SUMMARY OF FINDINGS

On March 21, 1974, an inspection of Westpro Labs, Inc. at 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, California 92640, revealed that:

I. Mr. Kurt W. Donsbach was a responsible officer of Westpro Labs, Inc. until December 28, 1973.

II. Prior to December 28, 1973, Mr. Kurt W. Donsbach, an officer of Westpro Labs, Inc., was personally involved in the manufacturing, packaging, repackaging, labeling, and sale of drugs, as defined in Sections 26010 and 26019, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, listed as follows:

added to Westpro file HS 6/24/74

1. Prescription drug labeled as "Magnesium, Potassium & Vitamin B-6", lot number 731106.
2. Drug labeled as "PAN ENZ 500", or "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", lot number 2702.
3. Drug labeled as "Pro-Go Super Derma-E Balm", lot number 50262.
4. Drug labeled as "PAN ENZ 500", or "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", lot number 730534.
5. Drug labeled as "Dr. Donsbach's Formula ENZ", "Master Formula Metazyme", or "Vitafare Digest", lot number 731112.
6. Drug labeled as "Dr. Donsbach's Formula ENZ", "ENZAID", or "Vital Life Digestive Enzymes", lot number 730934.
7. Prescription drug labeled as "Megavitamin A-C Plus E", or "Vitamins A C and E", lot number 2989.
8. Drug labeled as "Soft-Lax", lot number 87165.
9. Drug labeled as "Dr. Donsbach's Formula ENZ", "Vitafare Digest", or "Pak-A-Day", lot number 730807.
10. Drug labeled as "Dr. Donsbach's Formula ENZ", or "ENZAID", lot number 731111.
11. Drug labeled as "REN-EZ", or "Formula K", lot number 47210.
12. Drug labeled as "ENZ", "Gastro-Aid", or "ENZAID", lot number 730933.
13. Drug labeled as "ENZ", "ENZAID", "Dr. Donsbach's Formula ENZ", or "Digest", lot number 730521.
14. Drug labeled as "Pro-Go Super Derma-E Balm", lot number 50207.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9278

I. S. NO. A67729

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : Pan Enz 500, 100 tablets, lot #2702, Distributed by Metabolic Products

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Ave, Garden Grove, California 92640

Inspector: K. Suh

Contents:	102 tablets
Protease Activity:	equivalent to 324 mg per tablet of N. F. Pancreatin
Amylase:	equivalent to 297 mg N.F. pancreatin per tablet

Approved
6/21/74

Paul T. Clark

PTC:dlj
5/28/74

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67730

Obtained on March 21, , 1974, at 1630 a.m. p.m.

Sold as ~~xxxx~~ drug
xxx

Label (copied in part) Two Per, 60 tablets, Lot #730618, Star Brand 10428 Stanford Ave., Garden Grove, California 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave. City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See ~~xxx~~ attached (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 60 tabs/btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9279 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 60 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. [signature] L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9279

I.S. No. A 67730

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 **Number of Samples Received:** 1

Sold as : Drug

Label : Two Per, 60 tablets, lot #730618, Star Brand

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue Garden Grove, California 92640

Inspector: K. Suh

Held 6/21/74

Contents:	60 tablets
Vitamin C:	110 mg per 2 tablets
Iodine (as KI):	0.3 mg per 2 tablets 220 to 330 mcg
Iron:	5.2 mg per 2 tablets

Paul T. Clark
Mary W Claridge

MWC:PTC:dlj
6/20/74

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67731

Obtained on March 21, 1974 at 1630 p.m.
March 26, 1974 1630

Sold as Drug

Label (copied in part) Pro-Go Super Derma - E Balm, 2 oz., Lot # A 50262, Distributed by Pro-Go Products, Inc., Garden Grove, CA 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave. City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above. City

Inventory on Hand 6 jars, 2 oz./jar Amount Sampled 1 jar, 2 oz./jar on 3/21/74
2 jars, 2 oz./jar on 3/26/74

Quarantine Established 6 jars, 2 oz./jar, Lot # A 50262 (Amount, size of container and codes)

Reason for Quarantine Adulterated and misbranded

Where Stored Westpro Labs, Inc., 12791 Main St., Garden Grove, CA 92640

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION JUN 6 1974

Laboratory No. LA9280 Chief's Citation No.

Amount of Sample Submitted 3 jars, 2 oz./jar Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance samples. Check for the concentration of Vitamin E as declared on the label. Check for the total bacterial plate count also.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological x Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Hurk (Inspector) L.A. (District)

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9280

I. S. NO. A 67731

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 3

Sold As : Drug

Label : Pro-Go Super Derma - E Balm, 2 oz., Lot #A50262, dist. by Pro-Go Prod., Inc.

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Ave., Garden Grove, California 92640

Inspector: K. Suh

Contents: 2.2 ounces

Total Plate Count: none found at a 10^{-1} dilution
(48 hours at 35°C)

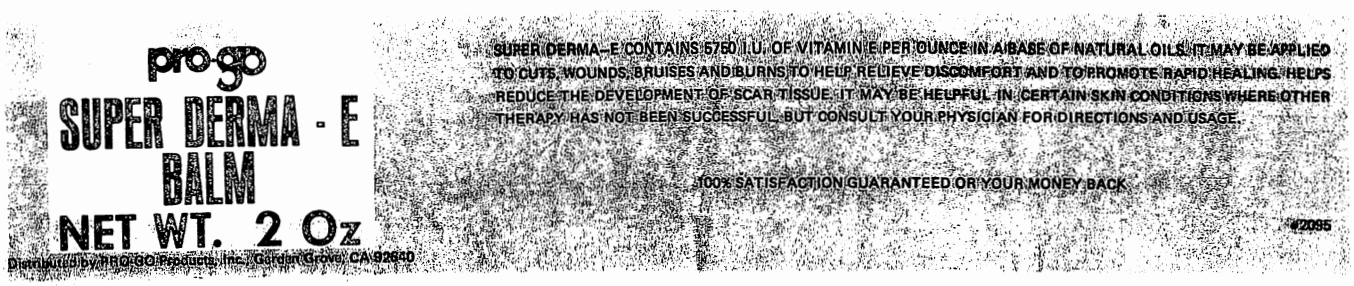
Vitamine E: 6850 IU/ounce
(dl alpha-tocopheryl acetate)

Hold
HW
6/21/74

50/0 over potency

Mary W Claridge

MCW:dlj
5/29/74



A 10332

STATE OF CALIFORNIA--DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67732

Obtained on March 21, 19 74, at 1630 p.m.

Sold as OTC Drug

Label (copied in part) Pan Enz 500 250 tablets, Lot # 730534, Distributed by Metabolic Products, Division of Westpro Labs, Inc., Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own
Name (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 250 tabs./btl.

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ----

Where Stored ----

Dan 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

JUN 6 1974

Laboratory No. LA9281 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 250 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample.. Check for the concentration of Pancreatin as declared on the label.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K Lark L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9281

I. S. NO. A 67732

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : Pan Enz 500 250 tablets, lot #730534, Distributed by Metabolic Products

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue, Garden Grove, California 92640

Inspector: K. Suh

Held
R
6/28/74

Contents:	250 capsules
Protease:	equivalent to 360 mg/capsule of pancreatin N. F.
Amylase:	equivalent to 343 mg of Pancreatin N. F. per capsule

Paul T. Clark

PTC:dlj
5/28/74

STATE CALIFORNIA—DEPARTMENT OF HEALTH

BUREAU OF FOOD AND DRUG

I. S. No. A 67733

Obtained on March 21, 1974, at 1630 p.m.

Sold as OTC drug

Label (copied in part) Dr Donsbach's Enz A digestive Aid, 250 tablets, Lot #731112, Westpro Labs, Inc. -- Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave. City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 250 tabs./btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ----

JUN 6 1974

(1) acct 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9282 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 250 tabs/btl. Release and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Suk L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9282

I. S. NO. A67733

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : Dr Donsbach's Enz A digestive Aid, 250 tablets, lot #731112

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue, Garden Grove, California 92640

Inspector: K. Suh

Held 6/21/74 HR

Contents:	253 tablets
Protease:	equivalent to 122 mg of Pancreatin (4 x NF) per tablet
Amylease:	equivalent to 91 mg of Pancreatin (4 x NF) per tablet

Paul D. Clark

PTC:dlj
5/28/74

STATE CALIFORNIA—DEPARTMENT OF PUBL EALTH

BUREAU OF FOOD AND DRUG

I. S. No. A 67734

Obtained on March 21, 19 74, at 1630 p.m.

Sold as OTC drug

Label (copied in part) Enzaid, A digestive Aid, 250 tablets, Lot # 730934, Distributed by Metabolic Products Division of Westpro Labs, Inc., Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above. City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 250 tabs/btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

Dan 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9283 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 250 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by T. Luh L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9283

I. S. NO. A 67734

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : Enzaid, A digestive Aid, 250 tablets, lot #730934, Distributed by Metabolic Products Division of Westpro Labs, Inc.

Dealer : Westpro Labs. Inc., 12791 Main Street, and 10422-10428 Stanford Ave., Garden Grove, California 92640

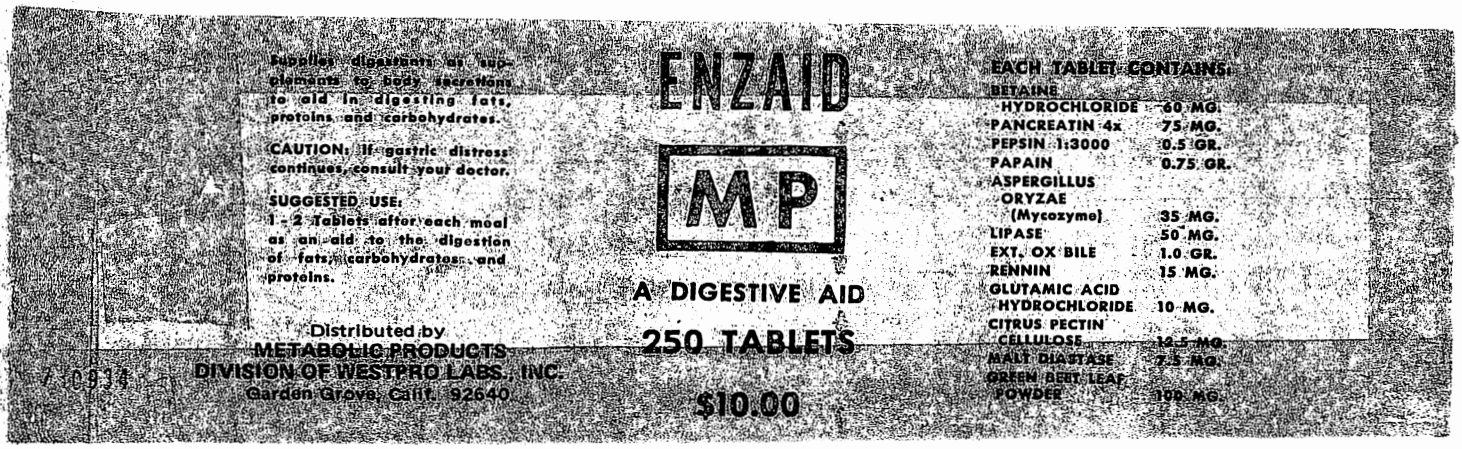
Inspector: K. Suh

Hold for 6/21/74

Contents:	251 tablets
Protease:	equivalent to 123 mg of Pancreatin (N. F. 4 x) per tablet
Amylase:	equivalent to 80 mg of Pancreatin (N. F. 4 x) per tablet
Lipase:	equivalent to 63 mg of Pancreatin N. F. per tablet

Paul T. Clark

PTC:dlj
5/28/74



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67735

Obtained on March 21, 19 74, at 1630 ~~a.m.~~ p.m.

Sold as ~~XXXX~~ drug

Label (copied in part) Megavitamin A-C plu s E, 100 tablets, Lot #2989, Star Brand, 10428 Stanford Ave., Garden Grove, Ca. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave. City Garden Grove, CA 92640 ~~92X~~

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above. City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 tabs./btl.

Quarantine Established none. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

NOTIFIED JUN 12 1974

(1) Dan 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9284 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. ~~Check~~ Check for the concentration of declared ingredients.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Lech L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9284

I.S. No. A 67735

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold as : Drug

Label : Megavitamin A-C plus E, 100 tablets, lot #2989, Star Brand

Dealer : Westpro Labs, Inc., 12791 Main Street and 10422-10428 Stanford Avenue Garden Grove, California 92640

Inspector: K. Suh

Hold 6/21/74

Contents:	100 tablets
Vitamin A:	13,000 USP units per tablet
Vitamin C:	200 mg per tablet
Vitamin E (dl alpha-tocopherol acetate):	50 IU per tablet

Mary W Claridge

MWC:dlj
6/11/74

EACH TABLET PROVIDES:		AMDR
Vitamin A	15,000 USP Units	375%
Vitamin C	200 mg.	666%
Vitamin E (d-Alpha Tocopherol) in a base of Rose Hips	50 I.U.	*

AMDR% Adult Minimum Daily Requirement.

*Minimum daily requirement not established.

MEGAVITAMIN

A-C Plus E

100 TABLETS $6.00

STAR BRAND
10428 Stanford Avenue
Garden Grove, Ca. 92640

SUGGESTED USE

One or more tablets daily.

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH

BUREAU OF FOOD AND DRUG

I. S. No. A 67736

Obtained on March 21, 19 74, at 1630 a.m. p.m.

Sold as OTC drug

Label (copied in part) Dr Donsbach's Formula Enz, A Digestive Aid, 100 tablets, Lot # 730807, Westpro Labs, Inc. -- Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 tablets/btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA 9285 Chief's Citation No. JUN 6 1974

Amount of Sample Submitted 1 bottle, 100 tabs. Retain and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Suh L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9285

I. S. NO. A67736

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : Dr Donsbach's Formula Enz, A Digestive Aid, 100 tablets, Lot #730807

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue., Garden Grove, California 92640

Inspector: K. Suh

Contents: 99 tablets

Protease: equivalent to 131 mg of Pancreatin (NF 4x) per tablet

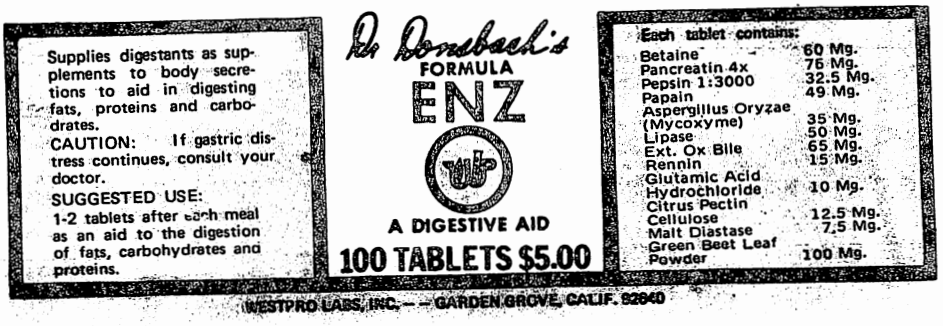
Amylase: equivalent to 66 mg of Pancreatin (NF 4x) per tablet

Lipase: equivalent to 84 mg of Pancreatin NF per tablet

Held 6/21/74

Paul T. Clark

PTC:dlj
5/28/74



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67737

Obtained on March 21, 19 74, at 1630 a.m. p.m.

Sold as OTC drug

Label (copied in part) Dr Donsbach's Formula Enz, A Digestive Aid, 100 tablets, Lot # 731111, Westpro Labs, Inc., Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address ~~xx~~ Ditto above. City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 tablets/btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

JUN 6 1974

Dan 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9286 Chief's Citation No.

Amount of Sample Submitted ~~xx~~ 1 btl., 100 tabs. Retain and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by X [signature] L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9286

I. S. NO. A67737

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : Dr Donsbach's Formula Enz, A Digenstive Aid, 100 tablets, lot #731111

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue, Garden Grove, California 92640

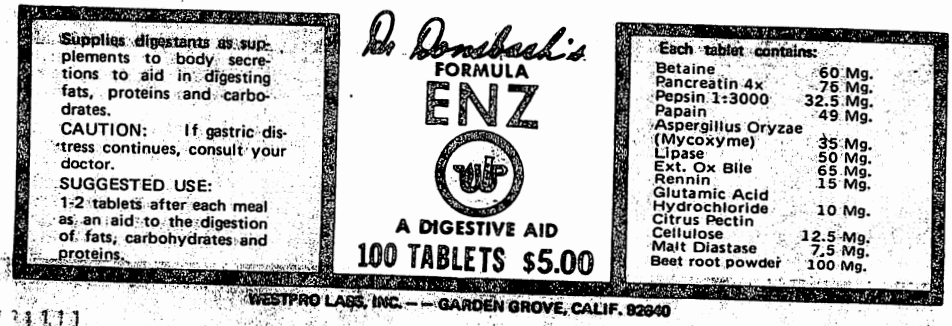
Inspector: K. Suh

Held
6/21/74

Contents:	101 tablets
Protease:	equivalent to 125 mg of Pancreatin (N. F. 4 x) per tablet
Amylase:	equivalent to 69 mg of Pancreatin (N. F. 4 x) per tablet
Lipase:	present

Paul T. Clark

PTC:dlj
5/28/74



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67738

Obtained on March 21, 19 74, at 1630 ~~a.m.~~ p.m.

Sold as OTC drug

Label (copied in part) Formula K, 90 tablets, Lot #47210, Distributed by Westpro Labs, Inc Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid none. Payment Refused r.g.

Guarantor Own /See attched.
Name (Make three copies of Invoice and attach)

Address Ditto above. City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 90 tabs./btl.

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ----

(1) Att 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9287 Chief's Citation No.

Amount of Sample Submitted 1 btl., 90 tabs./btl Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Lusk L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9287

I.S. No. A 67738

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold as : OTC Drug

Label : Formula K, 90 tablets, lot #47210, Distributed by Westpro Labs

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue, Garden Grove, California 92640

Inspector: K. Suh

Held
6/21/74

Contents:	90 tablets
Urea:	200 mg/tablet

Water soluble chlorophyllins are present.

WRS:dlj
6/17/74

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67739

Obtained on March 21, 19 74, at 1630 a.m. p.m.

