CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER: 80-600

Generic Name: Folic Acid 1mg Tablets
Sponsor: West-ward, Inc.
Approval Date: March 31, 1972
**APPLICATION NUMBER:**

80-600

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APPLICATION NUMBER:

80-600

APPROVAL LETTER
Westward, Inc.
Attention: Mr. Edward Green
745 Eagle Green
Bronx, New York 10456

Gentlemen:

Reference is made to your abbreviated new drug application dated August 25, 1971, 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 communication dated January 18, 1972, containing control information and printed package inserts.

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 and 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.

cc:
NYK-DO
Dup
BD-100 BD-69 BD-67
BD-22 BD-242 BD-310

Sincerely yours,

[Signature]

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

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

[Signature]

Date: 3/20/72

[Signature]
Date: 3/20/72
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-600

FINAL PRINTED LABELING
FOLIC ACID

DESCRIPTION: Folic Acid, C_{12}H_{14}N_{4}O_{6}, is a yellow or yellowish orange, odorless, crystalline powder, freely 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 (pteroylmonoglutamic acid) is not active as such in the mammalian 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 processes. One of the forms in which there is a transfer of a one carbon unit, viz., \( \text{CH}_2\text{CHO} - \text{CH} = \text{CH} \). 

INDICATIONS: Folic acid is effective in the treatment of megaloblastic anemias due to a deficiency of folic acid or as may be seen in tropical, 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 \( \text{B}_12 \) 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: Tablets 1 mg, scored in bottles of 100 and 1000.

CAUTION: Federal law prohibits dispensing without prescription.

Westward Inc.
October 1971
APPLICATION NUMBER:

80-600

CSO LABELING REVIEW(S)
REVIEW OF FPL

DATE COMPLETED: 2-15-72

ANDA #: 804600

F.R. DATE: 4-9-71

CO. NAME: West-Ward Incorporated

745 Eagle Avenue

Bronx, N.Y. 10456

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

Generic: (scored in bottles of 100 and 1,000)

DATE OF SUBMISSION: 1-18-72

TYPE OF SUBMISSION: FPL and data for chemist

CLINICAL EVALUATION:

1. Review of Studies:

   Chemist to review

2. Review of Labeling:

   FPL conforms to requirements
   Container labels accepted in M.O. review of 9-6-71

CONCLUSION:

1. FPL approvable.

2. Chemist to review.

RECOMMENDATIONS:

1. Approve FPL.

2. Chemist to review.

cc: Dup.
BD-69
JHEilert/rt/2-16-72

[Signature] John H. Eilert, M.D.
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-600

CHEMISTRY REVIEW(S)
REVIEW OF ANDA

Date Completed: 9/6/71

ANDA #: 80-600
F.R. Statement Date: 4/9/71
Co. Name: West-ward, Inc.
Bronx, N.Y.

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

DATE OF SUBMISSION: 8/25/71

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: Bioavailability studies submitted as required in NF XIII dissolution and disintegration data meet standards.

Manufacturing and control data to be analyzed by chemist.


However, it is recommended that "___" be changed to "How Supplied". Explanation should be requested of varied tablet strength, 0.1 mg., 0.25 mg. and 1 mg. when only 1 mg. is listed on application.

In Dosage & Administration, delete references to ___ as this is a tablet dosage form.

CONCLUSIONS: Bioavailability studies acceptable. Manufacturing-control data require chemist appraisal. Elucidation of differing tablet strengths necessary.

RECOMMENDATIONS: 1. Chemist appraisal
2. Tablet strength variance to be explained.
3. Package insert '___' to be changed to "How Supplied." and delete references to ___

cc:
Dup
BD-100
BD-69
JHEilert/bhy 9/9/71

John H. Eilert, M.D.
REVIEW OF RESUBMISSION OF ORIGINAL ANDA

DATE COMPLETED: 11/4/71                   ANDA#: 80-600

F.R. Date: 4/9/71
West Ward Incorporated
The Bronx, N.Y.

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

DATE OF SUBMISSION: 10/27/71

TYPE OF SUBMISSION: 1. Insert revision )

CLINICAL EVALUATION:

L. Review of Studies: To be evaluated by chemist.
2 Review of Labeling: Revised insert (October, 1971) conforms to FDA 10/4/71 request.

CONCLUSION: 1. Approvable insert.
             2. Studies require chemist appraisal.

RECOMMENDATION: 1. Chemist to review
                 2. Approve insert, and request FPL.

John H. Eilert, M.D.

CC:
Dup.
BD-100
BD 69
JHEilert/mc 11/4/71
Folic Acid

Nonproprietary Name

Folic Acid

Usage Form(s)

Tablet

Potency(ies)

1 mg.

