# **Approval Package for:**

## APPLICATION NUMBER: ANDA 084264

Name: Cyanocobalamin, 1000 mcg

Sponsor: West-ward, Inc.

Approval Date: December 10, 1974

## APPLICATION NUMBER: ANDA 084264

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APPLICATION NUMBER: ANDA 084264

# **APPROVAL LETTER**

NDA 34-264

AF 31-015

DEC 1 0 1974

West-ward, Inc. Attention: Mr. Edward Green 745 Eagle Avenue Bronz, 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.

20rel/ VOUT'S.

cc: NYK-DO HFD-107 M. Russ 12-9-74 HFD-8 HFD-106/ JRCarf/JLMeyer/JMRoss/11-27-74

R/D init. by MSeife/JMeyer/11-27-14/99 Enclosures: Whener 1999 Conditions of Approval of a New Drug Records and Reports Requirement Director Division of Generic Drug Monographs Office of Drug Monographs Bureau of Drugs

Application Final typing/kim/12-4-74

APPLICATION NUMBER: ANDA 084264

# **LABELING**

### CYANOCOBALAMIN (VITAMIN BÍ2) ORAL

<u>DESCRIPTION</u>: 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: C63HoSCON14014P. The cobalt content is 4.34%.

ACTIONS: VitaminaBre is essential to group, cell reproduction, hemato-poiesis, nucleorappeners and invelim synth**DEC.** 10 1974. INDICATIONS FOR USE: Pernicious anemia with mild of menomeners 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.

<u>WARNINGS</u>: Parenteral administration of Vitamin  $B_{12}$  is the preferred treat-ment for pernicious anemia particularly for the initial treatment. Some patients with pernicious anemia may not respond to oral vitamin  $B_{12}$ .

Protect from light.

Vitamin  $B_{12}$  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  $B_{12}$  diagnostic blood assays.

Colchicine, para-aminosalicylic acid and heavy alcohol intake longer than 2 weeks may produce malabsorption of vitamin  $B_{12}$ . A dietary deficiency of only vitamin  $B_{12}$  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

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

NMME OF DRUG: Cyanocobalamin Tablets, 1000 mg mg

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, 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 dwaft 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.

R Can 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 dfaft 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.

D.D.S.

cc: Dup HFD-107 JRCarr/w1b/4-29-74

APPLICATION NUMBER: ANDA 084264

# **CHEMISTRY REVIEWS**

· · · ·	CHEMIST'S REVIEW FOR State	ment Date	84-264
	ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT		F Number 31-015
	OK SOFFELMENT	2-15-73	Uriginal
	Name and Address of Applicant (City and	State)	Amendment
		West-ward, Inc.	Supplement
		745 Eagle Avenue	Resubmission
	•	Bronx ,NY 10456	Correspondance
	•		Report
			Other ·
-	Purpose of Amendment/Supplement		<pre>Date(s) of Submission(s)</pre>
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	submission $p$ of final printed la	Dels	7-9-74 10-16-74
			10-10-74
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	Vitamin	Cyanocobalamin	• • •
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	tablet 1	000 mcg.	
			OTC
	Environmental Impact Analysis Sa	umples (	Related IND/NDA/MF(s)
	Report		
	submitted		
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	active ingredient, excipients, f	inished dosage form are t	
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	Conclusion		
	Approved :	P	
	Reviewer: J.M.Ross	Par 12-9-74 Date	
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	CHEMIST'S REVIEW FO ABBREVIATED NEW DRUG APPLICATIO	Federal Register	NDA Number 84-264
	OR SUPPLEMENT	2-15-73	AF Number 31-015
· · · · · ·	Name and Address of Applicant	(City and State)	Amendment <u>x</u>
		West-ward, Inc. 745 Eagle Avenue Bronx, NY 10456	Supplement Resubmission Correspondance Report Other
-chet	Purpose of Amendment/Supplemen	t	Date(s) of Submission(s
	revise package insert sµ	bmitted	6-17-74
	Pharmacological Category	Name Of Drug	
	Vitamin	Cyanocobalamin	
	Dosage Form(s)	Potency	How Dispensed
	tablet	1000 mcg	orc
	Environmental Impact Analysis Report -submitted	Samples	Related IND/NDA/MF(s)
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	Components, Composition, Manufac	cturing and Controls	<u></u>
	active ingredient, exci	pients, & finished dosage form are	specs tested according toUSB
	Remarks -		A
	Requested: FPL o	of container label & package inert	
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	Reviewer: J.M.R	1. 1. Tara 8-29-7	*

