponsored by the applicant or received or otherwise obtained by the applicant should be attached. These reports should include adequate information concerning each subject treated with the drug or employed as a control, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all relevant clinical observations and laboratory examinations made, full information concerning any other treatment given previously or concurrently, and a full statement of adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation and a statement of where the underlying data are available for inspection. Ordinarily, the reports of clinical studies will not be regarded as adequate unless they include reports from more than one independent, competent investigator who maintains adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated and comparable records on any individuals employed as controls. An application for a combination drug may be refused unless there is substantial evidence that each ingredient designated as active makes a contribution to the total effect claimed for the drug combination. Except when the disease for which the drug is being tested occurs with such infrequency in the United States as to make testing impractical, some of the investigations should be performed by competent investigators within the United States.

d. Attach as a separate section a completed Form FD-1639, Drug Experience Report (obtainable, with instructions, on request from the Department of HEW. Food and Drug Administration. Bureau of Drugs *(BD-200)* Rockville, Maryland 20852), for each adverse experience or, if feasible, for each subject or patient experiencing one or more adverse effects, described in Item 12c, whether or not full information is available. Form FD-1639 should be prepared by the applicant if the adverse experience was not reported in such form by the investigator. The Drug Experience Report should be cross-referenced to any narrative description included in Item 12c. In lieu of a FD Form 1639, a computer-generated report may be submitted if equivalent in all elements of information with the identical enumerated sequence of events and methods of completion; all formats proposed for such use will require initial review and approval by the Food and Drug Administration.

e. All information pertinent to an evaluation of the safety and effectiveness of the drug received or otherwise obtained by the applicant from any source, including information derived from other investigations or commerical marketing (for example, outside the United States), or reports in the scientific literature, involving the drug that is the subject of the application and related drugs. An adequate summary may be acceptable in lieu of a reprint of a published report which only supports other data submitted. Reprints are not required of reports in designated journals, listed in §130.38 of the new-drug regulations, about related drugs; a bibliography will suffice. Include any evaluation of the safety or effectiveness of the drug that has been made by the applicant's medical department, expert committee, or consultants.

f. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigation and experience with its components, including all reports received or otherwise obtained by the applicant suggesting side effects, contraindications, and ineffectiveness in use of such components. Such summary should include an adequate bibliography of publications about the components and may incorporate by reference information concerning such components previously submitted by the applicant to the Food and Drug Administration.

g. The complete composition and/or method of manufacture of the new drug used in each submitted report of investigation should be shown to the extent necessary to establish its identity, strength, quality, and purity if it differs from the description in Item 6, 7, or 8 of the application.

13. If this is a supplemental application, full information on each proposed change concerning any statement made in the approved application.
Observe the provisions of §130.9 of the new-drug regulations concerning supplemental applications.

PREMO PHARMACEUTICAL LABORATORIES, INC.
(Applicant)

Per Ashok Patel
(Responsible official or agent)

Ashok Patel, Director of Laboratories
(Indicate authority)

(Warning: A willfully false statement is a criminal offense. U.S.C. Title 18, sec. 1001.)

NOTE: This application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the nar and post office address of and must be countersigned by an authorized attorney, agent, or official residing or maintaining a place of business within the United States.

NDA 84-472

AF#

OCT 17 1974

Promo Pharmaceutical
Division of Omega Medical Systems
Attention: Ashok Patel
111 Leuning Street
South Hackensack, New Jersey 07606

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: July 31, 1974

DATE OF COVER LETTER: September 17, 1974

DATE OF RECEIPT: September 19, 1974

We will correspond with you further after we have had the opportunity to review the application.

We would also like to call to your attention the Federal Register of March 15, 1973 (38 F.R. 7001) regulations establishing procedures for preparation of Environmental Impact Statements (Part 6 - Environmental Impact Considerations). Section 6.1(e) of these regulations requires that the applicant include an environmental impact analysis report as part of any new-drug application. Failure to submit an environmental impact analysis report is grounds for refusing to file or to approve an application (21 CFR 314.110(a)(8) or 314.111(a)(7)).

Please identify any communications concerning this application with the NDA number shown above.