Sold as drug

Label (copied in part) Two per, 60 tablets, Lot # 730414, Star Brand, 10428 Stanford Ave., Garden Grove, California 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address ditto above City

Inventory on Hand Undetermined. Amount Sampled 1 bottle, 60 tabs/btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

(1) Rec'd 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

JUN 21 1974

Laboratory No. LA9288 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 60 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

F, C, I

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Kuh L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9288

I.S. No. A 67739

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 **Number of Samples Received:** 1

Sold as : Drug

Label : Two per, 60 tablets, lot #730414, Star Brand

Dealer : Westpro Labs, Inc., 12791 Main st., and 10422-10428 Stanford Ave, Garden Grove, Cal

Inspector: K. Suh

Contents: 60 tablets 60 to 4 packages

Vitamin C: 110 mg per 2 tablets

Iodine (as KI): 0.2 mg per 2 tablets 100 to one

Iron: 6.8 mg per 2 tablets

Held in 6/21/74

Paul T. Clark.
Mary Willardge

MWC:PTC:dlj
6/20/74

DIRECTIONS:
As a dietary supplement two tablets daily.
EACH TWO TABLETS CONTAINS:

Vitamin		M.D.R.
A (Water Sol.)	25000 USP Units	625%
D (Irr. Ergost.)	400 USP Units	100%
BALANCED B COMPLEX FACTORS:		
B-1 (Thiamine HCL)	25 mg.	2500%
B-2 (Riboflavin)	25 mg.	2083%
B-6 (Pyridoxine HCL)	25 mg.	* *
B-12 (Cobal. Conc.)	50 mcg.	* *
C (Ascorbic Acid)	150 mg.	500%
Inositol	250 mg.	*
Choline Bitartrate	150 mg.	*
Methionine dl	50 mg.	*
Rutin	25 mg.	*
Niacinamide	100 mg.	1000%
Pantothenic Acid	25 mg.	* *
Vitamin E (Water Sol.)	12.5 I.U.	* *
Citrus Bioflavonoid Com.	25 mg.	*
Para Amino Benzoic Acid	25 mg.	*
Hesperidin Complex	5 mg.	*
Betaine HCL	25 mg.	*

TWO PER

60 TABLETS $3.50

STAR BRAND
10428 Stanford Avenue
Garden Grove, California 92640

Glutamic Acid	25 mg.	*
Bone Meal	87 mg.	*
Iron (Ferrous Fumerate) Buffered	5.7 mg.	57%
Magnesium (Oxide)	7.2 mg.	* *
Manganese (Carbonate)	6.1 mg.	* *
Copper (Gluconate)	.25 mg.	* *
Zinc (Gluconate)	.18 mg.	* *
Iodine (Potassium Iodide)	0.1 mg.	100%
Phosphorus (Bone Meal)	13 mg.	1.7%
Calcium (Bone Meal)	29 mg.	3.8%
Folic Acid	0.1 mg.	* *
Biotin	2 mcg.	*

In a base containing Alfalfa, Watercress, Parsley, Kelp and Lecithin.
M.D.R. - Minimum Daily Requisite.
* Need in human nutrition not established.
* * M.D.R. not established.
A special sugar free coating, with excipients.

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67740

Obtained on March 21, 19 74, at 1630 ~~a.m.~~ p.m.

Sold as drug

Label (copied in part) Sampled from bulk, labeled and "Enz" tablets, approx. 30 tablets, Manufactured by Westpro Labs, Inc., Lot #730933

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above. City

Inventory on Hand Undetermined. Amount Sampled Approx. 30 tablets.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ----

Where Stored ---

NOTIFIED JUN 12 1974

Date 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9289 Chief's Citation No.

Amount of Sample Submitted ~~Approx. 30 tablets.~~ Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by X Lark L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9289

I. S. NO. A 67740

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : Drug

Label : Sampled from bulk, labeles and "Enz" tablets, approx. 30 tablets

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Ave., Garden Grove, California 92640

Inspector: K. Suh

Contents: from bulk

Amylase: equivalent to 63 mg N. F. 4 x Pancreatin per tablet

Protease: equivalent to 127 mg N. F. 4 x Pancreatin per tablet

6/21/74

Paul T. Clark

PTC:dlj
5/28/74

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67741

Obtained on March 21, 19 74, at 1630 a.m. p.m.

Sold as drug

Label (copied in part) Megavitamin Vitamin A & D, 100 tablets, Lot # 204032, Star Brand
10428 Stanford Ave., Garden Grove, CA. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave. City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 tablets/btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ----

NOTIFIED JUN 13 1974

(1) BM 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9290 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Suh L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9290

I.S. No. A 67741

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold as : Drug

Label : Megavitamin Vitamin A and D, 100 tablets, lot # 204032, Star Brand

Dealer : Westpro Labs, Inc., 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, California 92640

Inspector: K. Suh

Contents: 100 tablets

Vitamin A: 18,000 USP units per tablet

Hold
Hr
6/21/74

Mary W Claridge

MWC:dlj
6/11/74

204032

EACH YELLOW TABLET PROVIDES:	%AMDR
Vitamin A (Palmitate) 25,000 USP Units	625%
Vitamin D 500 USP Units	125%

MEGAVITAMIN

VITAMIN A&D

100 TABLETS $1.75

STAR BRAND
10428 Stanford Avenue
Garden Grove, Ca. 92640

SUGGESTED USE
One tablet per day or as directed

STATE OF CALIFORNIA—DEPARTMENT OF PUBL HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67742

Obtained on March 21, 1974, at 1630 p.m.

Sold as OTC drug

Label (copied in part) Soft-Lax, A balanced herbal formula to aid in elimination, 100 tablets, Lot # 87165, Westpro Labs, Inc., -- Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined. Amount Sampled 1 bottle, 100 tabs./btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ----

Where Stored ----

RECEIVED JUN 27 1974

(1) aw 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9291 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of Dioctyl Sodium Sulfosuccinate.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sark L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA-9291

I.S. No. A 67742

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold as : OTC Drug

Label : Soft-Lax, A balanced herbal formula to aid in elimination, 100 tablets, lot #87165

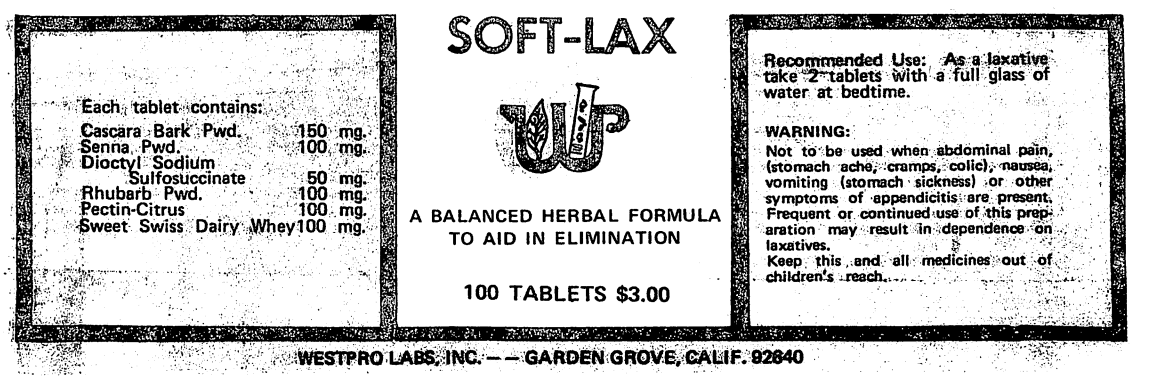
Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue, Garden Grove, California 92640

Inspector: K. Suh

Contents: 100 tablets

Dioctyl Sodium Sulfosuccinate: 45 mg/tablet

WRS:dlj
6/17/74



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH

BUREAU OF FOOD AND DRUG

I. S. No. A 67743

Obtained on March 21, 1974, at 1630 ~~a.m.~~ p.m.

Sold as drug

Label (copied in part) Megavitamin Vitamin A & D, 100 tablets, Lot # 3054, Star Brand

10428 Stanford Ave., Garden Grove, Ca. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 tabs./btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

NOTIFIED JUN 12 1974

Where Stored ---

(1) Dan 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9292 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Lusk L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9292

I.S. No. A 67743

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold as : Drug

Label : Magavitamin Vitamin A and D, 100 tablets, lot #3054, Star Brand

Dealer : Westpro Labs, Inc., 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, California 92640

Inspector: K. Suh

Contents: hold 6/21/74 HS — 100 tablets

Vitamin A: 18,000 USP units per tablet 75% of potency

Mary W Claridge

MWC:dlj
6/11/74

EACH YELLOW TABLET PROVIDES:	%AMDR
Vitamin A (Palmitate) 25,000 USP Units	625%
Vitamin D 500 USP Units	125%

MEGAVITAMIN
VITAMIN A&D
100 TABLETS $1.75
STAR BRAND
10428 Stanford Avenue
Garden Grove, Ca. 92640

SUGGESTED USE
One tablet per day or as directed

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67745 Obtained on March 21, 1974, at 1630 p.m.

Sold as Dietary supplement

Label (copied in part) Ni-Ma Products Rheumaplex, 100 caplets, Lot #730607, Distributed by Ni-Ma Products, 821 W. Grand Blvd., Corona, CA 91720

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own
Name (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 caplets /btl.

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ----

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9293 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 caplets/btl Retained Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Lark L.A.

(1) OAH 4-12-74

APR 25 1974

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9293

I. S. NO. A 67745

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : Dietary supplement

Label : Ni-Ma Products Rheumaplex, 100 caplets, Lot #730607, Distributed by Ni-Ma Products, 821 West Grand Boulevard, Corona, California 91720

Dealer : Westpro Labs, Incorporated, 12791 Main Street, Garden Grove, CA 92640

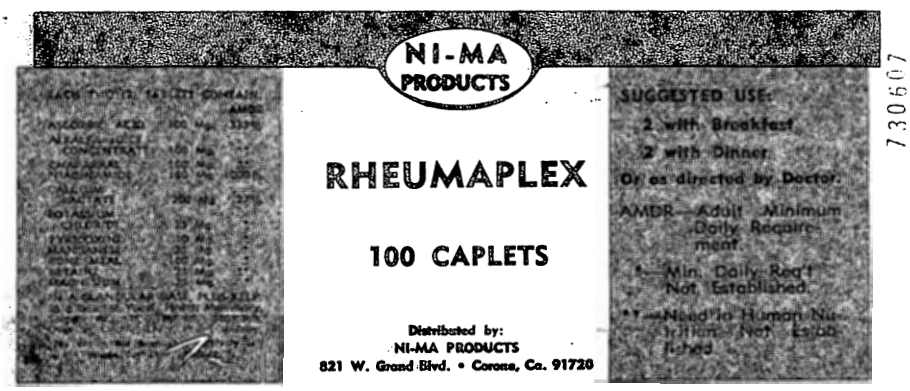
Inspector: K. Suh

Held
to
6/21/74

Contents:		101 tablets
Ascorbic Acid:		92 mg per 2 tablets
Vitamin B-6:		12 mg per 2 tablets
Potassuim Chloride:	100 70 mg	54 mg per 2 tablets
Magnesium:		28 mg per 2 tablets

Mary W Claridge

MWC:WRS:dlj
4/25/74



STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9294

I. S. NO. A 67746

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : ENZAID, A digestive Aid, 100 tablets, lot #730521, Distributed by Metabolic Products

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Ave., Garden Grove, California 92640

Inspector: K. Suh

Contents:	100 tablets
Protease:	equivalent to 131 mg of Pancreatin (N. F. 4x) per tablet
Amylase:	equivalent to 57 mg of Pancreatin (N. F. 4x) per tablet
Lipase:	equivalent to 95 mg of Pancreatin (N. F. 4x) per tablet

Paul T. Clark

PTC:dlj
5/28/74

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67747

Obtained on March 21, 1974, at 1630 ~~XXX~~ p.m.

Sold as drug

Label (copied in part) Sampled from bulk, Labeled as "Lymgest", Lot # 3065, Aljay, 2-15-73, manufactured by Westpro Labs, Inc.

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own
Name (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled Appox. 20 tabs.

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ----

Where Stored ----

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA 9295 Chief's Citation No.

Amount of Sample Submitted approx. 20 tablets. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of Ammonium Chloride.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by X. Lee L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9295

I.S. No. A 67747

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold as : Drug

Label : Samples from buld, labeled as "Lymgest", lot #3065, Aljay, 2/15/73

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Avenue, Garden Grove, California 92640

Inspector: K. Suh

Ammonium Chloride: 130 mg/tablet

Heard
LA
6/21/74

WRS:dlj
6/17/74

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67748

Obtained on March 26, 1974, at 1630 ~~a.m.~~ p.m.

Sold as Drug

Label (copied in part) Pro-Go Super Derma - E Balm, 2 oz., Lot # A 50422, Distributed by Pro-Go Products, Inc., Garden Grove, CA 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own
Name (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand 24 jars, 2 oz./jar Amount Sampled 2 jars, 2 oz./jar

Quarantine Established 24 jars, 2 oz./jar, Lot # A 50422
(Amount, size of container and codes)

Reason for Quarantine Adulterated and misbranded

Where Stored Westpro Labs, Inc., 12791 Main St., Garden Grove, CA 92640

JUN 6 1974

(2) Ltr 4-15-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9296 Chief's Citation No.

Amount of Sample Submitted 2 jars, 2 oz./jar Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of Vitamin E. as declared on the label. Check for the total bacterial plate count also.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological x Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Nash L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9296

I. S. NO. A 67748

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/15/74 Number of Samples Received: 2

Sold As : Drug

Label : Pro-Go Super Derma-E Balm, 2 oz., Lot #A50422, dist. by Pro-Go Prod., Inc

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Av., Garden Grove, California 92640

Inspector: K. Suh

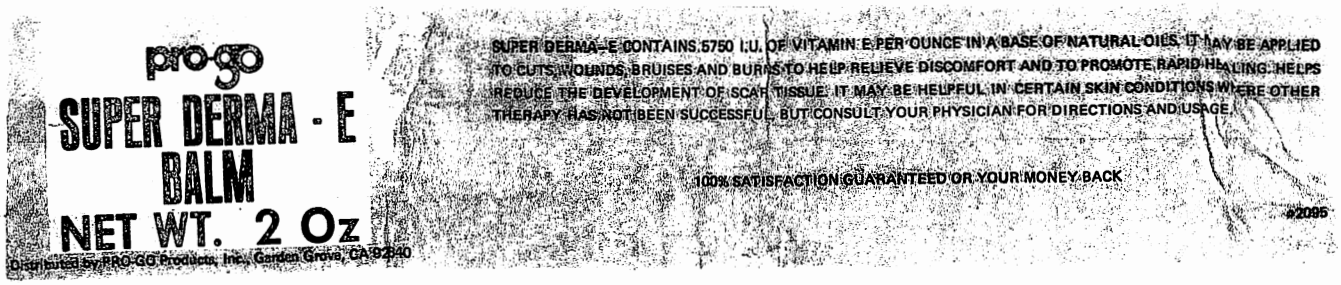
Contents: 2.0 ounces

Total Plate Count: (48 hours at 35°C) none found at a 10^{-1} dilution

Vitamin E: (dl alpha-tocopheryl acetate) 8280 IU/ounce

Mary W. Claridge

MWC:dlj
5/29/74



A 50422

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH

BUREAU OF FOOD AND DRUG

I. S. No. A 67749

Obtained on March 26, 1974, at 1630 a.m. p.m.

Sold as Cosmetic

Label (copied in part) Dr. Donsbach's Vitamin E Ointment, pH controlled, 2 oz., Lot # A 50436, Westpro Labs, Inc. -- Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own
Name (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand 77 jars, 2 oz./jar Amount Sampled 2 jars, 2 oz./jar

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

RECEIVED
JUN 6 1974

(2) Cert 4-15-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9297 Chief's Citation No.

Amount of Sample Submitted 2 jars/ 2 oz./jar Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for ~~them~~ the concentration of Vitamin E. as declared on the label. Also check for the total bacterial plate count.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological x Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Lesh L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9297

I. S. NO. A 67749

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/15/74 Number of Samples Received: 2 (two)

Sold As : Cosmetic

Label : Dr. Donsbach'd Vitamin E Ointment, pH controlled, 2 oz., lot #A50436,

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Ave., Garden Grove, CA 92640

Inspector: K. Suh

100% over
Held
on
6/21/74

Contents:	2.2 ounces
Total Plate Count: (48 hours at 35°C)	none found at a 10^{-1} dilution
Vitamin E: (dl alpha-tocopheryl acetate)	10,500 IU/ounce

Mary W. Claridge

MWC:dlj
5/29/74

Apply this soothing ointment externally in sparing amounts. It is not necessary or advisable to use excessive amounts.

Dr. Donsbach's
VITAMIN E OINTMENT
pH CONTROLLED
2 OZ. $3.00

Each ounce contains: 5760 I.U. (each gram contains 203 I.U.) of Vitamin E in a base of wheat germ oil.

WESTPRO LABS, INC. -- GARDEN GROVE, CALIF. 92640

A 50436

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67750 Obtained on March 26, 1974, at 1630 a.m. p.m.

Sold as Rx-drug

Label (copied in part) Magnesium, Potassium & Vitamin B-6, A food Supplement, 100 tablets, Lot # 740122, Westpro Labs, Inc. -- Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor Own
Name (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand 51 bottles, 100 tabs./btl. Amount Sampled 2 bottles, 100 tabs./btl.

Quarantine Established 51 bottles, 100 tablets/bottle, Lot # 740122
(Amount, size of container and codes)

Reason for Quarantine Adulterated and misbranded

Where Stored Westpro Labs, Inc., 12791 Main St., Garden Grove, CA 92640

NOTICE
APR 25 1974

(2) Ditto 4-15-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9298 Chief's Citation No.

Amount of Sample Submitted 2 bottles, 100 tabs. Retain and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients; K (elemental), Mg, and B-6.

