

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
ANDA 084264

Name: Cyanocobalamin, 1000 mcg

Sponsor: West-ward, Inc.

Approval Date: December 10, 1974

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 084264

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 084264

APPROVAL LETTER

NDA 34-264

AF 31-015

DEC 10 1974

West-ward, Inc.
Attention: Mr. Edward Green
745 Eagle Avenue
Bronx, NY 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 Cyanocobalamin Tablets, 1,000 mcg.

We acknowledge receipt of your communications (1) dated August 9, 1974, enclosing final printed container labels and (2) dated October 16, 1974, enclosing final 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 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.

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

Sincerely yours,

Marvin Seife 12/10/74
Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:

NYK-DO
HFD-107
HFD-8

HFD-106 *12-9-74*
HFD-127 *12/19/74*

JRCarr/JLMeyer/JMRoss/11-27-74

R/D init. by MSeife/JMeyer/11-27-74

Enclosures: *JMeyer* 12/19/74

Conditions of Approval of a New Drug Application

Records and Reports Requirement

Final typing/kim/12-4-74

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 084264

LABELING

JMK

CYANOCOBALAMIN (VITAMIN B12)

ORAL

DESCRIPTION: Cyanocobalamin appears as dark red crystals. It is very hygroscopic in the anhydrous form, and sparingly soluble in water (1:80). The vitamin B12 coenzymes are very unstable in light.

The chemical name is 5,6-dimethyl-benzimidazolyl-cyanocobalamin. The empirical formula is: $C_{63}H_{65}CoN_{14}O_{14}P$. The cobalt content is 4.34%.

ACTIONS: Vitamin B12 is essential to growth, cell reproduction, hematopoiesis, nucleoprotein and myelin synthesis.

INDICATIONS FOR USE: Pernicious anemia with mild or no neurologic signs in the rare patient having idiosyncrasy or sensitivity to parenteral administration or when parenteral therapy is refused.

As adjunctive treatment in megaloblastic anemia associated with sprue.

WARNINGS: Parenteral administration of Vitamin B12 is the preferred treatment for pernicious anemia particularly for the initial treatment. Some patients with pernicious anemia may not respond to oral vitamin B12.

Protect from light.

Vitamin B12 deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord, as observed when folic acid therapy is used as the only hematopoietic agent.

Lack of therapeutic response may be due to infection, uremia, chloramphenicol and misdiagnosis.

PRECAUTIONS: Persons taking most antibiotics, methotrexate and pyrimethamine invalidate folic acid and vitamin B12 diagnostic blood assays.

Colchicine, para-aminosalicylic acid and heavy alcohol intake longer than 2 weeks may produce malabsorption of vitamin B12. A dietary deficiency of only vitamin B12 is rare. Multiple vitamin deficiency is expected in any dietary deficiency.

ADVERSE REACTIONS: Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body.

DOSAGE AND ADMINISTRATION:

A. General Rules:

In patients with Addisonian Pernicious Anemia treatment will be required for the remainder of the patient's life. Reticulocyte plasma count, vitamin B12 and folic acid must be obtained prior to treatment and between the fifth and seventh day of therapy.

B. Treatment of Vitamin B12 Deficiency:

The usual or recommended dose is 1000 mcg. daily. Folic acid should be coadministered early in the treatment unless adequate.

HOW SUPPLIED: Compressed Tablets (Soluble) each containing 1000 mcg. Cyanocobalamin U.S.P. in bottles of 100

CAUTION: Federal law prohibits dispensing without a prescription.

West-ward, Inc.

JUNE 1974

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 084264

LABELING REVIEWS

REVIEW OF RESUBMISSION

DATE COMPLETED: 9-18-74

ANDA #: 84-264

CO. NAME: West-Ward, Inc.
745 Eagle Ave.
Bronx, NY 10456

NAME OF DRUG: Cyanocobalamin Tablets, 1000 ~~mg~~ *mcg*.

DATE OF SUBMISSION: 8-9-74

TYPE OF SUBMISSION: Resubmission;

CLINICAL EVALUATION:

1. Review of Studies: None submitted

2. Review of Labeling:

Container label for containers of 100 tablet only - Satisfactory

CONCLUSION: The container labels in this submission are acceptable.

RECOMMENDATION: The company is to be so notified.

J.R. Carr

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

cc:
Dup
HFD-107
JRCarr, D.D.S./kim/9-18-74

REVIEW OF RESUBMISSION

DATE COMPLETED: 8-12-74

ANDA #: 84-264

CO. NAME: West-ward, Inc.
745 Eagle Ave.
Bronx, NY 10456

NAME OF DRUG: Cyanocobalamin Tablets, 1000 mcg.