Sincerely yours,

JLMeyer 10/15/74

Marvin Seife 10/16/74

Marvin Seife, M.D.
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs

cc: NWK-DO
HFD-107 HFD-8
HFD-310
JLMeyer/9/27/74/tm/10/7/74
R/D init. by: MSeife/9/30/74

ACK

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 10-18-74
FROM: J. Ross (thru Jack L. Meyer)		OFFICE HFD-107
TO: Mr. Clifford G. Broker Office of Compliance		DIVISION HFD-340
SUBJECT: Inspection Request		

SUMMARY

In connection with ANDA - **84-472**

for: **Folic Acid Tablets, 1 mg.**

Applicant: **Premo Pharmaceutical**
South Hackensack, NJ 07606

AF -

REQUESTED:

[xx] 1. Evaluation of compliance with CGMP for:

[xx] a. The applicant

[xx] b. Others

[xx] 2. Recommendation for approval/disapproval of the application/ communication/supplement, based on your evaluation of compliance with CGMP

REMARKS: **"The monograph testing of all raw materials and finished products may be performed by Premo Pharm Labs, Inc or by one or all of the following..."**

(b) (4)

[redacted]

SIGNATURE

DOCUMENT NUMBER

FD FORM 2034 (2/72)

premo
"Pioneers in Generics"

Premo Pharmaceutical Laboratories, Inc.

(Division of Omega Medical Systems)
111 Leuning St., So. Hackensack, N.J. 07606 / (201) 343-5000

November 7, 1974

ORIG NEW CORRES
Reviewed
Submission
No Reply
1-30-75

Food and Drug Administration
Bureau of Drugs
5600 Fisher Lane
Rockville, Maryland 20852

Attention: Marvin Seife, M.D.
Director, Generic Drug Staff
Office of Scientific Evaluation

Gentlemen:

Reference: ANDA 84-472 Folic Acid Tablets, 1 mg.

This is in response to your letter of comments dated October 17, 1974 concerning the above new drug application.

Pursuant to your comments, we are enclosing the Enviornmental Impact Analysis Report, which was prepared according to the Federal Register of March 15, 1973 (38 F.R. 7001). This are the copies of our report filed with our original new drug application on September 17, 1974.

Sincerely yours,

PREMO PHARMACEUTICAL LABORATORIES, INC.

Ashok Patel

Ashok Patel
Director of Laboratories.

AP:ms
Enc.

RECEIVED 1 COPY
PHOTOSTATS OF
COVER LETTER MADE
FOR DUP TRIP

RECEIVED
NOV 12 1974
BUREAU OF DRUGS

Salmon Copy

NDA 84-472

NOV 14 1974

AF _____

Premo Pharmaceutical Laboratories, Inc.
Division of Omega Medical Systems
Attention: Mr. Ashok Patel
111 Leuning Street
South Hackensack, NJ 07606

Gentlemen:

Reference is made to your abbreviated new drug application dated July 31, 1974, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Folic Acid Tablets, 1 mg.

We have completed our review of this abbreviated application. However, before we are able to reach a final conclusion, the following additional information is necessary:

Container Label: Clarify the absence of a control number.

Package Insert: It is noted in the HOW SUPPLIED section that the tablets are in bottles of 100 and 1000, but there were no container labels for the 100 tablet containers. Please clarify.

Other information required under 314.1(f) of the regulations:

Assurances 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.

1. Clarify the source or reference for the tests and specifications performed on (b) (4).

Regarding stability, it is to be noted that Part 133.13 (21 CFR) of regulations defines the responsibilities for stability testing.

Please submit the above information promptly.

Sincerely yours,

J.M. Ross 11-11-74

Marvin Seife 11/14/74

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

cc:
NWK-DO
Dup
HFD-107 HFD-106 HFD-13 HFD-8
OMCarroll/JLMeyer/JMRoss/10-31-74
R/D init. MSeife/JMeyer/11-5-74
Final typing/rt/11-6-74 rev w/t

Salmon Copy

O.M. Carroll OMD 11/11/74

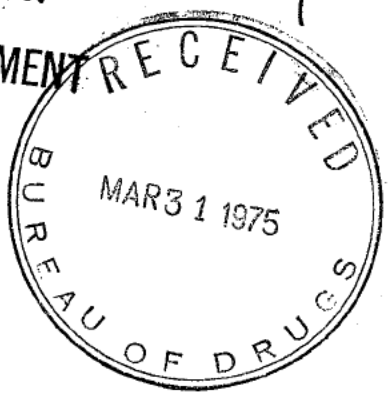
JMeyer 11/14/74

premo
"Pioneers in Generics"

Premo Pharmaceutical Laboratories, Inc.