Remark: According to the batch production and control records, one tablet consisted of 500 mg. of potassium bitartrate. (Cream of Tartar)

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Auk L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9298

I. S. NO. A67750

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/15/74 Number of Samples Received: 2 (two)

Sold As : Rx-drug

Label : Magnesium, Potassium and Vitamin B-6, A food Supplement, 100 tablets, Lot #740122

Dealer : Westpro Labs, Inc., 12791 Main Street, and 10422-10428 Stanford Ave. Garden Grove, California, 92640

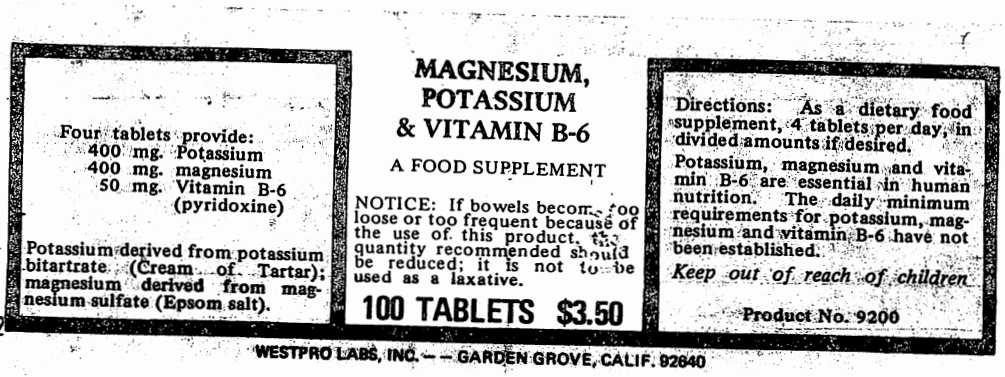
Inspector: K. Suh

Contents:	100 tablets
Potassium:	103 mg/tablet - equivalent to 495 mg potassium bitartrate/tablet
Magnesium:	52mg/tablet
Vitamin B-6:	52 mg/4 (four) tablets

Held 180 6/21/74

Mary W Claridge

WRS:MWC:dlj
4/24/74



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 68487 Obtained on March 26, 1974, at 1630 p.m.

Sold as Cream of Tartar

Label (copied in part) Schilling Cream of Tartar, 24 ozs. Net Wt., Mfg manufactuer's lot # 8254, identified as Westpro Lot # 74073, Baltimore, MD. McCormick & Co., Inc. San Francisco, Calif.

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marhall E. Turley Price Paid None. Payment Refused r.g.

Guarantor McCormick & Co., Inc.
Name (Make three copies of Invoice and attach)

Address City Baltimore, MD. San Francisco, Calif.

Inventory on Hand None. Amount Sampled Approx. 200 grams.

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ---

APR 25 1974

Where Stored ---

(1) Dan 4-15-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9299 Chief's Citation No.

Amount of Sample Submitted Approx. 200 grams. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of Potassium (elemental) as in Potassium Bitartrate.

Adulteration x Misbranding x False Advertising

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Lark L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9299

I. S. NO. A 68487

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/15/74 Number of Samples Received: 1 (one)

Sold As : Cream of Tartar

Label : Schilling Cream of Tartar, 24 ozs. Net Wt. Manufactuer's lot #8254

Dealer : Westpro Labs, Incorporated, 12791 Main Street, Garden Grove, California

Inspector: K. Suh

Potassium: 20.7 percent

Held
for
6/21/74

WRS:dlj
4/23/74

OFFICE OF
DISTRICT ATTORNEY
ORANGE COUNTY

CECIL HICKS
DISTRICT ATTORNEY

JAMES G. ENRIGHT
CHIEF DEPUTY DISTRICT ATTORNEY

700 CIVIC CENTER DRIVE WEST
SANTA ANA, CALIFORNIA 92701

MAIL: P. O. BOX 808
SANTA ANA, CALIFORNIA 92702

TELEPHONE: (AREA CODE 714) 834-3600

EDWARD J. MERRILEES
DIRECTOR, MUNICIPAL COURT OPERATIONS

EDGAR A. FREEMAN
DIRECTOR, SUPERIOR COURT OPERATIONS

RICHARD N. PARSLOW
CHIEF, FAMILY SUPPORT DIVISION

JOEL A. HAYES
CHIEF, INVESTIGATION DIVISION

WILLIAM J. MORISON
ADMINISTRATIVE SERVICES OFFICER

April 2, 1973

TO: WESTPRO LABORATORIES, INC.
and Kurt W. Donsbach, as Pres of Westpro Labs Inc.
10422-10428 Stanford Avenue
Garden Grove, California,

NOTICE OF COMPLAINT FILED

On April 2 1973, a complaint was filed in the Municipal Court charging you with violation of Sections 26619, 26650, 26653, 26670, and 26685 of the Health and Safety Code, and Section 4050 of the Business and Professions Code

To enter your plea of guilty or not guilty of said charges, you are hereby notified to appear on THURSDAY, April 12 19,73, at 9:00am in Division as posted of the Municipal Court checked below:

	CENTRAL ORANGE COUNTY	- 700 Civic Center Drive West, Santa Ana
	NORTH ORANGE COUNTY	- 1170 North Anaheim Blvd., Anaheim
	NORTH ORANGE COUNTY	- 1275 Berkeley Avenue, Fullerton
	SOUTH ORANGE COUNTY	- 30143 Crown Valley Pkwy, Laguna Niguel
X	WEST ORANGE COUNTY	- 8144 Westminster Avenue, Westminster
	ORANGE COUNTY HARBOR	- 567 West 18th Street, Costa Mesa

If you do not appear at said time and place, a warrant may issue for your arrest.

By S/ Jan Mueller
Secretary

IN THE MUNICIPAL COURT
OF WEST ORANGE COUNTY JUDICIAL DISTRICT
COUNTY OF ORANGE, STATE OF CALIFORNIA

THE PEOPLE OF THE STATE OF CALIFORNIA,
Plaintiff,
vs
KURT W. DONSBACH, as President of Westpro Laboratories, Inc.
WESTPRO LABORATORIES, Inc.
Defendant(s)

COMPLAINT – CRIMINAL
MISDEMEANOR

NO. .....

Indexed .....
Register CR 5-2546

The undersigned hereby certifies, upon information and belief:

COUNT I: That on or about the 8th day of January, 19 73, at and within West Judicial District, Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 26619 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc., and WESTPRO LABORATORIES, Inc. who at the time and place last aforesaid, did then and there willfully and unlawfully manufacture, sell, deliver, hold and offer for sale any drug or device that is adulterated.

COUNT II: That on or about the 8th day of January, 1973, at and within Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 26650 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc. and WESTPRO LABORATORIES, INC., who at the time and place last aforesaid, did willfully and unlawfully manufactu sell, deliver, hold and offer for sale a drug and device which was misbranded.

COUNT III: That on or about the 2nd day of February, 1973, at and within Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 26650 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc., and WESTPRO LABORATORIES, INC., who at the time and place last aforesaid, did willfully and unlawfully manufacture, sell, deliver, hold and offer for sale a drug and device which was misbranded.

COUNT IV: That on or about the 16th day of February, 1973, at and within Orange County, Califonir,a, the crime of Misdemeanor, to-wit: Violation of Section 26650 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc., and WESTPRO LABORATORIES, INC., who at the time and place last aforesaid, did willfully and unlawfully manufacture, sell, deliver, hold and offer for sale a drug and devich which was misbranded.

COUNT V: That on or about the 8th day of February, 1973, at and within Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 26653 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc., and WESTPRO LABORATORIES, INC., whc at the time and place last aforesaid, did alter, mutilate, destroy, obliterate and remove the label, or any part of the labeling of a drug and device,

IN THE MUNICIPAL COURT
OF ORANGE COUNTY JUDICIAL DISTRICT
COUNTY OF ORANGE, STATE OF CALIFORNIA

THE PEOPLE OF THE STATE OF CALIFORNIA,
Plaintiff,
vs
Defendant(s)

COMPLAINT – CRIMINAL
MISDEMEANOR

NO. .....

Indexed .....
Register .....

The undersigned hereby certifies, upon information and belief:

COUNT VI: That on or about the 2nd day of February, 1973, at and within West Judicial District, Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 26670 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc. and WESTPRO LABORATORIES, Inc. who at the time and place last aforesaid, did then and there willfully and unlawfully sell, deliver, and give away a new drug and device which failed to satisfy Subsections A & B of Section 26670 of the Health and Safety Code.

COUNT VII: That on or about the 16th day of February, 1973, at and within Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 26670 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Webtpro Laboratories, Inc., and WESTPRO LABORATORIES, INC., who at the time and place last aforesaid, did willfully and unlawfully, sell, deliver and give away a new drug and device which failed to satisfy Subsections A & B of Section 26670 of the Heal th and Safety Code.

COUNT VIII: That on or about the 8th day of January, 1973, at and within Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 26685 of the Health and Safety Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc., and WESTPRO LABORATORIES, INC., who at the time and place last aforesaid, did willfully and unlawfully manufactur a drug and device in this state without holding a valid license from the Department of Public Health, State of California.

COUNT IX: That on or about the 8th day of January, 1973, at and within Orange County, California, the crime of Misdemeanor, to-wit: Violation of Section 4050 of the Business and Professions Code was committed by KURT W. DONSBACH, as President of Westpro Laboratories, Inc., who at the time and place last aforesaid, did willfully and unlawfully manufacture, compound, sell and dispense a drug, poison, or chemical, or dispense and compound a prescription not being a registered pharmacist under provisions of Chapter 9, Division 2, of the Business and Professions Code.

Wherefore, and based upon the declaration attached, said complainant prays that a warrant may be issued for the arrest of KURT W. DONSBACH, as president of Westpro Laboratories, Inc. and Westpro Laboratories, Inc. and that they be dealt with according to law.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 2, 1973

Place of Execution: Orange County, California.

SE:jm

Franklin A. Reis, Complainant
Bureau of Food & Drug, Dept of Public Health, State of California

Case No. 52546A

DEFE. IT'S WAIVER OF CONSTITUTIONAL RI S
FOR ~~GUILTY~~ PLEA IN THE MUNICIPAL COURT

DEFENDANT: KURT W. NOLLO JONSBACH (PRINT) ATTORNEY: R. BROWER (PRINT)

(Defendant Must Initial After Reading) (INITIAL)

1. DEFENDANT: I understand that I am charged with violating Section 24670 (CT. VI) of the H+S Code, commonly known as —
I also understand that the maximum penalty for this offense is 6 MOS. OCJ AND/OR $500 FINE

2. DEFENDANT: I understand that I have the right to be represented by an attorney at all stages of these proceedings, and that if I cannot afford an attorney one will be appointed to represent me.

3(a) DEFENDANT: I understand that I have a right to a speedy and public trial either by jury or by court.

(b) DEFENDANT: I understand that by entering this plea I am waiving and giving up my right to a jury or court trial and that is my desire.

4(a) DEFENDANT: I understand that I have the right to be confronted by the witness(es) against me and to cross examine them myself or through an attorney.

(b) DEFENDANT: I understand that by entering this plea I will be waiving and giving up the right to be confronted by the witness(es) against me and that is my desire.

5(a) DEFENDANT: I understand that I have the right to call witnesses to testify in my own behalf and to invoke the compulsory process of the court to subpoena those witnesses and to produce real evidence to be used in my behalf.

(b) DEFENDANT: I understand that by entering this plea I will be waiving and giving up the right to call witnesses in my own behalf and the right to the compulsory process of the court in producing those witnesses and other evidence in my behalf and that is my desire.

6(a) DEFENDANT: I understand that I have the right to testify on my own behalf but that I cannot be compelled to be a witness against myself, and may remain silent if I so choose, and that if I exercise that right it cannot be used against me.

(b) DEFENDANT: I understand that by entering this plea I will be waiving and giving up the right to testify or not to testify on my own behalf if I so choose and that is my desire.

7. DEFENDANT: I have been advised of the nature of the charges against me, my possible defenses, and the consequences of my plea of (guilty) (no contest) (and the possible consequences of a subsequent violation of probation in this matter). I have also been advised that this plea may subject me to penalties on any other matter as to which I am currently on probation.

8. DEFENDANT: I am entering this plea in consideration that the penalty to be imposed for the offense will be as follows: (SEE ATTACHED SHEET)

E

If the court does not accept this negotiated plea and seeks to impose additional or a different penalty, I reserve the right to withdraw my plea. No other promises other than those above have been made to me in connection with this [illegible]

State of California
Department of Public Health
Bureau of Food and Drug

1449 West Temple Street Room 224
Los Angeles, California 90026

Headquarters:
2151 Berkeley Way
Berkeley, California 94704

NOTICE OF VIOLATION AND INTENT TO CONDEMN

1. Subject: Kurt V. Bonbach

2. Establishment Where Offence Occurred: Westgro Laboratories, Inc.

3. Address: 10422-10428 Stanford Avenue, Garden Grove 92640
(714) 636-2301

4. Corporate Officer: Kurt V. Bonbach Position: President

5. Date(s) of Offense(s): January 8, 1973; February 2, 1973; and February 16, 1973.

6. Violations: Violation of Section 26619 as defined in Section 26612, Health & Safety Code.

Violation of Section 26620 as defined in Sections 26632(a) and (b); 26633; 26638 (a),(b), and (c); Health & Safety Code.

Violation of Section 26653, Health and Safety Code.

Violation of Section 26670 as defined in Section 26021, Health & Safety Code.

Violation of Section 26685 as defined in Section 26019, Health & Safety Code.

Violation of Section 4070, Business and Professions Code.

The subject caused to be repackaged and delivered an unlabeled new drug for which the firm had no new drug approval, which was repackaged in unlicensed premises without benefit of supervision of a pharmacist or an exemptee.

Kurt W. Bombach - Westgro Laboratories, Inc.

7. Witness(es):

(a) Ly Stephen Soh
Food and Drug Inspector II
Bureau of Food and Drug
1449 West Temple Street Room 224
Los Angeles, California 90026
(213) 620-2965

WILL TESTIFY: (1) that on March 5, 1973, he made an inspection and determined that the firm had repacked Phendimetrazine Tartrate, 35 mg., Lot Numbers 25249, 25250, and 25251 on January 8, 1973, per Exhibit No. 1.

(2) that the drug repackaged on January 8, 1973, was received in bulk containers labeled per Exhibit No. 2.

(3) that the quality control records and procedures were not in compliance with the Current Good Manufacturing Practice regulations per Exhibit No. 3.

(4) that the repacked drug was delivered unlabeled per Exhibit No. 4.

(b) David A. Gillespie, President
Naval Drug Distributors
1674½ South Parkside Avenue
Cerritos, California 90701
(213) 926-3000

WILL TESTIFY: that Westgro Laboratories, Inc. had delivered repacked Phendimetrazine Tartrate, 35 mg., to him in an unlabeled condition.

(c) Joseph J. Santoro, Supervising Inspector
Los Angeles Office
California State Board of Pharmacy
107 South Broadway Room 7117
Los Angeles, California 90012
(213) 620-3660

WILL TESTIFY: that he is a keeper of the records of Licensed Pharmacists and Exemptees in Southern California and he has no record of a license with exemption certificate having been issued to anyone at the address of 10455 Stanford Avenue, Garden Grove 92640, on January 8, 1973, February 2, 1973, and February 16, 1973, the dates of offense.

Kurt V. Bambach - Westpro Laboratories, Inc.

(d) Bennett M. Ward
Food and Drug Inspector IV
Bureau of Food and Drug
2151 Berkeley Way
Berkeley, California 94704
(415) 843-7900 Ext. 425

WILL SUBSTANTIATE: that he is a keeper of the records of licensed drug manufacturers in the State of California and he has no record of this firm being licensed as a drug manufacturer at the address of 10848 Stanford Avenue, Garden Grove 92640 on January 8, 1973, February 2, 1973, and February 16, 1973, the dates of offense.

8. Evidence taken consists of Exhibit No. 1 through Exhibit No. 4.

Exhibit No. 1. (a) A letter from Darel Drug Distributors to Westpro Laboratories, Inc.

(b) Production Work Order (A repackaging record).

Exhibit No. 2. (a) Bulk labels and an insert.

(b) Nicklyn Laboratories, Inc., Invoices to Darel Drug Distributors

Exhibit No. 3. (a) Production Work Order (A repackaging record).

(b) Report of Observations.

Exhibit No. 4. (a) Repackaged, unlabeled, drug sample, I.S. No. A-67463.

(b) Invoices from Westpro Laboratories, Inc. to Darel Drug Distributors.

9. Details of Previous Record. See attached Report of Trial.

The above report is complete and in detail. The information contained therein is true to the best of my knowledge and belief.

Kyttezhew Suh
By Kyttezhew Suh, Inspector
Bureau of Food and Drug

EXHIBIT 1 (b)

WESTPRO LABS, INC.

10422 Stanford Ave., Garden Grove, Calif. 926..

PRODUCTION WORK ORDER

WORK ORDER # 170 DATE 1/6/72 DATE DUE _____ DATE COMP. _____ INSP. BY _____

CUSTOMER Daniel Drug

WESTPRO MATERIAL ☐
CUSTOMER MATERIAL ☐

QUANTITY	SIZE	PRODUCT	CODE #
1 1/2 lb	90	[illegible]	—

PRODUCT	CODE NUMBER	MATERIAL REQUIRED	MATERIAL SENT	CK BY	MATERIAL USED	CK BY	MATERIAL RETURN TO STOCK	C B
[illegible]	49980 [illegible] T. 15249	50 M						
	[illegible] 20250	50 M						
	[illegible] 20251	50 M.						
LABEL	——							
BOTTLE	# 703 - 2	compliment						
CAP	—							
CELON	—							
CARTON	—							

	RECEIVED IN PRODUCTION	RECEIVED IN SHIPPING	QUANTITY	RECEIVED IN WAREHOUSE	QUANTITY
CHECKED BY					

LIQUID & POWDER ROOM WORK ORDER

WORK ORDER # _____ DATE _____ DATE DUE _____ DATE COMP. _____ INSP. BY _____

CUSTOMER _____ CUSTOMER CODE # _____ WESTPRO CODE # _____

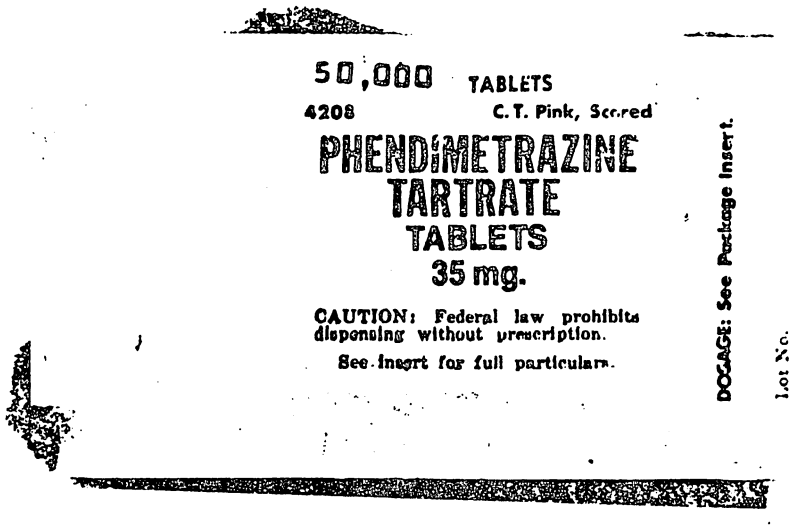
SIZE _____ PRODUCT _____

	CODE NUMBER	MATERIAL REQUIRED	MATERIAL SENT	CK BY	MATERIAL USED	CK BY	MATERIAL RETURN TO STOCK	CK BY
LABEL								
BOTTLE								
CAP								
CELON								
CARTON								

TOTAL QUANTITY FILLED _____ TOTAL QUANTITY LABELED _____ UNLABELED QUANTITY RETURNED TO WAREHOUSE _____

	RECEIVED IN PRODUCTION	RECEIVED IN SHIPPING	QUANTITY	RECEIVED IN WAREHOUSE	QUANTITY

EXHIBIT 2 (a)



PINK

Case No. 52546A

DEFE. /T'S WAIVER OF CONSTITUTIONAL RI S FOR ~~GUILTY~~ PLEA IN THE MUNICIPAL COURT

DEFENDANT: KURT W. (NOLLO) JONSBACH (PRINT) ATTORNEY: R. BROWER (PRINT)

(Defendant Must Initial After Reading) (INITIAL)

1. DEFENDANT: I understand that I am charged with violating Section 24670 (CT. VI) of the H+S Code, commonly known as —
I also understand that the maximum penalty for this offense is 6 MOS. OCJ AND/OR $500 FINE

2. DEFENDANT: I understand that I have the right to be represented by an attorney at all stages of these proceedings, and that if I cannot afford an attorney one will be appointed to represent me.