DATE(s) of Submission(s)

NDA Number

80-600

Purpose of Supplement

Pharmacological Category

Hematopoietic Vitamin

How Dispensed

Rx

OTC

AF Number

31-015

Related IND/NDA/MF

Satisfactory

Labeling

Date Due

M.O.R. (Dr. Eilert)

Satisfactory

Components, Composition, Manufacturing and Controls

Date Due

See Below

Satisfactory

Biologic Availability

Date Due

Not required.

Is data on current formulation? YES [ ] NO [ ]

Satisfactory

Probably or Possibly Effective Indications

(if in labeling)

Date data Due

None

Established Inspection

Recalls

TWX 3-17-71---Satisfactory

Is relabeling of drug in commercial channels required? YES [ ] NO [ ]

Remarks

1. Labeling requires revision.
2. Folic Acid Powder Residue on Ignition Test not performed and assay doesn't follow USP method.
3. Tablets—Content uniformity doesn't follow USP method.

Conclusions

LTR. to firm requesting:
1. Label Revision
2. Proper tests

R.E. Joyce

9-16-71

Reviewer

Signature

Date Completed
CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Name and Address of Applicant (City and State)

West-Ward, Inc.
Bronx, New York 10456

Name of Drug
Folic Acid

Nonproprietary Name
Folic Acid

Purpose of Supplement

Pharmacological Category
Hematopoietic Vitamin

How Dispensed
Rx

Dosage Form(s)
Tablet

Potency(ies)
1 mg.

Satisfactory
Labeling Date Due
Satisfactory M.O.R. 11-4-71 Dr. Eilert

Satisfactory
Components, Composition, Manufacturing and Controls
Date Due See below

Satisfactory
Biologic Availability
Date Due Not required

Is data on current formulation? YES NO

Satisfactory
Probably or Possibly Effective Indications
(if in labeling)

Establishment Inspection
Recalls

E.I. 3-17-71 Satisfactory

Is relabeling of drug in commercial channels required? YES NO

If so, what level:

Remarks

1. Require FPL.
2. Require data to substantiate use of different content uniformity test.

Conclusions

Rev. w/f 1 and 2

R. E. Joyce 12-2-71
<table>
<thead>
<tr>
<th>Pharmacological Category</th>
<th>How Dispensed</th>
<th>AF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin</td>
<td>Rx</td>
<td></td>
</tr>
<tr>
<td>Dosage Form(s)</td>
<td>Potency(ies)</td>
<td></td>
</tr>
<tr>
<td>Tablet</td>
<td>1.0 mg.</td>
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</tbody>
</table>

**Satisfactory**

- **Labeling**
  - Date Due: Satisfactory M.O.R. of 9/6/71 and 2/15/72

**Satisfactory**

- Components, Composition, Manufacturing and Controls
  - Date Due: Adequate

- Biologic Availability
  - Date Due: N.A.
  - Is data on current formulation? YES [ ]
  - NO [x]

- Probably or Possibly Effective Indications
  - (if in labeling)
  - Date due: 

**Establishment Inspection**

- EL 3/17/71 Satisfactory

**Recalls**

- Is relabeling of drug in commercial channels required? [ ] YES [x] NO

**If so, that level:**

**Remarks**

1. Labeling satisfactory
2. Firm will follow USP content uniformity test procedure.

**Conclusions**

Approval letter to issue

R. E. Joyce

[Signature] 3/20/72
APPLICATION NUMBER:

80-600

ADMINISTRATIVE DOCUMENTS
NOTICE OF APPROVAL
NEW-DRUG APPLICATION OR SUPPLEMENT

TO: Press Relations Staff (CE-300)

FROM: 

ATTENTION
Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION
[ ] ORIGINAL NDA [ ] 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

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 1.0 mg.

NAME OF APPLICANT (Include City and State)
Westward Incorporated
745 Eagle Avenue
Bronx, New York 10456

APPEARS THIS WAY ON ORIGINAL

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
Ronald E. Joyce
DATE

FORM APPROVED BY
NAME
Jack L. Meyer
DATE

FD FORM 1642 (7/69) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.
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. Folvite Elixir; 5 mg. folic acid per 5 cc.;
2. Folvite Tablets; 5 mg. and 20 mg. folic acid per tablet; and
3. Foltiver (Parenteral Solution); sodium folate equivalent to 15 mg. folic acid per cc.; marketed by Lederle Laboratories, Pearl River, New York 10965 (NDA 5-897).

Folic Acid Tablets; 5 mg. per tablet; marketed by Eli Lilly and Co., Box 618, Indianapolis, Indiana 46206 (NDA 6-135).

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 6-339).