DATE OF SUBMISSION: 6-17-74

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION:

1. Review of Studies: None submitted


2. Review of Labeling:

a. Container labels: None submitted

b. Package insert: (draft copy) Conform to labeling guidelines and is satisfactory. (The sentence under Dosage and Administration that the company refers to makes as much sense as most of the vitamin labeling).

CONCLUSION: The draft copy of the package insert is acceptable. Have the firm send in FPL identical in content to the draft copy.

RECOMMENDATION: The company is to be so notified.



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

cc:
Dup
HFD-107
JRCarr, D.D.S./kim/8-12-74

REVIEW OF ANDA

DATE COMPLETED: 4-25-74

ANDA #: 84-264

F.R. DATE: 2-15-73

CO. NAME: West-ward, Inc.
745 Eagle Ave
Bronx, NY 10456

NAME OF DRUG: Cyanocobalamin Tablets, 1000 mcg.

DATE OF SUBMISSION: 4-11-74

TYPE OF SUBMISSION: ANDA


CLINICAL EVALUATION:

1. Review of Studies: None submitted
2. Review of Labeling:
 - a) Container labels: Draft copy for containers of 100 tablets - Satisfactory
 - b) Package insert: Needs to be revised in accord with labeling guidelines.

CONCLUSION:

1. The draft copy of the container label is satisfactory.
2. The draft copy of the package insert needs revision as noted above.

RECOMMENDATIONS: The company is to be so notified and sent a copy of the labeling guidelines.



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

cc:
Dup
HFD-107
JRCarr/wlb/4-29-74

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 084264

CHEMISTRY REVIEWS

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date

2-15-73

AF Number

84-264
31-015

Name and Address of Applicant (City and State)

West-ward, Inc.
745 Eagle Avenue
Bronx, NY 10456

Original

Amendment

Supplement

Resubmission

Correspondance

Report

Other

Purpose of Amendment/Supplement

submission of final printed labels

Date(s) of Submission(s)

7-9-74

10-16-74

Pharmacological Category

Vitamin

Name Of Drug

Cyanocobalamin

Dosage Form(s)

tablet

Potency

1000 mcg.

How Dispensed

Rx

☒

OTC

☐

Environmental Impact Analysis
Report

submitted

Samples

Related IND/NDA/MF(s)

Labeling

Container label: Satisfactory(JRCarr)

Package insert:

Biologic Availability

deferred according to Dr. M. Seife

Establishment Inspection

West-ward, Inc.

in compliance 7-31-73

(b) (4)

in compliance 5-1-74

Components, Composition, Manufacturing and Controls

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

Remarks

Conclusion

Approved :

Reviewer:

J.M. Ross

J.M. Ross
12-9-74

Date:

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register

Statement Date

2-15-73

NDA Number

84-264

AF Number

31-015

Name and Address of Applicant (City and State)

West-ward, Inc.
745 Eagle Avenue
Bronx, NY 10456

Original

Amendment

Supplement

Resubmission

Correspondance

Report

Other

Purpose of Amendment/Supplement

revise package insert submitted

Date(s) of Submission(s)

6-17-74

Pharmacological Category

Vitamin

Name Of Drug

Cyanocobalamin

Dosage Form(s)

tablet

Potency

1000 mcg

How Dispensed

Rx

☒

OTC

☐

Environmental Impact Analysis
Report

-submitted

Samples

Related IND/NDA/MF(s)

Labeling

Container label: Satisfactory (Chem. Rev. of 6-1-74- JRCarr)
Package insert : Satisfactory (JRCarr)

Biologic Availability

Deferred (M Seife)

Establishment Inspection

West-ward, Inc. in compliance 7-31-73

(b)(4) in compliance 5-1-74

Components, Composition, Manufacturing and Controls

active ingredient, excipients, & finished dosage form are tested according to US specs

Remarks

Requested: FPL of container label & package insert

Conclusion

Approvable

Reviewer:

J.M. Ross

J.M. Ross 8-29-74

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register
Statement Date
2-15-73

NDA Number 31-015
AF Number

Original _____
Amendment _____
Supplement _____
Resubmission _____
Correspondance _____
Report _____
Other _____

Date(s) of Submission(s)

Name and Address of Applicant (City and State)

West-Ward, Inc.
745 Egel Avenue
Bronx, NY 10456

Purpose of Amendment/Supplement

New Application

Pharmacological Category

Vitamin

Name Of Drug

Cyanocobalamin

Dosage Form(s)

tablet

Potency

1000 mcg

How Dispensed

Rx ☒

OTC ☐

Environmental Impact Analysis
Report

submitted

Samples

Related IND/NDA/MF(s)