(Division of Omega Medical Systems)
111 Leuning St., So. Hackensack, N.J. 07606 / (201) 343-5000

RESUBMISSION Orig
NDA ORIG AMENDMENT



March 25, 1975

Food and Drug Administration
Bureau of Drugs
5600 Fisher Lane
Rockville, Maryland 20852

Attention: Marvin Seife, M. D.
Director, Generic Drug Staff
Office of Scientific Evaluation

Gentlemen:

Reference: NDA 84-472, Folic Acid Tablets, 1 mg.

This is in response to your letter of comments dated November 14, 1974, concerning the above New Drug Application.

1. The absence of a control or lot number on the container label noted, because we print the control or lot number when we are ready to use the container label.

2. The package insert shows the bottles of 100 and 1,000 in the "How Supplied" section but there were no container labels for 100 tablets, because at the present time, we are not packing bottles of 100. If we decide to use bottles of 100, we will submit the label for your approval...before we use it.

3. We assure you that the drug dosage form and components will comply with the specifications and tests described in our New Drug Application for identity, strength, quality and purity.

4. The source for the tests and specifications performed in [redacted] (b) (4) was supplied by:

[redacted] (b) (4)

5. Regarding stability stucy, the samples are on study as per the procedure outlined in our Drug Master File.

Thank you for your cooperation in having this material reviewed.

Sincerely yours,

Ashok Patel

Ashok Patel
Director of Laboratories
AP:ms

RECEIVED 1 COPY
PHOTOSTATS MADE
FOR DUP ✓ TRIP ✓

NDA 84-472

AF _____

Premo Pharmaceutical Laboratories, Inc.
Division of Omega Medical Systems
Attention: Mr. Ashok Patel
111 Leuning Street
South Hackensack, NJ 07606

JUN 9 1975

Gentlemen:

Reference is made to your abbreviated new drug application dated July 31, 1974, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Folic Acid Tablets, 1 mg.

We acknowledge receipt of your communication dated March 25, 1975, enclosing additional manufacturing information.

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:

1. Package insert: Submit twelve copies of the revised package insert.

We also call to your attention that the Bureau of Drugs, Office of Compliance is currently evaluating your status with regard to compliance with Current Good Manufacturing Practice (CGMP) regulations. We will correspond with you after their review is complete.

The material submitted is being retained as part of your application for this article.

Sincerely yours,

Marvin Seife 6/9/75

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

cc:
NWK-DO
Dup
HFD-530 HFD-614 HFD-616
JLMeyer/JMRoss/5-28-75
R/D init. MSeife/JMeyer/6-2-75
Final typing/rt/6-3-75
rev w/f

JLMeyer 6/6/75

J.M. Ross 6-5-75

premo
"Pioneers in Generics"

Orig
Premo Pharmaceutical Laboratories, Inc.
(Division of Omega Medical Systems)
111 Leuning St., So. Hackensack, N.J. 07606 / (201) 343-5000

Rec'd w/ltr

RESUBMISSION
NDA ORIG AMENDMENT
FPL

June 27, 1975

Food and Drug Administration
Bureau of Drugs
5600 Fishers Lane
Rockville, Maryland 20852

Attention: Marvin Seife, M. D.
Director, Generic Drug Monographs
Office of Drug Monographs

Gentlemen:

Reference: NDA 84-472 Folic Acid Tablets, 1 mg.

This is in response to the comments in your letter dated June 9, 1975, concerning the above new drug application. We are enclosing the revised twelve (12) copies of our package insert.

Thank you for your cooperation in having this material reviewed.

Sincerely yours,

PREMO PHARMACEUTICAL LABORATORIES, INC.

Ashok Patel

Ashok Patel
Director of Laboratories

AP:ms
enc.

RECEIVED 1 COPY
PHOTOSTATS MADE
FOR DUP ✓ TRIP ✓

RECEIVED
JUL 0 1 1975
BUREAU OF DRUGS

NDA 84-472

FEB 20 1976

Premo Pharmaceutical Laboratories, Inc.
Attention: Mr. Ashok Patel
111 Leuning Street
South Hackensack, NJ 07606

Gentlemen:

Reference is made to your abbreviated new drug application dated July 31, 1974 submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Folic Acid Tablets, 1 mg.

We acknowledge receipt of your communication dated June 27, 1975, enclosing printed package inserts.