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, is indicated in readily available reference sources, as follows:

A Pharmaceutical Co., Division of Bergher Distributing Co.
American Pharmaceutical Co.
American Quinine Co.
Approved Pharmaceutical Corp.
Avecum Pharmaceutical Co.
Associated Labs., Inc.
Barre Drug Co., Inc., The.
Barry-Markin Pharmaceutical, Inc.
Bell Pharmaceutical Co.
Carroll Chemical Co., The.
Columbia Medical Co.
Consolidated Midland Corp., OMC Research Division.
Corvit Pharmaceuticals.
Daniels, Robert and Co., Inc.
DuMONT Pharmaceutical Co.
Evron Pharmaceutical Co., Inc.
Faraday Laboratories, Inc.
Gold Leaf Pharmaceutical 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.
McMillan Laboratories, Inc.
Penhurst Pharmaceutical Co.
Pharmex, Inc.
Puchon-Franklin Pharmaceutical Co.
Richlyn Labs.
Robinson Laboratory, Inc.
Spencer-Med, Inc.
Stanhope, Inc.
Supreme Pharmaceutical Co., Inc.
Thompson, Wm. T., Co.
Trec, Research Corp., Inc.
Winson Laboratories, Inc.

Folic Acid Description

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 for such drugs. A new-drug application is required from any person marketing such drugs without prior authority.

The Food and Drug Administration is prepared to approve new-drug applications and supplements to previously approved new-drug applications under conditions described later, if 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: "Microcytic anemia associated with pallidum and similar deficiency states" and such vague, unspecific conditions as "macrocytic anemia of gastrointestinal origin" and "megaloblastic anemia 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. Folic acid is 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 births.

Preparations supplying no more than 0.1 mg. folic acid daily continue to be regarded as dietary supplements (21 CFR 3.43) 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 provided under another appropriate paragraph headings and should follow the information set forth below.)

D. Previously approved applications.

1. Each holder of a "previously approved" new-drug application for 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 claim for a new indication 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

                \( \delta \)
NOTICES

6814

a. 60 days for revised labeling; or, for those products which must be reformu-
lated, 180 days for revised labeling fully in accord with this announcement, pro-
vided claims for which substantial evi-
dence continues to be made and labeling
changes 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
permits for which the supplement is first to be effective at the
easiest possible time.
b. 180 days for updated information.
c. 3 months for any new applications
submitted under section 505 of the Act (21
CFR Part 355), and for each new applica-
tion submitted under section 505(c)(2) of
the Act (21 CFR Part 352), the Comissioner
will give the holders of any such
applications, and any interested person
who would be adversely affected by such
new application, an opportunity for a hearing
to show why such indications should not be
deleted from labeling. A request for a
hearing must be made 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 allega-
tions or denials, but must set forth spe-
cific facts showing that a genuine and
materially different view of fact requires a hear-
ing, 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
such data submitted in response to this notice
must be previously unsubmitted and
include data from adequate and well-
controlled clinical investigations (iden-
tified for ready review) as described in
§130.4(a)(5) of the regulations pub-
lished in the Federal Register of May 8,
1970 (35 F.R. 7250). Carefully con-
ducted and documented clinical studies obtained
under uncontrolled or partially controlled designs are not a sole
basis for approval of claims of effective-
ness, but such studies may be considered
on their merits for corroborative support
of accuracy 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 no-
tice of the time and place at which the
hearing will commence.

4. Unapproved use or form of drug.
   a. If the article is labeled or advertised
      for use in any condition other than
      those provided for in this announce-
      ment, it may be regarded as an unapproved
      new drug subject to regulatory action
      until such recomended use is approved
      in a new-drug application, or is other-
      wise in accord with this announcement.
   b. If the article is proposed for market-
      ing in another form or for use other than
      the use provided for in this announce-
      ment, appropriate additional informa-
      tion as described in §130.4(a)(5) 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 for such
      use.

Representatives of the Administration
are willing to meet with any interested
person who desires to have a conference
concerning proposed changes in the
labeling for the product. 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 appro-
perate office named below.

Communications forwarded in re-
spose to this announcement should be
identified with the reference number
DESI 5397, directed at the attention of
the following appropriate office, and
addressed (unless otherwise specified) to
the Food and Drug Administration, 5600
Foshers 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-8),
Bureau of Drugs.

Request for Hearing (Identify with Docket
number): Hearing Clerk, Office of Gen-
eral Counsel (GC-1), Room 6-62, Parklawn.

All other communications regarding this
announcement:
Drug Efficacy Study
Implementation Project Office (BD-8), Bureau of
Drugs.

Requests for NABS-NRC reports. Press Rela-
tions Office (CE-200), 200 C Street, S.W.,
Washington, D.C. 20204.