Labeling

Container label: Satisfactory(JRCarr)

Package insert: Revise according to m.o. report (JRCarr)

Biologic Availability

Deferred

Establishment Inspection

WestWard, Inc. - in compliance 7-31-73

(b) (4)

- in compliance
5-1-74

Components, Composition, Manufacturing and Controls

Satisfactory according to USP specifications

Remarks

Requested:

1. FPL of container labels
2. Package insert: revise according to labeling guidelines

Conclusion rev w/f

Reviewer: J.M. Ross

J. M. Ross 6-10-74

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 084264

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT		NDA NUMBER 84-264
		DATE APPROVAL LETTER ISSUED DEC 10 1974
TO: Press Relations Staff (CE-309)	FROM: <input checked="" type="checkbox"/> Bureau of XXXXXX Drugs <input type="checkbox"/> Bureau of Veterinary Medicine	
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 <input type="checkbox"/> ORIGINAL NDA <input checked="" type="checkbox"/> ABBREVIATED <input type="checkbox"/> SUPPLEMENT <input checked="" type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> TO NDA		CATEGORY <input checked="" type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY
TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG Cyanocobalamin		
DOSAGE FORM tablet	HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	
ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.) Cyanocobalamin 1000 mcg		
NAME OF APPLICANT (Include City and State) West-ward, Inc. 745 Eagle Avenue Bronx, NY 10456		
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	

NDA 84-284

AF 31-015

SEP 03 1974

West-ward, Inc.
Attention: Mr. Edward Green
745 Eagle Avenue
Bronx, NY 10456

Gentlemen:

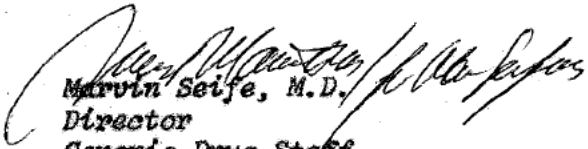
Reference is made to your abbreviated new drug application, dated April 11, 1974, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act, for Cyanocobalamin Tablets, 1000 mcg.

We acknowledge receipt of your communication, dated June 17, 1974, enclosing a revised draft package insert.

We have completed the review of this abbreviated 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 printed labeling.

Sincerely yours,


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

cc:

NYK-DO


Dup

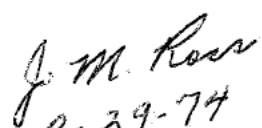
HFD-107

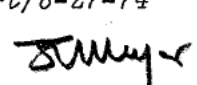
HFD-106

HFD-13

HFD-8

 JRCarr/JLMeyer/JMRoss/8-27-74
R/D init. JMeyer/8-27-74
Final typing/rt/8-27-74
Approvable


8-29-74

 8/29/74

NDA 84-264

AF 31-015

JUN 12 1974

West-ward, Inc.
Attention: Mr. Edward Green
745 Eagle Avenue
Bronx, NY 10456

Gentlemen:

Reference is made to your abbreviated new drug application dated April 11, 1974, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cyanocobalamin Tablets, 1000 mcg.

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:

1. Container labels: Please submit twelve copies of printed labels. The labels should be identical in content to the draft copy.
2. Package Insert: Revise in accordance with enclosed labeling guidelines.

Please submit the above information promptly.

Sincerely yours,

Marvin Seife 6/12/74
Marvin Seife, M.D.

Director

Generic Drug Staff

Office of Scientific Evaluation

Bureau of Drugs

Enclosure: labeling guidelines

cc:

NYK-DO

Dup

HFD-107 HFD-106 HFD-13 HFD-8

JRCarr/JLMeyer/JMRoss/6-4-74

R/D init. MSeife/JMeyer/6-6-74

Final typing/rt/6-7-74

rev w/f

JMeyer 6/11/74

JM Ross
6-10-74

JRCarr
6/10/74

NDA 84-264

AF 31-015

APR 24 1974

Nest-Ward, Incorporated
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: Cyanocobalamin Tablets, 1000 mcg.

DATE OF APPLICATION: April 11, 1974

DATE OF RECEIPT: April 12, 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(a) 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 130.5(a)(8) or 130.12(a)(7)).

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

cc: NYK-DO
HFD-107 HFD-8
HFD-310
JLMeyer/4/17/74/ep/4/19/74
R/D init. by: MSeife/4/18/74

ACK

JLMeyer 4/23/74

Sincerely yours,

Marvin Seife 4/24/74
Marvin Seife, M.D.

Director

Generic Drug Staff

Office of Scientific Evaluation

Bureau of Drugs