3(a) DEFENDANT: I understand that I have a right to a speedy and public trial either by jury or by court.

(b) DEFENDANT: I understand that by entering this plea I am waiving and giving up my right to a jury or court trial and that is my desire.

4(a) DEFENDANT: I understand that I have the right to be confronted by the witness(es) against me and to cross examine them myself or through an attorney.

(b) DEFENDANT: I understand that by entering this plea I will be waiving and giving up the right to be confronted by the witness(es) against me and that is my desire.

5(a) DEFENDANT: I understand that I have the right to call witnesses to testify in my own behalf and to invoke the compulsory process of the court to subpoena those witnesses and to produce real evidence to be used in my behalf.

(b) DEFENDANT: I understand that by entering this plea I will be waiving and giving up the right to call witnesses in my own behalf and the right to the compulsory process of the court in producing those witnesses and other evidence in my behalf and that is my desire.

6(a) DEFENDANT: I understand that I have the right to testify on my own behalf but that I cannot be compelled to be a witness against myself, and may remain silent if I so choose, and that if I exercise that right it cannot be used against me.

(b) DEFENDANT: I understand that by entering this plea I will be waiving and giving up the right to testify or not to testify on my own behalf if I so choose and that is my desire.

7. DEFENDANT: I have been advised of the nature of the charges against me, my possible defenses, and the consequences of my plea of (guilty) (no contest) (and the possible consequences of a subsequent violation of probation in this matter). I have also been advised that this plea may subject me to penalties on any other matter as to which I am currently on probation.

8. DEFENDANT: I am entering this plea in consideration that the penalty to be imposed for the offense will be as follows: (SEE ATTACHED SHEET)

If the court does not accept this negotiated plea and seeks to impose additional or a different penalty, I reserve the right to withdraw my plea. No other promises other than those above have been made to me in connection with the disposition of this case or any other matter I may have pending.

9. DEFENDANT: I am entering this plea because I (~~am in fact guilty of the charges~~) (do not wish to contest the charges) and am taking this action freely and voluntarily.

10. DEFENDANT WITHOUT ATTORNEY: I have been ~~advised~~ and understand that I have the right to an attorney and I do freely and voluntarily waive my ~~right~~ to have an attorney represent me in these proceedings.

11. DEFENDANT: I have personally initialed each of the above and I understand each and every one of the rights outlined above and I hereby waive and give up each of them in order to enter my plea of ~~(guilty)~~ (no contest) and request the court to accept that plea.

Dated: 7/13/73 Signed: [signature] (DEFENDANT)

12. DEFENDANT'S ATTORNEY: I am attorney for the defendant in this proceeding. I have fully explained to the defendant each of his rights referred to above and that he is waiving and giving up all of those rights by taking this action. In addition I have explained to him the nature of the charge, his possible defenses to the charge, the possible penalties and the consequences of his plea in this matter. I am of the opinion that he understood my explanations and is taking this action freely and voluntarily with a full understanding of the nature of his rights and the consequences of his action. I stipulate that this document may be received by the court as evidence of defendant's intelligent waiver of these rights.

Dated: 7/13/73 Signed: R BROWER

☑ Court advised defendant of the elements of and the nature of the charges against him, the possible consequences of his plea of (guilty) (no contest), including violation of any probation that he may currently be on, the consequences of a second conviction, (and the consequences of a violation of the probation he is being placed on in this matter).

☑ The court finds that this is a negotiated plea of (guilty) (no contest).

☑ Court after examination of defendant finds that the waivers herein have been made knowingly and intelligently by the defendant.

☑ Court after examination of defendant finds defendant did execute this document and that he does understand his action taken in this matter and its consequences.

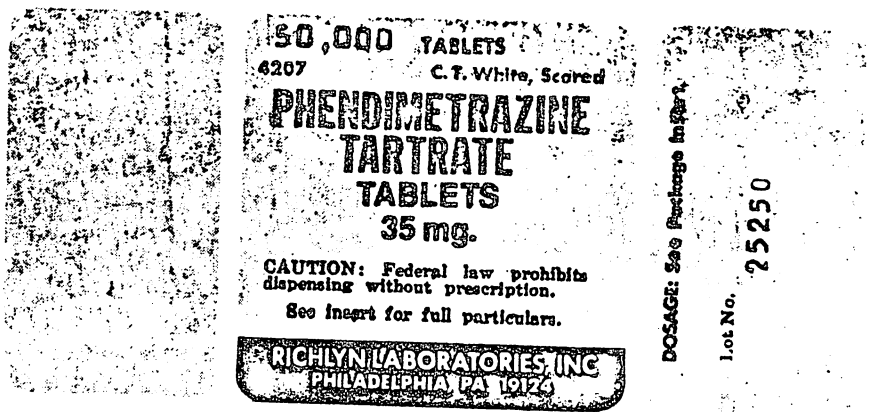
☑ Court finds a factual basis for the plea.

Dated: 7/13/73 Signed: [signature] (JUDGE)

Defendant acknowledges that he has received a copy of this executed document for his files.

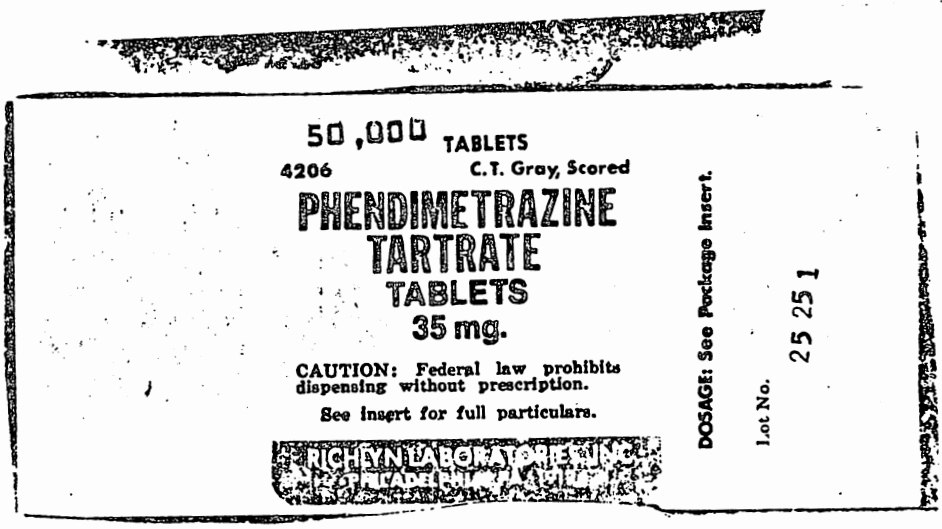
F 0367-2261.1 TAHL WAIVER (REV. 4/73)

EXHIBIT 2 (a)



BLUE

EXHIBIT 2 (a)



GOLD

EXHIBIT 2 (a

PHENDIMETRAZINE TARTRATE TABLETS

DESCRIPTION: Phendimetrazine (bi-)tartrate, chemically 3,4 dimethyl-2-phenylmorpholine hydrogen tartrate, is a white, crystalline, odorless powder that is highly soluble in water and in alcohol, and insoluble in acetone and in ether.

ACTIONS: Phendimetrazine tartrate is a sympathomimetic amine with a short-term anorectic activity that is probably due to CNS stimulation. The precise mode of action is unknown. Phendimetrazine is readily absorbed from the gastrointestinal tract, and its activity persists for about 4 hours following oral administration. Peripheral actions include elevation of systolic and diastolic blood pressures and weak bronchodilator and respiratory stimulant action. The anorectic effect diminishes after a few weeks.

INDICATIONS: Exogenous obesity, as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction.

CONTRAINDICATIONS: Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines.
Nervous or agitated states.
Patients with a history of drug abuse. During or within 14 days following the administration of monoamine oxidase inhibitors, hypertensive crises may result.

WARNINGS: Tolerance to the anorectic effect usually develops within a few weeks. When this occurs, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.
This drug may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly.
DRUG DEPENDENCE: This drug has a significant potential for abuse. Tolerance and extreme psychological dependence have occurred. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with drugs of this class include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

USAGE IN PREGNANCY: Safe use in pregnancy has not been established. Reproduction studies in mammals at high multiples of the human dose have suggested both an embryotoxic and a teratogenic potential. Use of this drug by women who are or who may become pregnant, and especially those in the first trimester of pregnancy, requires that the potential benefit be weighed against the possible hazard to mother and infant.
USAGE IN CHILDREN: Phenmetrazine tartrate is not recommended for use in children under 12 years of age.

PRECAUTIONS: Caution is to be exercised in patients with even mild hypertension.
Insulin requirements in diabetes mellitus may be altered in association with the use of anorectic agents and the concomitant dietary regimen.
Drugs of this class may decrease the hypotensive effect of guanethidine.
Psychological disturbances have been reported in some patients who were on a restrictive diet with or without the concomitant use of an anorectic agent.
The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.

ADVERSE REACTIONS: Cardiovascular: Palpitation, tachycardia, elevation of blood pressure.
Central nervous system: Overstimulation, nervousness, anxiety, agitation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, flushing, sweating, blurring of vision, headache; rarely, psychotic episodes at recommended doses.
Gastrointestinal: Dryness of the mouth, unpleasant taste, nausea, constipation, diarrhea, stomach pain, other gastrointestinal disturbances.
Urinary: frequency, dysuria.
Allergic: Urticaria.
Endocrine: Impotence, changes in libido.

DOSAGE & ADMINISTRATION: The usual suggested adult (not recommended for children under 12 years of age) dosage is 1 tablet b.i.d. or t.i.d., given one hour before meals. Dosage, however, should be individually adjusted to the lowest effective level. In some cases, 1/2 tablet per dose may suffice; in others, 2 tablets b.i.d. or t.i.d. may be required. Late evening medication should be avoided because of the resulting insomnia. For best results, dietary caloric restriction is the recommended basis of management.

OVERDOSAGE: Manifestations of acute overdosage with this drug include restlessness, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension, and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning usually terminates in convulsions and coma. Management of acute intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendations in this regard.

CAUTION: Federal law prohibits dispensing without prescription.

HOW SUPPLIED: Each scored, compressed tablet contains 35 mg. of phendimetrazine tartrate.

NOVEMBER, 1972

EXHIBIT 2 (b.

INVOICE

RICHLYN LABORATORIES INC.

CABLE ADDRESS "RICHLYN"

• PHARMACEUTICALS • ANTIBOTICS • GENERICS

CASTOR & KENSINGTON AVES. • PHILADELPHIA, PA. 19124 • 215 CU9-2220

SOLD TO
DAREL DRUG DIST
PO BOX 955
CERRITOS CALIF 90701

SHIP TO
IF BLANK SAME AS "SOLD TO"
DAREL DRUG DIST
16741 1/2 S PARKSIDE
CERRITOS CALIF 90701

SM	CUST NO	MO	DAY	YR	TERMS: NET 30 DAYS	INVOICE NO
2	3125	11	29	72	PLEASE REFER TO THIS NO IN ALL CORRESPONDENCE →	69516

THANK YOU FOR THIS ORDER

IN CASE OF BREAKAGE OR SHORTAGE, KINDLY FURNISH CARRIER'S SIGNED DELIVERY RECEIPT OR COPY THEREOF BEARING NOTATIONS AS TO THE LOSS OR DAMAGE.

P.O. NUMBER	CAT. NO.	DESCRIPTION	LABEL	LOT NO.	QUANTITY	UNIT (■=M)	PRICE	EXTENSION
1016	3976	METHENAMINE MANDELATE 0.5 GM E.C.	R	24706	4	1000	5.77	23.08
849	1330	PHENACETOPHEN CAPS #1 BROWN/CLEAR	R	24756	25	1000	5.55	138.75
844	4208	PHENDIMETRAZINE TART 35MG CT PINK	R	25249	1	50■	6.25	312.50
844	4208	PHENDIMETRAZINE TART 35MG CT PINK	C	25249	50	1000	6.55	327.50
844	4207	PHENDIMETRAZINE TART 35MG CT WHITE	R	25250	1	50■	6.25	312.50
844	4207	PHENDIMETRAZINE TART 35MG CT WHITE	C	25250	50	1000	6.55	327.50

per 12/71/72 .25¢ per M

per 12/71 32.89 = .25¢ per M

ALL CLAIMS MUST BE REPORTED WITHIN 5 DAYS AFTER RECEIPT OF MERCHANDISE. WRITTEN PERMISSION TO RETURN MERCHANDISE MUST BE AUTHORIZED FROM THIS OFFICE. MERCHANDISE NEVER SOLD ON CONSIGNMENT. WE GUARANTEE ALL DRUGS LISTED ABOVE COMPLY WITH THE LAWS OF THE STATES AND THE UNITED STATES GOVERNING WEIGHTS, MEASURES AND SIZES, AND THE DRUGS ARE NOT ADULTERATED OR MISBRANDED WITHIN THE MEANING OF THE PURE FOOD AND DRUG LAWS OF THE STATES AND THE UNITED STATES.

RICHLYN LABORATORIES, INC.

TOTAL	$ 1441.83
PARCEL POST	

EXHIBIT 2 (b)

INVOICE

RICHLYN LABORATORIES INC.

CABLE ADDRESS RICHLYN

• PHARMACEUTICALS • ANTIBOTICS • GENERICS

CASTOR & KENSINGTON AVES. • PHILADELPHIA, PA. 19124 • 215 CU9-2220

SOLD TO
DAREL DRUG DIST
PO BOX 955
CERRITOS CALIF 90701

SHIP TO
IF BLANK SAME AS SOLD TO
DAREL DRUG DIST
16741 1/2 S PARKSIDE
CERRITOS CALIF 90701

SM	CUST. NO.	MO	DAY	YR	TERMS: NET 30 DAYS	INVOICE NO
2	3125	12	13	72	PLEASE REFER TO THIS NO. IN ALL CORRESPONDENCE →	69684

THANK YOU FOR THIS ORDER

IN CASE OF BREAKAGE OR SHORTAGE, KINDLY FURNISH CARRIER'S SIGNED DELIVERY RECEIPT OR COPY THEREOF BEARING NOTATIONS AS TO THE LOSS OR DAMAGE.

P.O. NUMBER	CAT NO.	DESCRIPTION	LABEL	LOT NO.	QUANTITY	UNIT (M=M)	PRICE	EXTENSION
844	4206	PHENDIMETRAZINE TART 35MG CT GRAY	R	25251	1	50	6.25	312.50
844	4206	PHENDIMETRAZINE TART 35MG CT GRAY	C	25251	50	1000	6.55	327.50

Rec'd 12/19/72
640.00 Int
14.95
654.95 av 6.13

ALL CLAIMS MUST BE REPORTED WITHIN 5 DAYS AFTER RECEIPT OF MERCHANDISE. WRITTEN PERMISSION TO RETURN MERCHANDISE MUST BE AUTHORIZED FROM THIS OFFICE. MERCHANDISE NEVER SOLD ON CONSIGNMENT. WE GUARANTEE ALL DRUGS LISTED ABOVE COMPLY WITH THE LAWS OF THE STATES AND THE UNITED STATES GOVERNING WEIGHTS, MEASURES AND SIZES, AND THE DRUGS ARE NOT ADULTERATED OR MISBRANDED WITHIN THE MEANING OF THE PURE FOOD AND DRUG LAWS OF THE STATES AND THE UNITED STATES.

RICHLYN LABORATORIES, INC.

ORIGINAL INVOICE

TOTAL	$ 640.00
PARCEL POST	
TOTAL	$

EXHIBIT 3 (

WESTPRO LABS, INC.