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CHEMIST'S REVIEW FOR Statement Date 31-015 ABBREVIATED STUD RULE FOR Statement Date 2-15-73 AF Number 31-015 OR SUPPLEMENT 2-15-73 AF Number 31-015 AF Nu	Federal Register	NDA NUMBER OT-LOT
The and Address of Applicant (City and State)       Amendment         Y45 Eagel Avenue Bronx, NY 10456       Amendment         Purpose of Amendment/Supplement New Application       Correspondence Report Other         Pharmacological Category Vitamin       Name Of Drug Cyanocobalamin       How Dispensed Rx         Pharmacological Category Vitamin       Name Of Drug Cyanocobalamin       How Dispensed Rx         Dosage Form(s) tablet       Potency No       Rx       Lale         tablet       1000 mcg       Orc       Orc         tablet       0000 mcg       Orc       Implement (Rx       Implement Rx         Labeling       Container label: Satisfactory(JRCarr) Package insert: Revise according to m.o. report (JRCarr)       - in compliance S-1-74         Diologic Availability       Deferred       -         Establishment Inspection       VistsWard, Inc. : in compliance S-1-74       - in compliance S-1-74         Components, Composition, Manufacturing and Controls Satisfactory according to USP specifications       - in compliance S-1-74         Remarks       Requested:       1. FPL of container labels 2. Package insert: revise according to labeling guidelines         Conclusion       rev w/f       A word       - 74	CHEMIST'S REVIEW FOR Statement Date ABGREVIATED NEW DRUG APPLICATION 2-15-72	AF Number
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Purpose of Amendment/Supplement New Application       Date(s) of Submission:         Pharmacological Category Vitamin       Name Of Drug Cyahopobalamin       How Dispensed Ry         Dosage Form(s)       Potency       Ry       L         tablet       1000 mcg       orc       IT         Environmental Impact Analysis       Samples       Related IND/NDA/MF(s)         Report       submitted       Deferred         Labeling       Container label:       Satisfactory(JRCarr) Package insert:       Revise according to m.o. report (JRCarr)         Biologic Availability       Deferred       - in compliance 5-1-74         Components, Composition, Manufacturing and Controls Satisfactory according to USP specifications       - in compliance 5-1-74         Remarks       Requested:       1. FPL of container labels 2. Package insert: revise according to Tabeling guidelines         Conclusion       Pev w/f       A m A		Other
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APPLICATION NUMBER: ANDA 084264

# ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

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		NDA NUMBER 84-264
	CE OF APPROVAL	DATE APPROVAL LETTER ISSUED
NEW DRUG AP	PLICATION OR SUPPLEMENT	DEC 1 0 1974
το:	FROM:	X Bureau of XXXXXX Drugs
Press Relations	Staff (CE-300)	
		Bureau of Veterinary Medicine
	ATTENTION his form for publication or yafter approval	letter has been issued and the date of
approval has been on TYPE OF APPLICATION		CATEGORY
TTPEOF APPEICATION	BBREVILLED	
TRADE NAME (or other designated	Rame ANT STABLISHED OR NONPROPRIET	ARY NAME (if any) OF DRUG
	Cyanocobalamin	
DOSAGE FORM	4-17-4	HOW DISPENSED
	tablet	
ACTIVE INGREDIENT(S) (as decla declared on label.)	red on label. List by established of nonpropriet	ary name(s) and include amount(s), if amount is
	Cyanocobalamin 10	00 mca
	oj ano ob a ramini re	<b>J</b>
NAME OF APPLICANT (Include Ci	West-	ward,Inc.
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PRINCIPAL INDICATION OR PHAN	West- 745 E Bronx <u>Vitamin</u> <u>COMPLETE FOR VETERINARY</u> COMPLETE FOR SUPPLEMENT	agle Avenue , NY 10456 ONLY
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PRINCIPAL INDICATION OR PHAN	West- 745 E Bronx <u>Vitamin</u> <u>COMPLETE FOR VETERINARY</u> COMPLETE FOR SUPPLEMENT	agle Avenue , NY 10456 ONLY
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PRINCIPAL INDICATION OR PHAN	West- 745 E Bronx <u>Vitamin</u> <u>COMPLETE FOR VETERINARY</u> COMPLETE FOR SUPPLEMENT	agle Avenue , NY 10456 ONLY
PRINCIPAL INDICATION OR PHAN ANIMAL SPECIES FOR WHICH APP CHANGE APPROVED TO PROVIDE	West- 745 E Bronx <u>Vitamin</u> <u>COMPLETE FOR VETERINARY</u> COMPLETE FOR SUPPLEMENT FOR	agle Avenue , NY 10456 ONLY ONLY
PRINCIPAL INDICATION OR PHAN	West- 745 E Bronx <u>Vitamin</u> <u>COMPLETE FOR VETERINARY</u> COMPLETE FOR SUPPLEMENT FOR	agle Avenue , NY 10456 ONLY ONLY
PRINCIPAL INDICATION OR PHAN ANIMAL SPECIES FOR WHICH APP CHANGE APPROVED TO PROVIDE	West- 745 E Bronx Vitamin COMPLETE FOR VETERINARY PROVED COMPLETE FOR SUPPLEMENT FOR FORM PREPARED BY	agle Avenue , NY 10456 ONLY ONLY

NDA

AF 31-015

SEP 0 3 1974

West-ward, Inc. Attention: Mr. Edward Green ?45 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 Tablete, 1000 meg.

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,

p./ la papas Mervin Seife, M.D./ Director

Generic Drug Staff Office of Scientific Evaluation Bureau of Drugs

Dup HFD-107 HFD-106 HFD-13 HFD-8 VICan JRCarr/JLMeyer/JMRoss/8-27-74 KM/Y R/D init. JMeyer/8-27-74 Final typing/rt/8-27-74 Approvable

ec: NYK-DO

J. M. Kors 8-29-74

NDA 84-264

AF 31-015

JUN 1 2 1974

West-ward, Inc. Attention: Mr. Edward Green 745 Eagle Avenue Broux, 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.

Sancerely yours, 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

W for in

NDA 84-264

AF 31-015

APR 2 4 1974

West-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(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 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

5Meyer 7/23/74 ACK

incerely yours, Marvin Selfe, M.D.

Birector Generic Drug Staff Office of Scientific Evaluation Bureau of Drugs