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 indicated that the testing of raw materials and finished dosage form is performed by your firm or by one of the listed laboratories. In this regard:

Identify any person other than the applicant who performs a part of these operations and designate the part.

Please submit the above information promptly.

Sincerely yours,

Marvin Seife 2/20/76

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

NWK-DO
Dup
HFD-614,HFD-616
RBarzilai/JLMeyer/JMRoss
R/D init. JMeyer/MSeife 2-18-76
final typing/cjb/2-18-76
rev w/f

JMRoss 2/19/76

RBarzilai 2/19/76

JMeyer 2/19/76

Rev w/F ORIG

premo

"Pioneers in Generics"

Premo Pharmaceutical Laboratories, Inc.

(Division of Omega Medical Systems)

111 LEUNING ST., SO. HACKENSACK, N.J., U.S.A. 07606 / (201) 343-5000

February 25, 1976

NDA ORIG AMENDMENT

Food & Drug Administration
Bureau of Drugs
5600 Fishers Lane
Rockville, Maryland 20852

Att: Marvin Seife, M.D.
Director
Division of Generic Drug Monographs

NOTED:
NO MEDICAL REVIEW INDICATED
SIG: R Sanghvi
DATE: 3/31/76

Gentlemen:

Ref: NDA 84-472 Folic Acid Tablets, 1 Mg.

We wish to acknowledge receipt of your letter dated February 20, 1976.

In your letter you have asked us to identify any person other than the applicant who performs a part of the testing operation for raw materials and finished product...enclosed you will find a list of outside testing facilities and test (s) performed by them.

We wish to reserve the right to have theconsulting laboratories and Premo Labs. do any and all tests on the raw materials or finished products, interchangeably, should circumstances warrant.

Sincerely yours,

PREMO PHARMACEUTICAL LABORATORIES, INC.

Ashok Patel

Ashok Patel
Director of Quality Control
APGF
enc.

RECEIVED COPY
PHOTOSTATS MADE
FOR DUP ✓ TRIP

RECEIVED
MAR 0 1 197
BUREAU OF DRUGS

NDA 84-472

APR 13 1976

Premo Pharmaceuticals Laboratories, Inc.
Attention: Mr. Ashok Patel
111 Leuning Street
South Hackensack, NJ 07606

Gentlemen:

Reference is made to your abbreviated new drug application date July 31, 1974 submitted pursuant to section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Folic Acid Tablets, 1 mg.

We acknowledge receipt of your communication dated February 25, 1976 enclosing additional information concerning testing laboratories.

We will complete our review of this abbreviated new drug application after the inspection reports from the testing laboratories are completed.

The material submitted is being retained as part of your application for this article.

Sincerely yours,

Marvin Seife 4/13/76

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

cc:
New-DO

HFD-614 HFD-616
JL Meyer/JMRoss
R/D init JMeyer/MSeife/4/12/76
ps/4/12/76
rev w/f

JMMeyer 4/12/76

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 6/10/76
FROM: JMeyer		OFFICE #FD530
TO: 84-492		DIVISION

SUBJECT: Folic Acid Tablets

SUMMARY Telephone Conversation.

Sol Silverang Premo
South Hackensack,
N.J.

and

JMeyer

Mr. Silverang agreed to ~~dr~~ withdraw [redacted] (b) (4) as a testing Lab.

He was advised that when the testing Lab was approved by FDA Compliance, ~~he~~ ~~the~~ he would resubmit [redacted] (b) (4)

SIGNATURE JMeyer	DOCUMENT NUMBER 84-492

FD FORM 2034 (2/72)

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 84-472

DATE APPROVAL LETTER ISSUED: JUN 16 1976

TO: Press Relations Staff (HFI-40)

FROM:
- [X] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication. Copy after approval letter has been issued and the date of approval has been established.

ORIGINAL ABBREVIATED

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [X] ABBREVIATED ORIGINAL NDA
- [X] SUPPLEMENT TO ANDA

CATEGORY
- [X] HUMAN
- [ ] VETERINARY

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

DOSAGE FORM: tablet

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.)*

Folic Acid 1 mg.

NAME OF APPLICANT *(Include City and State)*

Premo Pharmaceuticals,Laboratories,Inc.
111 Leuning Street
South Hackensack,NJ 07606

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY: vitamin

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: J.M.Ross — DATE:

FORM APPROVED BY

NAME: J.L Meyer — DATE:

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