10422 Stanford Ave., Garden Grove, Calif. 92640

PRODUCTION WORK ORDER

WORK ORDER # 170 DATE 1/4/72 DATE DUE _____ DATE COMP. _____ INSP. BY _____

CUSTOMER [illegible] WESTPRO MATERIAL ☐ CUSTOMER MATERIAL ☐

QUANTITY	SIZE	PRODUCT	CODE #
[illegible]	90	[illegible]	[illegible]

PRODUCT	CODE NUMBER	MATERIAL REQUIRED	MATERIAL SENT	CK BY	MATERIAL USED	CK BY	MATERIAL RETURN TO STOCK	C B
[illegible]	49980 [illegible]	[illegible]						
	[illegible]	[illegible]						
	[illegible]	[illegible]						
LABEL	—							
BOTTLE	# TO2 - 2	[illegible]						
CAP	—							
CELON	—							
CARTON	—							

	RECEIVED IN PRODUCTION	RECEIVED IN SHIPPING	QUANTITY	RECEIVED IN WAREHOUSE	QUANTITY
CHECKED BY					

LIQUID & POWDER ROOM WORK ORDER

WORK ORDER # _____ DATE _____ DATE DUE _____ DATE COMP. _____ INSP. BY _____

CUSTOMER _____ CUSTOMER CODE # _____ WESTPRO CODE # _____

SIZE _____ PRODUCT _____

	CODE NUMBER	MATERIAL REQUIRED	MATERIAL SENT	CK BY	MATERIAL USED	CK BY	MATERIAL RETURN TO STOCK	CK BY
LABEL								
BOTTLE								
CAP								
CELON								
CARTON								

TOTAL QUANTITY FILLED _____ TOTAL QUANTITY LABELED _____ UNLABELED QUANTITY RETURNED TO WAREHOUSE _____

	RECEIVED IN PRODUCTION	RECEIVED IN SHIPPING	QUANTITY	RECEIVED IN WAREHOUSE	QUANTITY

EXHIBIT 3 (b)

744 P Street
Sacramento 95814
(916) 445-2264

1449 Temple Street
Los Angeles 90026
(213) 620-2965

30 Van Ness Avenue
San Francisco 94102
(415) 557-1860

68 North Winchester
Santa Clara 95050
(408) 244-1353

5545 E. Shields Avenue
Fresno 93727
(209) 291-6676

31 E. Channel Street
Stockton 95202
(209) 464-6533

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH

BUREAU OF FOOD AND DRUG

2151 BERKELEY WAY, BERKELEY 94704
(415) 843-7900

REPORT OF OBSERVATIONS

Date March 6, 1973

Firm Name Westpro Laboratories, Inc. License Number

Address 12791 Main St., 10422 Standford Ave., City Garden Grove, Ca. 92640 Garden Grove, Ca. 92640

Person Interviewed Mr. Kurt W. Donsbach Position President

The Department, in the interest of developing good manufacturing practices, hereby notifies you that the following conditions and/or practices were observed on your premises this date. They may constitute violations of one or more provisions of the California Health and Safety Code, Division 21, and Division 22, pertaining to the manufacture, storage, sale, labeling and/or advertising of foods, drugs, cosmetics and hazardous substances. An immediate effort to correct the objectionable conditions shall be made.

1. Master Formula incomplete as regards:

a. A specimen or copy of each label and all other labeling associated with the product not included.

b. A specimen or copy of each label and all other labeling associated with the product not signed or initialed and dated.

c. A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic not indicated.

d. ~~An appropriate statement concerning any calculated excess of ingredients not included.~~

e. A description of the containers closures, and packaging and finishing materials not indicated.

f. Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed not adequate.

May 2, 1973
Reinspection Date

K. Falk
Authorized Agent

Kurt Donsbach
Authorized Representative of Firm

President
Position

REPORT OF OBSERVATIONS—Continued

g. Master record for the products to be repacked or relabeled not provided.

h. Master formula not provided or revised when the batch production has been revised.

2. Batch production record incomplete as regards:

a. An accurate reproduction of the appropriate master formula not checked, dated, and signed or initialed.

b. A record of each significant or critical step in the manufacturing, processing, etc. not endorsed by two competent and responsible individuals independently.

c. A specimen and/ or copy of each label and all other labeling associated with the product not included.

d. A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic not indicated.

e. Manufacturing and control instructions, procedures, specifications, special notations, and precaution to be followed not adequate.

3. Production and control procedures inadequate as regards:

a. An exempted individual not on the premise while manufacturing.

b. The written record of the significant steps in the process not attached.

c. All containers, lines, and equipment used during the production not properly identified.

d. Previous batch identification or label not removed adequately.

e. Appropriate precautions not taken to minimize the possibilities of an extraneous contamination.

g. Some finished product not adequately identified.

h. Product containers and their components not adequately checked to determine whether would alter the safety, identity, strength, quality, or purity of the product.

REPORT OF OBSERVATIONS—Continued

4. Packaging and labeling record incomplete as regards:

- a. A record of each significant or critical steps in the manufacturing not checked by second competent and responsible individual.

b. Labeling control inadequate.

c. coded label and unused label not destroyed.

d. Yield correlation between theoretical and actual yields when repacked not adequately recorded.

5. Laboratory control not provided.

6. Raw materials or ingredients storage inadequate.

7. Labeling review as regards:

a. Inconspicuous statement.

b. warning and/ or caution statements.

c. A qualifying phrase "distributed by" , "manufactured for and distributed by" etc.

8. Packaging and labeling operation of dietary supplements and drugs except protein powder and cosmetic items at 10428 Stanford Ave., Garden Grove 92640.

9. A prescription drug, Phendimetrazine Tartrate, 35mg., Lot Numbers 25249, 25250, & 25251 being repacked for Darel Drug Distributors.

SPECTION REPORT - KEYPUNCH F

CARD 1-6, COL. 1

(Col. 2) TYPE OF INSPECTION
(1) ☐ General Inspection
(2) ☒ License Inspection

(Col. 3) PHASE OF INSPECTION
(0) ☒ Original
(1) ☐ First Reinspection
(2) ☐ Second Reinspection

(Col. 4) ENTRY NUMBER
(1) ☒ Add New Record
(3) ☐ Modify Record
(5) ☐ Delete-Remove Record

Firm Name: Westpro Laboratories, Inc.

Address: 12791 Main Street, Garden Grove, Ca. 92640

	COL. NO.	KEYPUNCH
Firm File Number	5-9	2 0 1 2 6
Date of Inspection	10-15	Mo. 0 1 Day 3 0 Year 7 3
Inspector's I.D. Number	16-18	0 4 7
Joint Inspector's I.D. Number	19-21	

CARD 1-COL. 1 / CARD 2-COL. 1

PRACTICES NOTED	COL. NO.	VIOLATIONS CODE	NA	NO. OF VIOL.	ACTION ON VIOLATIONS Co.	Pl.	NC
1. Ingredients and Raw Materials	22-31						
2. Production Procedures	32-41						
3. Packaging	42-51						
4. Storage-Transportation-Distrib.	52-61						
5. Labeling - Advertising	62-71						
6. Personnel Sanitation	16-25						
7. Quality Control	26-35						
8. (Currently not used)	36-45		1				
9. (Currently not used)	46-55		1				
10. Other	56-65						
	66-73	Total		66-67	68-69	70-71	72-73

CARD 3-COL. 1 / CARD 4-COL. 1

CONDITIONS NOTED	COL. NO.	VIOLATIONS CODE	NA	NO. OF VIOL.	ACTION ON VIOLATIONS Co.	Pl.	NC
11. Equipment Sanitation	16-25						
12. Sanitation of Bldgs and Grounds	26-35						
13. Pest Control	36-45						
14. Construction of Premises and Bldgs	46-55						
15. Construction of Equipment	56-65						
16. Water Supply	66-75						
17. Sewage & Solid Waste Disposal	16-25						
18. Toilet Requirements	26-35						
19. Handwashing Requirements	36-45						
20. Other	46-55						
	56-63	Total		56-57	58-59	60-61	62-63

4/30/73

CARD 5 - COL. 1

ACTIONS TAKEN	Col. No.	(0) No	(1) Yes	FOLLOW-UP ACTIONS NEEDED	Col. No.	(0) No	(1) Yes
VC & D	16	X		Reinspection	26		X
Embargo	17	X		Embargo Disposition	34	X	
Embargo Disposition	18	X		Lab. Chem. Analy.	36	X	
Citation	19	X		Lab. Micro Analy.	38	X	
Lab Sample	20	X		Admin. Rev. of Label	40		X
Label	21	X		Obtain Sample	42		X
Advertising	22		X	Letter	44	X	
Other Evidence	23	X		Hearing	46	X	
None	24	X		Citation	48	X	
Other	25	X		Other	50	X	

CARD 6 - COL. 1

Complete the next 2 items only if this is a License Inspection (any phase).

Recommend Licensing? (Col. 28)
NO (0) X YES (1)

If 'Yes' to above, New License or Renewal? (Col. 29)
NEW (1) RENEWAL (2)

FOR OFFICE USE ONLY
F3 _____ (Col. 35-38) F5 _____ (Col. 39-42)

Major Commodities Covered by Inspection

	Col. 52-54	Col. 55-57	Col. 58-60
1. Drug License	9 1 1		
2.			
3.			

Cont'd (Over)

Cont'd

This firm manufactures dietary supplements and OTC drugs including liquids. This firm repacks and relabels dietary supplements and OTC drugs under both own and private labels. This firm also manufactures cosmetics under "Exquisite Cosmetics by Elyse".

On the date indicated above, this inspection was made to observe the manufacturing facility throughout the premise located at 12791 Main Street, Garden Grove 92640.

On the date indicated above, from approximately 1300 p.m., to 1830 p.m., this inspection was also made to observe raw materials or ingredients storage areas and revealed the following:

1. No exempted individual was on the premises at this time. However, no drug being manufactured. (See Report of Observations, 3, a)

   Mr. Donsbach stated that Ms. Suzanne Hlavin is a part-time registered pharmacist (License No. 19047, renewal No. 004447, 9852 Hibiscus Dr., Garden Grove 92641) and on the premises whenever drug product being manufactured.
   Mr. Donsbach also stated that Mr. William Alfred Rueckert is now a production supervisor who has been with the subject firm since August 1972, and has applied for the State Board of Pharmacy exemption.
   (Mr. Rueckert previous exemption certificate showed M-1789, Austra Chemicals, Inc., 18130 Mt. Washington St., Fountain Valley)

2. "Phendimetrazine Tartrate tablets 35 mg., Lot Nos. 25249, 25250, and 25251" not found at this location.

3. Appropriate precaution not taken to minimize the possibilities of extraneous contaminations in powder packaging room beside the granulation room. (See Report of Observations, 3, e)

   Mr. Donsbach stated that he was aware of dust problem, and has ordered new ventilation system to be installed to eliminate cross contamination by dust build up.

4. Some raw materials or ingredients not adequately identified. (See Report of Observations, 6)

5. Some finished products not adequately identified. (See Report of Observations, 3, g)

6. Previous identification from reused containers not adequately removed to prevent mixups. (See Report of Observations, 3, d)

   Mr. Donsbach stated that these deviations would be corrected. He further stated that packaging and labeling operations would be moved to the Stanford location where the firm's order department located at.

Advised Mr. Donsbach that complete inspection would be made at later date at which time Report of Observations would be provided if any deviations from the Current GMP requirements for drugs are found.

Devitations noted this date included in the Report of Observations made on March 6, 1973. a. Wing Lee Chan 3-73 mg

DRUG INSPECTION FIELD CHECK LIST

INSPECTOR K. Suh DATE 1/30/73 FIRM FILE NUMBER 20126

Inspection not completed at this tim

1. INGREDIENTS AND RAW MATERIALS

_____ A. Containers not examined on receipt.
_____ B. Not adequately sampled for testing.
_____ C. Not withheld from use until tested.
_____ D. Records not maintained or incomplete.
_____ E. Not retested after extended storage.
_____ F. Container specifications inadequate.
PL G. Noncompliance with 133.6.
PL Z. Other.

2. PRODUCT PROCEDURES

_____ A. No master record for each size batch.
_____ B. Master record fails to include required information.
_____ C. No batch record for each batch and size.
_____ D. Batch records do not include each significant step.
_____ E. Equipment not identified as to contents.
PL F. Inadequate procedure to minimize cross-contamination.
_____ G. Drugs not tested before distribution.
_____ H. No review of contr. record prior to rel.
_____ I. Proc., records do not comply with 133.7, 133.8.
_____ Z. Other.

3. PACKAGING

_____ A. No master record for drugs to be repackaged.
_____ B. Drugs to be packaged not examined.
_____ C. Record does not identify labeling issued.
_____ D. Label storage, handling does not comply.
_____ E. No record of reconciliation of labeling.
_____ F. No record of reconciliation of drug.
_____ G. No examination of finished products.
_____ H. Packaging procedures do not comply with 133.10.
_____ Z. Other.

4. STORAGE – TRANSPORTATION – DISTRIBUTION

_____ A. Drugs not stored, handled in orderly manner.
_____ B. No first in, first out, in warehouse.
_____ C. Record will not facilitate recall.
_____ D. Prov. inadequate to assure suitable expiration dates.
_____ E. Complaint record not maintained.
PL F. Records do not comply with 133.12, 133.13, 133.14.
PL Z. Other.

5. LABELING, ADVERTISING

_____ A. Label or labeling false and misleading.
_____ B. Label does not include mandatory information.
_____ C. Inadequate directions for use.
_____ D. Presc. warning legend not included.
_____ E. Product advertised to effect diseases, prohib.
_____ Z. Other.

6. PERSONNEL/SANITATION

_____ A. Inadequate number.
_____ B. Personnel not capable of duties they perform.
PL C. No exemption on duty.
_____ D. Responsible personnel inadequate background.
_____ E. Diseased person handling drugs.
_____ F. Not washing or sanitizing hands.
_____ G. Inadequate supervision of employees' personal hygiene.
_____ H. Dirty clothes, gloves; no hair covering.
_____ I. Personal hygiene not adequate; smoking, etc.
_____ J. Sleeping in drug preparation area.
_____ K. Inadequate storage of clothes and personal items.
_____ Z. Other.

✓ 7. QUALITY AND LABORATORY CONTROL

_____ A. Master record with tests nonexistent.
_____ B. Inadequate provisions for testing (133.11(a)).
_____ C. Inadequate provisions for testing (133.11(d) and (e)).
_____ D. No retesting of products subject to deterioration.
_____ E. No sterility, pyrogen test as required.
_____ F. Lab record not maintained.
_____ G. No check of lab instruments.
_____ H. Reserve samples not maintained.
_____ I. Lab contr. do not comply with 133.11.
_____ J. No provisions to assure stability.
_____ Z. Other.

10. OTHER (a-e)

✓ 11. EQUIPMENT SANITATION

_____ A. Equipment not adequately cleaned or stored.
_____ B. No insp. lines before new batch.
_____ Z. Other.

✓ 12. SANITATION OF BUILDINGS, GROUNDS

_____ A. Not maintained clean and orderly.
_____ B. Inadequate ventilation, screening, etc.
_____ C. No dust controls when necessary.
_____ D. Insufficient space and/or facilities.
_____ Z. Other.

✓ 13. PEST CONTROL

_____ A. Improper control methods.
_____ B. Evidence of infestation.
_____ C. Improper use of pesticides.
_____ Z. Other.

✓ 14. CONSTRUCTION OF PREMISES AND BUILDINGS

_____ A. Size, construction and location not suitable.
_____ Z. Other.

✓ 15. CONSTRUCTION OF EQUIPMENT

_____ A. Design, size, accuracy not suitable.
_____ Z. Other.

✓ 16. WATER SUPPLY

_____ A. None, nonpotable, or inadequate.
_____ B. Cross-connections present.
_____ C. Not suitable temperature for cleaning, etc.
_____ Z. Other.

✓ 17. SEWAGE AND SOLID WASTE DISPOSAL

_____ A. Inadequate facilities for sewage waste removal.
_____ B. Inadequate methods to eliminate odors and nuisance.
_____ C. Waste containers not adequate.
_____ D. Waste products not removed daily.
_____ Z. Other.

✓ 18. TOILET REQUIREMENTS

_____ A. Insufficient or no facilities for number and sex.
_____ B. Toilet facilities dirty.
_____ C. Openings from toilet area to drug area.
_____ D. Inadequate light.
_____ Z. Other.

✓ 19. HANDWASHING REQUIREMENTS

_____ A. Dirty handwashing facilities.
_____ B. No handwashing facilities.
_____ C. Not conveniently located.
_____ D. Water not at suitable temperature.
_____ E. Inadequate number of facilities.
_____ F. Soap, sanitizer inadequate or not available.
_____ Z. Other.

20. OTHER (a-e)

See remark re: R.O. bottom of rpt.

5/4/73

III. Prior to December 28, 1973, Mr. Kurt W. Donsbach, an officer of Westpro Labs, Inc., was personally involved in the approval of Production Orders (Master Formula and Records), as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, for the following drug products:

1. Prescription drug labeled as "Magnesium, Potassium & Vitamin B-6".
2. Drug labeled as "PAN ENZ 500", "ENZAID", "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", "Dr. Donsbach's Formula ENZ", "Master Formula Metazyme", "Vitafare Digest", "Digest", or "Vital Life Digestive Enzymes"

Detailed evidence of above is contained in the attached reports.

LIMITED INSPECTION REPORT

KEYPUNCH: Punch Code 5 in Column 1, and Punch Code 3 in Column 2.

Phase of Inspection *(Col. 3)*
(0) ☒ Original

Entry Number *(Col. 4)*
(1) ☒ Add New Record
(3) ☐ Modify Record
(5) ☐ Delete - Remove Record

Firm File No. *(Col. 5 - 9)* 2 0 1 2 6

Date of Inspection *(Col. 10 - 15)* 0 3 2 6 7 4 (Mo. Day Yr.)

Firm Name: Westpro Labs, Inc.

Firm Address: 12791 Main Street, Garden Grove, California 92640

ACTIONS TAKEN	Col. No.	(0) NO	(1) YES	FOLLOW-UP ACTIONS NEEDED	Col. No.	(0) NO	(1) YES
V. C. AND D.	16	x		General Inspection	26		x
EMBARGO	17		x	Embargo Disposition	34		x
EMBARGO DISPOSITION	18	x		Lab Chem. Anal.	36		x
CITATION	19	x		Lab Micro. Anal.	38		x
LAB SAMPLE	20		x	Adm. Rev. Label	40		x
LABEL	21		x	Obtain Sample	42	x	
ADVERTISING	22		x	Letter	44	x	
OTHER EVIDENCE	23		x	Hearing	46	x	
NONE	24	x		Citation	48	x	
OTHER	25		x	Other	50		x

file in 6/21/74

COMMODITIES COVERED BY ACTIONS TAKEN:

Name	Col. No.	Commodity Code		
1. Drug Manufacturing License	52-54	9	1	1
2.	55-57			
3.	58-60			
4.	61-63			
5.	64-66			
6.	67-69			

See attached report.

Inspector's Name Ky Stephen Suh Inspector's I.D. No. 0 4 7 *(Col. 70-72)*

Joint Inspector's Name _____ Joint Inspector's I.D. No. _____ *(Col. 73-75)*

Original: L.A.
c: Sacramento
cc: HD + Santa

(Rev. 7/72) Form 446-140

Westpro Labs, Inc.