This notice is issued pursuant to
provisions of the Federal Food, Drug,
and Cosmetic Act (secs. 502, 505, 52 Stat.
and the regulations promulgated there-
under (21 CFR Parts 130, 350, and 352).

Commissioner of Food and Drugs (21
CFR 2.120).


SAM D. FINE,
Associate Commissioner
for Compliance.

(FED 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 intra-
venous use:

Lorfan Injection, containing levallor-
phorphine tartrate; Roche Laboratories.
Division of Hoffman-LaRoche, Inc., 510
Kingsland Street, Nutley, New Jersey
07110 (NDA 10-422).

FEDERAL REGISTER, VOL. 36, NO. 69—FRIDAY, APRIL 9, 1971
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

80-600

CORRESPONDENCE
West-Ward, Inc.
Attention: Mr. Edward Green
745 Eagle Avenue
Bronx, New York 10456

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: August 25, 1971

DATE of RECEIPT: August 30, 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 FDA number shown above.

Sincerely yours,

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

ACK
ACK-90
DUP
BD-69
BD-67
BD-22
BD-310
JMeyer/wlb/9-2-71
Ack

JMeyer 9/2/71
West-Ward, Inc.
Attention: Mr. Edward Green
745 Eagle Avenue
Bronx, New York 10456

Gentlemen:

Reference is made to your abbreviated new drug application dated August 25, 1971, 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 new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. Revised Package Insert:
   a) DOSAGE and ADMINISTRATION section: Delete reference to

   b) ____________________________ Change heading to "HOW SUPPLIED": Reference is made to 0.1 mg. and 0.25 mg. tablets. Please clarify.

2. Please clarify the following deviations from the USP XVIII monographs.
   a) Folic Acid Powder
      1) Residue on Ignition Test is not performed.
      2) Assay is not performed according to procedure.
   b) Folic Acid Tablet
      1) The Content Uniformity test does not follow USP XVIII procedure.

Please submit the above information promptly.

Sincerely yours,

[Signature]

cc: NYK-DO

[Signature]
[Date]
Paul A. Bryan, M.D.
Director
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Dear Dr. Bryan:

This is in answer to your letter of October 4, 1971 with reference to our abbreviated new drug application for Folic Acid Tablets 1 mg.

The information requested follows the numbering sequence of your letter.

1. a and b Enclosed is a printer's proof of the package insert with the Dosage and Administrative section and the revised in accordance with your recommendations. If satisfactory we will send you 12 copies of the final printed copy.

2. a. Folic Acid Powder

   1) Please amend our application to include the Ignition Test.

   2) Please amend our application to follow the U.S.P. XVII assay procedure.

   b. Folic Acid Tablet

   1) The actual method for determining the Content Uniformity is herewith attached. This is a relatively simple method which we can apply since we make the tablets ourselves and have full knowledge of the excipients which do not introduce any error. We have verified the reliability of the method by checking the results against those obtained using the Official U.S.P. method. The results agree well within acceptable limits.

We trust you will find the change satisfactory.

Sincerely,
West-ward, Inc.

Edward Green
Technical Director

EG/eb encl.
Salmon

ANDA 80-600
AF 31-015

West-Ward, Inc.
Attention: Mr. Edward Green
745 Eagle Avenue
Bronx, New York 10456

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 communication dated October 27, 1971, containing requested information and proofs of revised labeling.

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.

Please submit twelve copies of the final printed labeling.

It is also requested that you submit a commitment to follow the USP XVIII content uniformity test or data to substantiate the claim that the alternate procedure is comparable to the USP XVIII procedure.

Please submit the above information promptly.

Sincerely yours,

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

cc:
NYK-D0
Dup.
BD-67
BD-69
BD-22
BD-100
BD-242
JHEilert/JIMeyer/REJoyce 12-2-71
Initialed by JIMeyer 12-3-71
rt 12-7-71
Approvable
ANDA 80-600  

January 18, 1972

Paul A. Bryan, M.D.  
Director  
Drug Efficacy Study Implementation  
Project Office  
Bureau of Drugs  
Food and Drug Administration  
Rockville, Maryland 20852

Dear Dr. Bryan:

This is in answer to your letter of December 17, 1971 with reference to our abbreviated new drug application for Folic Acid Tablets 1 mg.

As requested we are enclosing 12 final printed copies of the package insert, identical to the draft copy submitted with our letter of October 27, 1971.

Further as requested we herewith commit ourselves to follow the U.S.P. XVIII content uniformity test.

We trust you will find the above satisfactory.

Sincerely,

West-ward, Inc.

Edward Green  
Technical Director

EG/eb  
encl.