12791 Main Street, and
10422-10428 Stanford Avenue,
Garden Grove, CA 92640

On March 26, 1974, at approximately 08:30 hours, the inspection of Westpro Labs, Inc. at 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, California 92640, was made to do the following:

Westpro Labs, Inc. was instructed to initiate drug recalls on the following products to the retail level:

1. Prescription drug, labeled as "Magnesium, Potassium & Vitamin B-6", lot number 731106, identified as I.S. number A-67726, 24,754 tablets, actually manufactured on November 14, through November 15, 1973. (See Exhibit 9)

   a. Production work orders (packaging and labeling records) showed that 24,700 tablets of "Magnesium, Potassium & Vitamin B-6", lot number 731106, packaged and labeled as follows:

      i. 72 bottles of "Magnesium, Potassium & Vitamin B-6", 100 tablets per bottle, packaged from lot number 731106, and labeled under the Star Brand label on November 2, through November 23, 1973.
      ii. 12 bottles of "Magnesium, Potassium & Vitamin B-6", 100 tablets per bottle, packaged from lot number 731106, and labeled under the Dr. S. Chess & Dr. V. Rao label on January 15, through January 16, 1974.
      iii. 163 bottles of "Magnesium, Potassium & Vitamin B-6", 100 tablets per bottle, packaged from lot number 731106, and labeled under the Westpro Labs, Inc. label on March 20, through March 21, 1974.

   b. Invoices (distribution records) showed that 3,000 tablets (30 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6", lot number 731106, had been distributed from December 27, 1973 to February 12, 1974.

   c. 16,100 tablets (161 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6", lot number 731106, placed under embargo on March 26, 1974 as per attached "Embargo Notice". (See attached)

   d. 200 tablets (2 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6", lot number 731106, sampled on March 26, 1974 as per attached "Official Sample Receipt". (See attached)

   e. Westpro Labs, Inc. failed to show whether 5,400 tablets (54 bottles, 100 tablets per bottle) had been distributed. Mr. Bushong stated that 5,400 tablets may have been distributed as a sample by Dr. Kurt W. Donsbach.

Westpr Labs, Inc.

f. Prescription drug, labeled as "Magnesium, Potassium & Vitamin B-6", lot number 731106, was recalled, and placed under embargo because of the following reasons:

i. "Magnesium, Potassium & Vitamin B-6", lot number 731106, was adulterated in that laboratory results on the samples disclosed 205 mg. of magnesium per four tablets (equivalent to 51.25 mg. of magnesium per tablet), whereas the label claimed as 400 mg. of magnesium per four tablets (equivalent to 100 mg. of magnesium per tablet) as defined in Section 26617, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

ii. "Magnesium, Potassium & Vitamin B-6", lot number 731106, was adulterated in that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug not in conformity with the Current Good Manufacturing Practice Regulations to assure the appropriate standards of safety, identity, strength, quality and purity which it purports or is represented to possess as defined in Section 26612, Division 21 Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

iii. "Magnesium, Potassium & Vitamin B-6", lot number 731106, was manufactured by Westpro Labs, Inc. without the benefit of registered pharmacists or exemptees as defined in Sections 4050 and 4050.5, Business and Professions Code, State of California. (See Attachment 2)

iv. "Magnesium, Potassium & Vitamin B-6", lot number 731106, was misbranded in that labels and all other labeling associated with the drug product failed to include the following:

(a) Prescription legend,

(b) Adequate direction for use,

and (c) Appropriate warning or caution statement, as defined in Sections 26638 and 26664, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

v. "Magnesium, Potassium & Vitamin B-6", lot number 731106, was misbranded in that labels and all other labeling associated with the drug product appeared to be false and misleading as defined Section 26630, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

vi. "Magnesium, Potassium & Vitamin B-6", lot number 731106, was misbranded in that this prescription drug was manufactured in unlicensed premises as defined in Section 26648, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

Westpro Labs, Inc.

2. Prescription drug, labeled as "Magnesium, Potassium & Vitamin B-6", lot number 740122, identified as I.S. number A-67750, 25,090 tablets, actually manufactured on January 28, through February 6, 1974. (See Exhibit 24)

   a. Production work order (packaging and labeling record) showed that 25,500 tablets (255 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6" packaged from lot number 740122, and labeled under the Westpro Labs, Inc. label on February 12, through February 13, 1974.

   b. Invoices (distribution records) showed that 17,100 tablets (171 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6", lot number 740122, had been distributed from February 14, 1974 to March 26, 1974.

   c. 5,100 tablets (51 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6", lot number 740122, placed under embargo on March 26, 1974 as per attached "Embargo Notice". (See attached)

   d. 200 tablets (2 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6", lot number 740122, sampled on March 26, 1974 as per attached "Official Sample Receipt". (See attached)

   e. Westpro Labs, Inc. had no records to show whether 3,100 tablets (31 bottles, 100 tablets per bottle) of "Magnesium, Potassium & Vitamin B-6", lot number 740122, had been distributed. Mr. Bushong thought that 3,100 tablets may have been distributed by Dr. Kurt W. Donsbach as a sample, as he always did.

   f. Prescription drug, labeled as "Magnesium, Potassium & Vitamin B-6", lot number 740122, was recalled, and placed under embargo because of the following reasons:

      i. "Magnesium, Potassium & Vitamin B-6", lot number 740122, was adulterated in that laboratory result on the sample disclosed 208 mg. of magnesium per four tablets (equivalent to 52 mg. of magnesium per tablet), whereas the label claimed as 400 mg. of magnesium per four tablets (equivalent to 100 mg. of magnesium per tablet) as defined in Section 26617, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

      ii. "Magnesium, Potassium & Vitamin B-6", lot number 740122, was adulterated in that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug not in conformity with the Current Good Manufacturing Practice

Regulations to assure the appropriate standards of safety, identity, strength, quality and purity which it purports or is represented to possess as defined in Section 26612, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

iii. "Magnesium, Potassium & Vitamin B-6", lot number 740122, was manufactured by Westpro Labs, Inc. without the benefit of registered pharmacists or exemptees as defined in Sections 4050 and 4050.5, Business and Professions Code, State of California. (See Attachment 2)

iv. "Magnesium, Potassium & Vitamin B-6", lot number 740122, was misbranded in that this prescription drug was manufactured in unlicensed premises as defined in Section 26648, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

v. "Magnesium, Potassium & Vitamin B-6", lot number 740122, was misbranded in that labels and all other labeling associated with the drug product failed to include the following:

(a) Prescription legend,

(b) Adequate direction for use,

and (c) Appropriate warning or caution statement, as defined in Sections 26638 and 26664, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

vi. "Magnesium, Potassium & Vitamin B-6", lot number 740122, was misbranded in that labels and all other labeling associated with the drug product appeared to be false and misleading as defined in Section 26630, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

Westpro Labs, Inc.

3. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50422, identified as I.S. number A-67748, 280 ounces, actually manufactured on February 4, 1974. (See Exhibit 28)

   a. Production work order (packaging and labeling record) showed that 96 ounces (48 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm" packaged from lot number 50422, and labeled under the Pro-Go Products, Inc. label on January 29, through February 4, 1974.

   b. Invoices (distribution records) failed to include the appropriate lot or control numbers by which the distribution of each lot of drug can be readily determined to facilitate its recall.

   c. 4 ounces (2 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50422, sampled on March 26, 1974, as per attached "Official Sample Receipt". (See attached)

   d. 48 ounces (24 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50422, placed under embargo on March 26, 1974, as per attached "Embargo Notice". (See attached)

4. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50207, 288 ounces, actually manufactured on June 15, 1973. (See Exhibit 25)

   a. Production work order (packaging and labeling record) showed that 24 ounces (12 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm" packaged from lot number 50207, and labeled under the Pro-Go Products, Inc. label on July 18, 1973.

   b. Invoices (distribution records) failed to include the appropriate lot or control numbers by which the distribution of each lot of drug can be readily determined to facilitate its recall.

5. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50262, 262 ounces, actually manufactured on July 27, 1973. (See Exhibit 11)

   a. Production work order (packaging and labeling record) showed that 262 ounces (131 jars, 2 ounces per jar) packaged from lot number 50262, but that only 72 ounces (36 jars, 2 ounces per jar) labeled under the Pro-Go Products, Inc. label on July 26, through July 30, 1973.

b. Production work order (packaging and labeling record), work order # 50371, showed that 80 ounces (40 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50262, identified as I.S. number A-67731, labeled under the Pro-Go Products, Inc. label from unlabeled 95 jars on November 26, through November 29, 1973. (See Exhibit 23)

c. Production work order (packaging and labeling record), work order # 50282, showed that 90 ounces (45 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50262, identified as I.S. number A-67731, labeled under the Pro-Go Products, Inc. label from unlabeled 45 jars on August 14, through August 15, 1973. (See Exhibit 26)

d. Invoices (distribution records) failed to include the appropriate lot or control numbers by which the distribution of each lot of drug can be readily determined to facilitate its recall.

e. 12 ounces (6 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50262, identified as I.S. number A-67731, placed under embargo on March 26, 1974, as per attached "Embargo Notice". (See attached)

f. 4 ounces (2 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50262, identified as I.S. number A-67731, sampled on March 26, 1974, as per attached "Official Sample Receipt". (See attached)

6. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50137, 306 ounces, actually manufactured on April 10, 1973. (See Exhibit 29)

a. Production work order (packaging and labeling record) showed that 178 ounces (89 jars, 2 ounces per jar) of "Pro-Go Super Derma-E Balm" packaged from lot number 50137, and labeled under the Pro-Go Products, Inc. label on April 10, through April 17, 1973.

b. Invoices (distribution records) failed to include the appropriate lot or control numbers by which the distribution of each lot of drug can be readily determined to facilitate its recall.

Westpro Labs, Inc.

Drug, labeled as "Pro-Go Super Derma-E Balm", lot numbers 50137, 50207, 50262, and 50422, were recalled because of the following reasons: (See # 3, # 4, #5, and # 6 above)

1. Drug, labeled as "Pro-Go Super Derma-E Balm", lot numbers 50137, 50207, 50262, and 50422, were adulterated in that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug not in conformity with the Current Good Manufacturing Practice Regulations to assure the appropriate standards of safety, identity, strength, quality, and purity which they purport to possess as defined in Section 26612, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

2. Drug, labeled as "Pro-Go Super Derma-E Balm", lot numbers 50137, 50207, 50262, and 50422, were manufactured by Westpro Labs, Inc. without the benefit of registered pharmacists or exemptees as defined in Sections 4050 and 4050.5, Business and Professions Code, State of California. (See Attachment 2)

3. Westpro Labs, Inc. caused to be manufactured new drugs for which the firm had no new drug approval as defined in Sections 26021 and 26670, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 13 and 23)

4. Drug, labeled as "Pro-Go Super Derma-E Balm", lot numbers 50137, 50207, 50262, and 50422, were misbranded in that these products were manufactured in unlicensed premises as defined in Section 26648, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

5. Drug, labeled as "Pro-Go Super Derma-E Balm", lot numbers 50137, 50207, 50262, and 50422, were misbranded in that labels and all other labeling associated with these products failed to include the following:
   (a) Adequate direction for use,
   (b) Appropriate warning or caution statement,
   and (c) General warning re accidental ingestion by children, as defined in Section 26638, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

6. Drug, labeled as "Pro-Go Super Derma-E Balm", lot numbers 50137, 50207, 50262, and 50422, were misbranded in that labels and all other labeling associated with these products appeared to be false and misleading as defined

Westpro Labs, Inc.

in Section 26630, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 7)

The following drug products were placed under embargo on this date: (See attached)

1. 24 jars (2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50422.
2. 6 jars (2 ounces per jar) of "Pro-Go Super Derma-E Balm", lot number 50262.
3. 161 bottles, 100 tablets per bottle, of "Magnesium, Potassium & Vitamin B-6", lot number 731106.
4. 51 bottles, 100 tablets per bottle, of "Magnesium, Potassium & Vitamin B-6", lot number 740122.

Samples obtained as an evidence per attached "Official Sample Receipt". (See attached)

Management of Westrpo Labs, Inc. and Rich Life, Inc. was instructed to provide the following on this date:

1. A proposed drug recall letter for "Magnesium, Potassium, & Vitamin B-6", including the returnable questionaire or reply, whichever is appropriate.
2. A proposed drug recall letter for "Pro-Go Super Derma-E Balm", including the returnable questionaire or reply, whichever is appropriate. Advised management at this time that a drug recall letter for "Pro-Go Super Derma-E Balm" can be proposed by either party since Westpro Labs, Inc. and Pro-Go Products, Inc. are mutually responsible.
3. Two separate envelopes for each product as per Section 3.501, Parts 1 to 119, Title 21, Code of Federal Regulations, revised as of January 1, 1971. (See Attachment 24)
4. Management was also instructed to submit proposed drug recall letter to Food and Drug Section in order to be reviewed.

LIMITED INSPECTION REPORT

KEYPUNCH: Punch Code 5 in Column 1, and Punch Code 3 in Column 2.

Phase of Inspection *(Col. 3)*
(0) ☒ Original

Entry Number *(Col. 4)*
(1) ☒ Add New Record
(3) ☐ Modify Record
(5) ☐ Delete - Remove Record

Firm File No. *(Col. 5 - 9)* 3 0 8 0 9

Date of Inspection *(Col. 10 - 15)* 0 3 2 1 7 4 (Mo. Day Yr.)

Firm Name: Westpro Labs, Inc.

Firm Address: 10422-10428 Stanford Avenue, Garden Grove, California 92640

ACTIONS TAKEN	Col. No.	(0) NO	(1) YES	FOLLOW-UP ACTIONS NEEDED	Col. No.	(0) NO	(1) YES
V. C. AND D.	16		x	General Inspection	26		x
EMBARGO	17	x		Embargo Disposition	34	x	
EMBARGO DISPOSITION	18	x		Lab Chem. Anal.	36		x
CITATION	19	x		Lab Micro. Anal.	38		x
LAB SAMPLE	20		x	Adm. Rev. Label	40		x
LABEL	21		x	Obtain Sample	42		x
ADVERTISING	22		x	Letter	44	x	
OTHER EVIDENCE	23		x	Hearing	46	x	
NONE	24	x		Citation	48	x	
OTHER	25		x	Other	50		x

COMMODITIES COVERED BY ACTIONS TAKEN:

Name	Col. No.	Commodity Code		
1. Drug Manufacturing License	52-54	9	1	1
2.	55-57			
3.	58-60			
4.	61-63			
5.	64-66			
6.	67-69			

See attached report.

Inspector's Name Ky Stephen Suh Inspector's I.D. No. 0 4 7 *(Col. 70-72)*

Joint Inspector's Name _____ Joint Inspector's I.D. No. _____ *(Col. 73-75)*

Original: L.A.
c: Sacramento

(Rev. 7/72) Form 446-140

Westpro Labs, Inc.

12791 Main Street, and
10422-10428 Stanford Avenue,
Garden Grove, CA 92640

On March 21, 1974, at approximately 08:30 hours, this inspection was made as a follow-up.

Interviewed the following personnel at Westpro Labs, Inc.

1. William W. Ward
2. Jake Bushong
3. Richard Hundley

A follow-up inspection on this date revealed that Westpro Labs, Inc. at 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, California 92640, had manufactured the following drug products on the premises:

1. Prescription drug, labeled as "Magnesium, Potassium & Vitamin B-6", lot number 731106, sampled from bulk, identified as I.S. number A-67726, 25,000 tablets manufactured on November 14, through November 15, 1973. (See Exhibit 9)

   a. Production work orders (packaging and labeling records) showed the following:

      i. 72 bottles of "Magnesium, Potassium & Vitamin B-6", 100 tablets per bottle, packaged and labeled from lot number 731106 under the Star Brand label on November 2, through November 23, 1973.
      ii. 12 bottles of "Magnesium, Potassium & Vitamin B-6", 100 tablets per bottle, packaged and labeled from lot number 731106 under the Dr. S. Chess & Dr. V. Rao label on January 15, through January 16, 1974.
      iii. 163 bottles of "Magnesium, Potassium & Vitamin B-6", 100 tablets per bottle, packaged and labeled from lot number 731106 under the Westpro Labs, Inc. label on March 20, through March 21, 1974.

   b. Production order (batch production and control record) indicated that "Magnesium, Potassium & Vitamin B-6", lot number 731106, identified as I.S. number A-67726, contained 500 mg. of potassium bitartrate as an ingredient (also known as cream of tartar) which supplied at least 103.9 mg. of potassium per tablet. (See Attachments 9 and 10)

   c. Laboratory results on the samples, identified as I.S. number A-67726, showed that "Magnesium, Potassium & Vitamin B-6" , lot number 731106, disclosed 103.75 mg. to 106.25 mg. of potassium per tablet containing potassium bitartrate as a salt. (See Attachments 9 and 10, and I.S. slip, identified as I.S. number A-67726)

   d. "Magnesium, Potassium & Vitamin B-6", lot number 731106, identified as I.S. number A-67726, considered as a Rx-drug because of the following

reason in that Section 3.15 "Potassium salt preparations intended for oral ingestion by man.", Part 1 to 119, Title 21, Code of Federal Regulations, revised as of January 1, 1971, states that "(b) The Food and Drug Administration may initiate regulatory proceedings after 30 days from the date of publication of this section, with respect to the marketing of uncoated tablets containing potassium chloride or other potassium salts which supply 100 milligrams or more of potassium per tablet or with respect to liquid preparations containing potassium chloride or other potassium salts which supply 20 milligrams or more of potassium per milliliter, labeled or intended for human use, unless all the following conditions are met:
(1) The labeling of the drug bears the prescription caution statement quoted in section 503 (b) (4) of the Federal Food, Drug, and Cosmetic Act; and
(2) The labeling on or within the package from which the drug is to be dispensed bears adequate information for its use by practitioners in accord with the "full disclosure" labeling requirements of section 1.106 (b) of this chapter, including a recommendation that patients be directed to dissolve any such tablets in an appropriate amount of liquid and to dilute any such liquid preparations adequately to assure against gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations." (See Attachments 4, 5, and 9)

e. Production order (master production and control record) for "Magnesium, Potassium & Vitamin B-6" was prepared by Mr. William Rueckert on November 8, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on November 18, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 11, and 12)

f. Production order (batch production and control record) for "Magnesium, Potassium & Vitamin B-6", lot number 731106, showed that the appropriate Production order (master production and control record) was prepared by Mr. William Rueckert on November 8, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on November 18, 1973, as required per Section 133.7 (a), and (b) (1), Current Good Manufacturing Practice Regulations under Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Exhibit 9, and Attachments 11 and 12)

g. Label for "Magnesium, Potassium & Vitamin B-6" failed to include the following:

   i. Prescription legend.
   ii. Adequate direction for use

iii. Appropriate warning or caution statement. (See Attachment 9)
iv. General warning re accidental ingestion by children, if applicable.

h. "Magnesium, Potassium & Vitamin B-6", lot number 731106, identified as I. S. number A-67726, also considered as drug as defined in Section 26010, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

2. Drug, labeled as "PAN ENZ 500" or "PANCREATIN", lot number 2702, identified as I.S. number A-67729, 50,000 tablets manufactured on December 22, 1972. (See Exhibit 10)

a. Production work orders (packaging and labeling records) showed the following:

i. 144 bottles of "PAN ENZ 500", 100 tablets per bottle, packaged and labeled from lot number 2702 under the Metabolic Products label on May 7, through May 8, 1973.
ii. 5,000 tablets in bulk from lot number 2702 packaged and labeled under Restoration label on July 12, 1973.
iii. 66 bottles of "PANCREATIN(4X) 500 Mg. A DIGESTIVE AID", 100 tablets per bottle, packaged and labeled from lot number 2702 under the Westpro Labs, Inc. label on December 7, 1973.
iv. Production work orders failed to show whether approximately 21,586 tablets from lot number 2702 have been packaged and labeled.
v. Production work order indicated that the batch of this drug product was being identified and assigned as lot number 730534. However, the identical product with the assigned lot number 730534 was not manufactured until May 8, 1973. (See #4, below)

b. Label claims, such as "Each tablet provides 500 milligrams of pancreatin....", "Provides digestive enzymes of pancreatin for improved digestion of starch, fat and protein." or "Use: One or more tablets with each meal as desired, as a preventive in minor indigestion", for "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", lot number 2702, made this product a drug as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety code. (See Attachment 3)

c. "Pancreatin" used as an ingredient has been recognized in an official compendium; the latest edition of the National Formulary as defined in Sections 26010 and 26022, Division 21 Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

d. "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID" used as the name of the product has been recognized in an official compendium; the latest edition of the National Formulary, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

e. Production order (master production and control record) for "PAN ENZ 500" or "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID" was checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 28, 1973. (See Exhibit 10), as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 11, and 12)

f. Label for "PAN ENZ 500" or "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID" failed to include the following:
   i. Appropriate warning or caution statement.
   ii. General warning re accidental ingestion by children.

3. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50262, identified as I.S. number A-67731, 300 ounces, manufactured on July 27, 1973. (See Exhibit 11)

a. Production work order (packaging and labeling record) showed that 36 jars of "Pro-Go Super Derma-E Balm", 2 ounces per jar, packaged and labeled from lot number 50262 under the Pro-Go Products, Inc. label on July 26, through July 30, 1973.

b. Production work order (packaging and labeling record) showed that 131 jars, 2 ounces per jar, packaged for Pro-Go Products, Inc. from lot number 50262, but that 95 jars, 2 ounces per jar, retained unlabeled at 12791 Main Street, Garden Grove, on July 26, through July 30, 1973.

c. Production work order (packaging and labeling record) failed to show whether 95 jars, 2 ounces per jar, retained unlabeled have been labeled.

d. Label for "Pro-Go Super Derma-E Balm" states that "Super Derma - E contains 5750 I.U. of Vitamin E per ounce in a base of natural oils. It may be applied to cuts, wounds, bruises and burns to help relieve discomfort and to promote rapid healing. Helps reduce the development of scar tissue. It may be helpful in certain skin conditions where other therapy has not been successful, but consult your physician for directions and usage."

e. Label claims, such as "It may be applied to cuts, wounds, bruises and burns to help relieve discomfort and to promote rapid healing.","Helps reduce the development of scar tissue.", or "It may be helpful in certain skin conditions where other therapy has not been successful, but consult your physician for directions and usage.", made "Pro-Go Super Derma-E Balm", lot number 50262, a drug as defined in Sections 26002, 26010, 26016,and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

f. "Pro-Go Super Derma-E Balm", lot number 50262, identified as I.S. number A-67731, may be considered as a "New Drug" as defined in Section 26021, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, in that the safety and effectiveness of the drug,which is used or intended for use by man, under the conditions prescribed, recommended or suggested in the labeling or advertising are not generally recognized. (See Attachment 13)

g. Label for "Pro-Go Super Derma-E Balm" failed to include the following:
   i. Adequate direction for use
   ii. Appropriate warning or caution statement, if any.
   iii. General warning re accidental ingestion by children.

4. Drug, labeled as "PAN ENZ 500", or "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", lot number 730534, identified as I. S. number A-67732, 100,000 tablets, manufactured on May 10, through May 17, 1973. (See Exhibit 12)

   a. Production work orders (packaging and labeling records) showed the following:

      i. 72 bottles of "PAN ENZ 500", 250 tablets per bottle, packaged and labeled from lot number 730534 under the Metabolic Products label on July 12, through July 13, 1973.
      ii. 432 bottles of "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", 100 tablets per bottle, packaged and labeled from lot number 730534 under the Westpro Labs, Inc. label on October 12, 1973.
      iii. 144 bottles of "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", 100 tablets per bottle, packaged and labeled from lot number 730534 under the Westpro Labs, Inc. label on November 15, 1973.
      iv. 6 bottles of "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", 100 tablets per bottle, packaged and labeled from lot number 730534 under the Westpro Labs, Inc. label on December 7, 1973.
      v. 12 bottles of "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", 100 tablets per bottle, packaged and labeled from lot number 730534 under the Westpro Labs, Inc. label on January 4, 1974.
      vi. 12 bottles of "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", 100 tablets

per bottle, packaged and labeled from lot number 730534 under the the Westpro Labs, Inc. label on January 22, 1974.

b. Label claims, such as "Each tablet provides 500 milligrams of pancreatin.....", "Provides digestive enzymes of pancreatin for improved digestion of starch, fat and protein." or "Use: One or more tablets with each meal as desired, as a preventive in minor indigestion", made "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID", lot number 730534, a drug as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

c. "Pancreatin" used as an ingredient in "PAN ENZ 500" has been recognized in an official compendium; the latest edition of the National Formulary, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

d. "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID" used as the name of the product has been recognized in an official compendium; the latest edition of the National Formulary, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

e. Production order (master production and control record) for "PAN ENZ 500" or "PANCREATIN (4X) 500 Mg. A DIGESTIVE AID" was chekced, reconciled, and approved by Mr. Kurt W. Donsbach on December 28, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title, 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 11 and 12)

f. Labeling review - See # 2, f, above.

5. Drug, labeled as "Dr. Donsbach's Formula ENZ", "Master Formula Metazyme", or "Vitafare Digest:, lot number 731112, identified as I. S. number A-67733, 100,000 tablets, manufactured on November 19, through December 6, 1973. (See Exhibit 13)

a. Production work orders (packaging and labeling records) showed the following:

i. 12 bottles of "Vitafare Digest", 100 tablets per bottle, packaged and labeled from lot number 731112 under the Vitafare label on January 29, through January 31, 1974.

ii. 30 bottles of "Dr. Donsbach's Formula ENZ", 250 tablets per bottle, packaged and labeled from lot number 731112 under the Westpro Labs, Inc.

label on February 5, trhough February 6, 1974.

iii. 24 bottles of "Master Formula Metazyme", 250 tablets per bottle, packaged from lot number 731112 and labeled under the Nutritional Products Company label on February 5, through February 11, 1974.

iv. 20,000 tablets in bulk packaged from lot number 731112 for Dr. Alsleben on February 11, through February 14, 1974.

v. 48 bottles of "Master Formula Metazyme", 250 tablets per bottle, packaged from lot number 731112, and labeled under the Nutritional Products Company label on February 21, through February 25, 1974.

vi. 144 packs of "Pak-A-Day", 50 tablets per pack, packaged from lot number 731112, and labeled under the Westpro Labs, Inc. label on February 14, through February 26, 1974.

vii. 200 bottles, 30 tablets per bottle, packaged from lot number 731112, and labeled for Jon Cole on February 22, through February 27, 1974.

viii. 12 bottles of "Dr. Donsbach's Formula ENZ", 1,000 tablets per bottle, packaged from lot number 731112, and labeled under the Westpro Labs, Inc. label on February 27, through February 28, 1974.

b. Labels for "Dr. Donsbach's Formula ENZ", "Master Formula Metazyme", or "Vitafare Digest", state that "Supplies digestants as supplements to body secretions to aid in digesting fats, proteins and carbohydrates." , "Caution: If gastric distress continues, consult your doctor." , and "Suggested Use: 1-2 tablets after each meal as an aid to the digestion of fats, carbohydrates and proteins."

c. Label claims, such as "Supplies digestants as supplements to body secretions to aid in digesting.....", ".....gastric distress .....", or ".....as an aid to the digestion.....", made "Dr. Donsbach's Formula ENZ", "Master Formula Metazyme", and "Vitafare Digest", packaged from lot number 731112, drugs as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

d. "Pancreatin" used as an ingredient in "Dr. Donsbach's Formula ENZ", "Master Formula Metazyme", and "Vitafare Digest", has been recognized in an official compendium; the latest edition of the National Formulary, NF XIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13 and 14)

e. Production orders (master production and control records; batch production and control records) were checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 20, 1972.

f. Newly revised production order (master formula and records) for "ENZ Tablet F.C.T.", Formula No. 129, was prepared by Mr. William Rueckert on December 5, 1973, and checked, reconciled, and approved by Mr. Kurt

W. Donsbach on December 5, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Exhibit 13, and Attachments 11 and 12)

g. Label failed to include general warning re accidental ingestion by children.

6. Drug, labeled as "Dr. Donsbach's Formula ENZ", "ENZAID", or "Vital Life Digestive Enzymes", lot number 730934, 100,000 tablets, identified as I. S. number A-67734, manufactured on October 2, through October 8, 1973. (See Exhibit 14)

a. Production work orders (packaging and labeling records) showed the following:

i. 500 packs, 30 tablets per pack, packaged from lot number 730934, and labeled for Ken Anderson on October 25, through October 31, 1973.
ii. 36 kits, 30 tablets per kit, packaged from lot number 730934, and labeled under the Bragg label on October 30, through November 1, 1973.
iii. 36 kits, 90 tablets per kit, packaged from lot number 730934, and labeled under the Bragg label on October 30, through November 1, 1973.
iv. 48 packs, 30 tablets per pack, packaged from lot number 730934, and labeled under the Pak-A-Day label for Hadley on November 2, through November 6, 1973.
v. 144 bottles of "ENZAID", 250 tablets per bottle, packaged from lot number 730934, and labeled under the Metabolic Products label on November 5, through November 6, 1973.
vi. 144 packs of "Pak-A-Day", 50 tablets per pack, packaged from lot number 730934, and labeled under the Westpro Labs, Inc. label on November 7, through November 14, 1973.
vii. 12 bottles, 30 tablets per bottle, packaged from lot number 730934, and labeled for Del Mac on November 13, through November 19, 1973.
viii. 20,000 tablets in bulk from lot number 730934 packaged and labeled for Dr. Alsleben on November 20, 1973.
ix. 36 packs, 30 tablets per pack, packaged and labeled from lot number 730934 for Hadley on November 26, through November 27, 1973.
x. 5,000 tablets in bulk from lot number 730934 packaged and labeled for Dr. Fram on December 6, through December 7, 1973.
xi. 48 bottles of "Vital Life Digestive Enzymes", 180 tablets per bottle, packaged from lot number 730934, and labeled under the Vital Life

label on December 7, through December 10, 1973.

b. Labels for "Dr. Donsbach's Formula ENZ", "ENZAID", or "Vital Life Digestive Enzymes", state that "Supplies digestants as supplements to body secretions to aid in digesting fats, proteins, and carbohydrates.", "Caution: If gastric distress continues, consult your doctor.", and "Suggested Use: 1-2 tablets after each meal as an aid to the digestion of fats, carbohydrates and proteins."

c. Label claims, such as "Supplies digestants as supplements to body secretions to aid in digesting.....", ".....gastric distress.....", or ".....as an aid to the digestion.....", made "Dr. Donsbach's Formula ENZ", "ENZAID", and "Vital Life Digestive Enzymes", packaged from lot number 730934, drugs as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

d. "Pancreatin" used as an ingredient in "Dr. Donsbach's Formula ENZ", "ENZAID", and "Vital Life Digestive Enzymes", has been recognized in an official compendium; the latest edition of the National Formulary, NF XIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13 and 14)

e. Production orders (master production and control records; batch production and control records) were checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 20, 1972.

f. Newly revised production order (master formula and records) for "ENZ Tablet F.C.T.", Formula No. 129, was prepared by Mr. William Rueckert on December 5, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 5, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Exhibit 14, and Attachments 11 and 12)

g. Label failed to include general warning re accidental ingestion by children.

7. Prescription drug, labeled as "Megavitamin AC Plus E" or "Vitamins AC and E", lot number 2989, identified as I. S. number A-67735, 100,000 tablets, manufactured on March 5, through March 6, 1973. (See Exhibit 15)

Westpro Labs, Inc.

a. Production work orders (packaging and labeling records) showed the following:

   i. 144 bottles of "Vitamins A C and E", 120 tablets per bottle, packaged from lot number 2989, and labeled under the Elysee label on March 27, through March 28, 1973.
   ii. 850 bottles of "Megavitamin A-C Plus E", 100 tablets per bottle, packaged from lot number 2989, and labeled under the Star Brand label on September 24, 1973.

b. Production order (batch production and control record) indicated that "Megavitamin A-C Plus E" and "Vitamins A C and E", lot number 2989, identified as I. S. number A-67735, contained the total quantity of 16,500 U.S.P. units of Vitamin A Palmitate per tablet, including 1,500 U.S.P. units of Vitamin A Palmitate used as the calculated excess of an ingredient per tablet, that equivalent to the overage of 10 %. (See Exhibit 15)

c. Labels for "Megavitamin A-C Plus E" and "Vitamins A C and E" state in part that "Suggested Use: One or more tablets daily." or "Each tablet contains Vitamin A 15,000 USP units....."

d. Labels for "Megavitamin A-C Plus E" and "Vitamins A C and E" implicate in such a manner that 4 tablets, 15,000 U.S.P. units of Vitamin A Palmitate per tablet, that are orally administered daily as suggested in the labeling, will supply at least 60,000 U.S.P. units of Vitamin A Palmitate daily, excluding 6,000 U.S.P. units of Vitamin A Palmitate used as the calculated excess per four tablets. (See Attachment 15)

e. Federal Register, Volume 36, No. 161, published on Thursday, August 19, 1971, B. "Conditions for approval and marketing." states that "The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under the conditions described herein.

   1. Form of Drug. These preparations are in capsule form suitable for oral administration of 50,000 U.S.P. units per capsule.
   2. Labeling conditions.
      a. The labels bear the statement "Caution : Federal law prohibits dispensing without prescription"
      b. Each drug is labeled to comply with all requirements of the Act and Regulations. Its labeling bears adequate information for safe and effective use of the drug and is in accord with the guidelines for uniform labeling published in the Federal Register of February 6, 1970. "

(See Attachment 15)

f. "Megavitamin A-C Plus E" and "Vitamins A C and E" , lot number 2989, identified as I. S. number A-67735, considered as Rx-drugs.

g. Labels for "Megavitamin A-C Plus E" and "Vitamins A C and E" failed to include the following:

i. Prescription legend.
ii. Adequate direction for use.
iii. Adequate information for safe and effective use.
iv. Adequate labeling.

Westpro Labs, Inc.

8. Drug, labeled as "Soft-Lax", lot number 87165, identified as I. S. Number A-67742, repackaged and relabeled as follows: (See Exhibit 16)

   a. Production work order (repackaging and labeling record) showed the following:

      i. 48 bottles of "Soft-Lax", 100 tablets per bottle, repackaged from lot number 87165, and labeled under the Elysee label on May 22, 1973.
      ii. 85 bottles of "Soft-Lax", 100 tablets per bottle, repackaged from lot number 87165, and labeled under the Westpro Labs, Inc. label on November 1, through November 11, 1973.
      iii. 12 bottles of "Soft-Lax", 100 tablets per bottle, repackaged from lot number 87165, and labeled under the California Health Foods label on November 19, through November 20, 1973.
      iv. 141 bottles of "Soft-Lax", 100 tablets per bottle, repackaged from lot number 87165, and labeled under the Westpro Labs, Inc. label on December 10, 1973.
      v. 24 bottles of "Soft-Lax", 100 tablets per bottle, relabeled under the California Health Foods label on January 24, 1974.

   b. Labels used for "Soft-Lax" state that "Recommend Use: As a laxative take 2 tablets with a full glass of water at bedtime.", "Warning: Not to be used when abdominal pain, (stomach ache, cramps, colic), NAUSEA, VOMITING (stomach sickness) or other symptoms of appendicitis are present. Frequent or continued use of this preparation may result in dependence on laxatives. ", or "Keep this and all medicines out of children's reach", " Each tablet contains ..... Senna Pwd. 100 mg. .... Dioctyl Sodium Sulfosuccinate 50 mg. ....."

   c. "Dioctyl Sodium Sulfosuccinate" used as an ingredient has been recognized in an official compendium; the latest edition of the United States Pharmacopoeia, U.S.P. XVIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 16)

   d. "Senna" used as an ingredient has been recognized in an offical compendium; the latest edition of the National Formulary, NF XIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

   e. Mr. Jake Bushong, Production Manager of Westpro Labs, Inc. stated that "Soft-Lax", lot number 87165, identified as I. S. number A-67742, was manufactured and supplied by Linwilco in Costa Mesa.

Westpro Labs, Inc.

f. "Soft-Lax", lot number 87165, considered as a drug as defined Section 26010, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code.

g. Labels used for "Soft-Lax" failed to indicate the active ingredients intended for use as laxatives.

h. Remington's Pharmaceutical Sciences, Fourteenth Edition, Chapter 44 "Gastrointestinal Drugs", pages 787 through 814, states the following:

i. "Gastrointestinal drugs"- "Drugs appropriate for this chapter include gastric antacids, digestants, cathartics, emetics, antiemetics, adsorbents, and some miscellaneous agents which act on the gastro-intestinal tract."

ii. "Cathartics are drugs that facilitate the passage and elimination of feces from the colon and rectum."

iii. "The cathartics are so numerous that they require classification. This has been done in a variety of ways. The drugs very considerably in their intensity of action, and thus, have been classified as "Laxatives", "purgatives", and "drastics", in the order of increasing potency."

iv. "Senna, NF" has been classified under "Irritant (Stimulant) Cathartics"

v. ".... they are usually divided into four group: irritant (stimulant) cathartics, bulk cathartics, emollient cathartics, and fecal softners."

vi. "Dioctyl Sodium Sulfosuccinate, USP" has been classified under fecal softners. (See Attachment 20)

i. Section 26019, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, states that "Manufacture means the preparation, compounding, porpagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer." (See Attachment 21)

Westrpo Labs, Inc.

9. Drug, labeled as "Dr. Donsbach's Formula ENZ", "Vitafare Digest" , or "Pak-A-Day", lot number 730807, identified as I. S. number A-67736, 100,000 tablets, manufactured on August 10, through August 15, 1973. (See Exhibit 17)

   a. Production work orders (packaging and labeling records) showed the following:

      i. 288 bottles of "Dr. Donsbach's Formula ENZ", 100 tablets per bottle, packaged from lot number 730807, and labeled under the Westpro Labs, Inc. label on August 30, 1973.
      ii. 144 bottles of "Dr. Donsbach's Formula ENZ", 250 tablets per bottle, packaged from lot number 730807, and labeled under the Westpro Labs, Inc. label on August 30, 1973.
      iii. 430 packs of "Pak-A-Day", 30 tablets per pack, packaged from lot number 730807, and labeled under the Westpro Labs, Inc. label on September 6, through September 31, 1973. (It was very interesting to point out that the month of September never consisted of thirty one days) (See Attachment 17)
      iv. 20,000 tablets in two bulk containers, 10,000 tablets each, packaged from lot number 730807, and labeled for Dr. Alsleben on September 12, 1973.
      v. 12 bottles of "Vitafare Digest", 100 tablets per bottle, packaged from lot number 730807, and labeled under the Vitafare label on September 13, 1973.
      vi. 103 bottles of " Dr. Donsbach's Formula ENZ", 250 tablets per bottle, packaged from lot number 730807, and labeled under the Westpro Labs, Inc. label on October 3, 1973.

   b. Labels for "Dr. Donsbach's Formula ENZ", or "Vitafare Digest" state that "Supplies digestants as supplements to body secretions to aid in digesting.. ...", ".....gastric distress ......", or ".....as an aid to the digestion .....", made these products packaged from lot number 730807 drugs as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

   c. "Pancreatin" used as an ingredient in "Dr. Donsbach's Formula ENZ", "Vitafare Digest", or "Pak-A-Day", has been recognized in an official compendium; the latest edition of the National Formulary, NF XIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

   d. Production orders (master production and control records; batch production and control records) were checked, reconciled, and approved by Mr. Donsbach on December 20, 1972.

   e. Newly revised production order (master formula & records) for "ENZ Tablet

F.C.T.", Formula No. 129, was prepared by Mr. William Rueckert on December 5, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 5, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Exhibit 17, and Attachments 11 and 12)

g. Label failed to include general warning re accidental ingestion by children.

10. Drug, labeled as "Dr. Donsbach's Formula ENZ", "ENZAID", lot number 731111, identified as I. S. number A-67737, 100,000 tablets, manufactured on November 19, through December 5, 1973. (See Exhibit 18)

a. Production work orders (packaging and labeling records) showed the following:

i. 20,000 tablets in bulk, 10,000 tablets each, packaged from lot number 731111, and labeled for Dr. Alsleben on January 18, through January 21, 1974.
ii. 116 bottles 30 tablets each, packaged from lot number 731111 and labeled for Ken Anderson on January 23, 1974.
iii. 177 bottles of "Dr. Donsbach's Formula ENZ", 100 tablets per bottle, packaged from lot number 731111, and labeled under the Westpro Labs, Inc. label on January 25, through January 29, 1974.
iv. 72 bottles of "Dr. Donsbach's Formula ENZ", 250 tablets per bottle, packaged from lot number 731111, and labeled under the Westpro Labs, Inc. label on January 25, through January 30, 1974.
v. 114 bottles of "Dr. Donsbach's Formula ENZ", 250 tablets per bottle, packaged from lot number 731111, and labeled under the Westpro Labs, Inc. label on February 5, through February 6, 1974.
vi. 41 bottles of "ENZAID", 250 tablets per bottle, packaged from lot number 731111, packaged and labeled under the Metabolic Products label on March 7, through March 12, 1974.

b. Label claims, such as "Supplies digestants as supplements to body secretions to aid in digesting.....", "..... gastric distress.....", or "..... as an aid to the digestion .....", made these products packaged from lot number 731111 drugs as defined in Sections 26002, 26010, 26016 and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

c. "Pancreatin" used as an ingredient in these products has been recognized in an official compendium; the latest edition of the National Formulary,

Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

d. Production order (master production and control record; batch production and control record) checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 20, 1972.

e. Newly revised production order (Master formula and records) for "ENZ Tablet, F.C.T.", Formula No. 129, was prepared by William Rueckert on December 5, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 5, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Exhibit 18, and Attachments 11 and 12)

11. Drug, labeled as "REN-EZ", or "Formula K", lot number 47210, identified as I. S. number A-67738, suggested for use as a mild diuretic, repackaged relabeled on the dates indicated as follows: (See Exhibit 19)

a. Production work orders (repackaging and labeling records) showed the following:

i. 72 bottles of "REN-EZ", 90 tablets per bottle, repackaged from lot number 47210, and labeled under the Metabolic Products label on April 26, through April 27, 1973.
ii. 144 bottles of "Formula K", 90 tablets per bottle, repackaged from lot number 47210, and labeled under the Westpro Labs, Inc. label on May 1, through May 2, 1973.
iii. 12 bottles of "Walt Deland's Formula K", 90 tablets per bottle, repackaged from lot number 47210, and labeled under the Walt Deland's Nutrition Center label on July 9, through July 10, 1973.
iv. 72 bottles of "REN-EZ", 90 tablets per bottle, repackaged from lot number 47210, and labeled under the Metabolic Products label on August 21, through August 27, 1973.
v. 12 bottles of "Walt Deland's Formula K", 90 tablets per bottle, repackaged from lot number 47210, and labeled the Walt Deland's Nutrition Center label on October 29, 1973.
vi. 72 bottles of "REN-EZ", 90 tablets per bottle, repackaged from lot number 47210, and labeled under the Metabolic Products label on October 30, 1973.

b. Labels used for "REN-EZ" and "Formula K" state in part that "This product contains Carbamide (Urea N.F.) which may act as a mild diuretic.","....

....Each tablet contains: ..... 200 mg. Carbamide (Urea N.F.)..... .5 Gr. Extract of Ox Bile (NF XI)....."

c. Remington's Pharmaceutical Sciences, Fourteenth Edition,53 "Diuretic Drugs", Pages 936 through 950, states that "Urea is used orally as a diuretic.", and that "Diuretics are drugs used to increase the volume of urine excreted by the kidneys." (See Attachment 18)

d. "Urea (Carbamide)", used as an ingredient, has not been recognized in the National Formulary, NF XIII, as labeled, but has been recognized in an official compendium; the latest edition of the United States Pharmacopoeia, U.S.P. XVIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13 and 19)

e. Mr. Jake Bushong, Production Manager of Westpro Labs, Inc. stated that He was not quite certain as to whether this product labeled as "REN-EZ" "Formula K", suggested for use as a diuretic, manufactured and supplied by Linwilco in Costa Mesa or by Birch Laboratories, Inc. in Anaheim.

f. "REN-EZ" and "Formula K", suggested for use as a diuretic in the labeling, considered drugs as defined in Section 26010, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

g. Labels used for "REN-EZ" and "Formula K" failed to include general warning re accidental ingestion by children.

h. Section 26019, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, states that "Manufacture means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer." (See Attachment 21)

Westpro Labs, Inc.

12. Drug, labeled as "ENZ", "Gastro-Aid", or "ENZAID", lot number 730933, identified as I. S. number A-67740, 100,000 tablets, manufactured on October 2, through October 14, 1973. (See Exhibit 20)

a. Production work orders (packaging and labeling records) showed the following:

i. 48 bottles of "ENZ", 100 tablets per bottle, packaged from lot number 730933, and labeled under the Hadley Fruit Orchards label on October 11, through October 12, 1973.
ii. 48 bottles of "ENZ', 250 tablets per bottle, packaged from lot number 730933, and labeled under the Hadley Fruit Orchards label on October 11, through October 12, 1973.
iii. 5,000 tablets in bulk from lot number 730933 packaged and labeled for Dr. Fram on October 15, 1973.
iv. 72 bottles of "Gastro-Aid", 250 tablets per bottle, packaged from lot number 730933, and labeled under the Restoration label on October 15, 1973.
v. 20,000 tablets in bulk containers, 10,000 tablets each, from lot number 730933, packaged and labeled for Dr. Alsleben on October 19, 1973.
vi. 160 bottles of "ENZAID", 250 tablets per bottle, packaged from lot number 730933, and labeled under the Metabolic Products label on October 26, 1973.

b. Label claims, such as "Supplies digestants as supplements to body secretions to aid in digesting.....", ".....gastric distress.....", or ".....as an aid to the digestion.....", made these products packaged from lot number 730933 drugs as defined in Sections 26002, 26010, 26016 and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

c. "Pancreatin" used as an ingredient in these products has been recognized in an official compendium; the latest edition of the National Formulary, NF XIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13 and 14)

d. Production order (master formula and records) checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 20, 1972.

e. Newly revised production order (Master formula and records) for "ENZ Tablet F.C.T", Formula No. 129, was prepared by Mr. William Rueckert on December 5, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 5, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations, under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic

Law, California Health and Safety Code. (See Exhibit 20, and Attachments 11 and 12)

13. Drug, labeled as "ENZ", "ENZAID", "Dr. Donsbach's Formula ENZ" or "Digest", lot number 730521, identified as I. S. number A-67746, 100,000 tablets, manufactured on May 15, through May 25, 1973. (See Exhibit 21)

a. Production work orders (packaging and labeling records) showed the following:

i 144 bottles of "ENZAID", 100 tablets per bottle, packaged from lot number 730521, and labeled under the Metabolic Products label on June 11, 1973.

ii. 72 bottles of "ENZAID", 250 tablets per bottle, packaged from lot number 730521, and labeled under the Metabolic Products label on June 11, 1973.

iii. 144 bottles of "Di-Gest", 100 tablets per bottle, packaged from lot number 730521, and labeled under the Elysee label on June 13, 1973.

iv. 144 bottles of "Dr. Donsbach's Formula ENZ", 100 tablets per bottle, packaged from lot number 730521, and labeled under the Westpro Labs, Inc. label on June 13, 1973.

v. 143 bottles of "ENZ", 250 tablets per bottle, packaged from lot number 730521, and labeled under the Westpro Labs, Inc. label on June 13, 1973.

b. Labels for "ENZ", "ENZAID", "Dr. Donsbach's Formula ENZ", or "Di-Gest" state in part that "Supplies digestants as supplements to body secretions to aid in digesting fats, proteins, and carbohydrates.", "Caution: If gastric distress continues, consult your doctor.", "Suggested Use: 1-2 tablets after each meal as an aid to the digestion of fats, carbohydrates and proteins." or "Each tablet contains: .....Pancreatin (4X) 75 mg. ....."

c. Label claims, such as "Supplies digestants as supplements to body secretions to aid in digesting.....", ".....gastric distress.....", or "..... as an aid to the digestion.....", made these products drugs as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

d. "Pancreatin" used as an ingredient in these products has been recognized in an official compendium; the latest edition of the National Formulary, NF XIII, as defined in Sections 26010 and 26022, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3, 13, and 14)

e. Production orders (master production and control records; batch production and control records) were chekced, reconciled, and approved by Mr. Kurt W. Donsbach on December 20, 1972.

f. Newly revised production order (master formula and records) for "ENZ Tablet F.C.T", Formula No. 129, was prepared by Mr. William Rueckert on December 5, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on December 5, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, Califronia Health and Safety Code. (See Exhibit 21, and Attachments 11 and 12)

Remington's Pharmaceutical Sciences, Fourteenth Edition, Chapter 44 "Gastro-intestinal Drugs", pages 793 through 795, states, in part, that "Digestants are drugs which promote the process of digestion in the gastrointestinal tract. They have limited usefulness in the treatment of conditions characterized by a deficiency of one or more of the specific substances essential for the digestion of foodstuffs in the alimentary canal. Thus, in general way, they may be classified as drugs used for replacement therapy in the deficiency states."

All the products suggested for use as digestants, which were manufactured by Westpro Labs, Inc. according to the production order (Master formula and records), Formula No. 129, of "ENZ Tablet F.C.T", described and reviewed herein are, therefore, drugs as defined in Section 26010, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 3 and 22)

Westpro Labs, Inc.

14. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50207, 300 ounces, manufactured on June 15, 1973. (See Exhibit 25)

a. Production work order (packaging and labeling record) showed that 12 jars of "Pro-Go Super Derma-E Balm", 2 ounces per jar, packaged from lot number 50207, and labeled under the Pro-Go Products, Inc. label on July 18, 1973.

b. Production work order (packaging and labeling record) showed that 132 jars of Vitamin E Ointment, 2 ounces per jar, packaged from lot number 50207, and labeled under the Westpro Labs, Inc. label on June 15, through July 18, 1973.

c. Production order (batch production and control record) issued for "Pro-Go Super Derma-E Balm" , lot number 50242, showed that a record of each significant step in the manufacturing and processing, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, had been checked and initialed by the individual(s) actively performing or directly supervising. However, complete review of the distribution records (invoices) revealed that "Pro-Go Super Derma- E Balm", lot number 50242, 300 ounces, never been manufactured on the premises. (See Exhibits 25 and 22)

d. Label used for "Pro - Go Super Derma- E Balm" states that "Super Derma -E contains 5750 I. U. of Vitamin E per ounce in a base of natural oils. It may be applied to cuts, wounds, bruises and burns to help relieve discomfort and to promote rapid healing. Helps reduce the development of scar tissue. It may be helpful in certain skin conditions where other therapy has not been successful, but consult your physician for directions and usage."

e. Label claims, such as "It may be applied to cuts, wounds, bruises and burns to help relieve discomfort and to promote rapid healing.", "Helps reduce the development of scar tissue.", or ""It may be helpful in certain skin conditions where other therapy has not been successful, but consult your physician for directions and usage." made this product a drug as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

f. "Pro-Go Super Derma- E Balm", lot number 50207, may be considered as a "new drug" as defined in Section 26021 , Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, in that the safety and effectiveness of the drug, which is used or intended for use by man, under the conditions prescribed, recommended or suggested in the labeling or advertising are not generally recognized. (See Attachment 13)

Westpro Labs, Inc.

15. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50262 , identified as I.S. number A-67731 , 300 ounces, manufactured on July 27, 1973. (See Exhibit 11)

    a. Production work order (packaging and labeling record), work order # 50371, showed that 40 jars of "Pro-Go Super Derma-E Balm", 2 ounces per jar, lot number 50262, from 95 jars packaged on July 26, through July 30, 1973, and retained unlabeled, labeled under the Pro-Go Products, Inc. label on November 26, through November 29, 1973. (See # 3, c, above) (See Exhibit 23)

    b. Production work order (packaging and labeling record) failed to show whether 45 jars, 2 ounces per jar, lot number 50262, retained unlabeled at 12791 Main Street, Garden Grove, have been labeled.

    c. Label claims, as mentioned in # 3 and # 14 above, made "Pro-Go Super Derma-E Balm", lot number 50262, labeled on this date, a drug as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

16. Prescription drug, labeled as "Magnesium, Potassium & Vitamin B-6", lot number 740122, identified as I.S. number A-67750, 25,000 tablets, manufactured on January 28, through February 6, 1974. (See Exhibit 24)

    a. Production work order (packaging and labeling record) showed that 255 bottles of "Magnesium, Potassium & Vitamin B-6", 100 tablets per bottle, packaged from lot number 740122, and labeled under the Westpro Labs, Inc. label on February 12, through February 13, 1974.

    b. Production order (master production and control record) for "Magnesium, Potassium & Vitamin B-6" was prepared by Mr. William Rueckert on November 8, 1973, and checked, reconciled, and approved by Mr. Kurt W. Donsbach on November 18, 1973, as required per Section 133.7 (a), Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21 , Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachments 11 and 12)

    c. Production order (batch production and control record) indicated that "Magnesium, Potassium & Vitamin B-6", lot number 740122, identified as I.S. number A-67750, contained 500 mg. of potassium bitartrate as an ingredient (also known as cream of tartar) which supplied at least 103.9 mg. of potassium per tablet. (See Exhibit 24, and Attachments 9 and 10)

d. Laboratory result on the sample, identified as I.S. number A-67750, showed that "Magnesium, Potassium & Vitamin B-6", lot number 740122, disclosed 103.00 mg. of potassium per tablet containing potassium bitartrate as a salt. (See Attachments 9 and 10, and I.S. slip, identified as I.S. number A-67750)

e. "Magnesium, Potassium & Vitamin B-6", lot number 740122, identified as I.S. number A-67750, considered as a Rx-drug according to Section 3.15 "Potassium salt preparations intended for oral ingestion by man.", Part 1 to 119, Title 21, Code of Federal Regulations, revised as of January 1, 1971. (See Attachments 4, 5, and 9)

17. Drug, labeled as "Pro-Go Super Derma-E Balm", lot number 50262, identified as I.S. number A-67731, 300 ounces, manufactured on July 27, 1973. (See Exhibit 11)

a. Production work order (packaging and labeling record), work order # 50282, showed that 45 jars of "Pro-Go Super Derma-E Balm", 2 ounces per jar, lot number 50262, from 95 jars packaged on July 26, through July 30, 1973, and retained unlabeled, labeled under the Pro-Go Products, Inc. label on August 14, through Agust 15, 1973. (See # 3, c, and # 15 above, and Exhibit 26)

b. Label claims, as indicated in # 3, # 14, and # 15 above, made "Pro-Go Super Derma-E Balm", lot number 50262, labeled on this date, a drug as defined in Sections 26002, 26010, 26016, and 26017, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code. (See Attachment 3)

Westpro Labs, Inc.

The inspection on this date obtained the following:

1. Production orders (master production and control records), production orders (batch production and control records), production work orders (packaging and labeling records), invoices and inventory control cards (distribution and components control records obtained as requested. (See Exhibits)

2. Samples obtained as per attached Official Sample Receipts, dated March 21, 1974. (See attached I.S. slips)

3. Copies of labels and all other labeling associated with the products manufactured by Westpro Labs, Inc. obtained as requested. (See Exhibit 4)

4. A copy of "Passport To Good Health" written by Kurt W. Donsbach obtained as a sample. (See Official Sample Receipt, and Exhibit 7, identified as I.S. number A-67744)

5. A copy of "Westpro-Gram, As-It-Is" published by Westpro Labs, Inc. obtained as requested. (See Exhibit 8)

6. A copy of Drug Manufacturing License, # 40299, expired on January 17, 1974, obtained as requested. (See Exhibit 5)

7. An attempt was made to obtain the appropriate laboratory control records for all the components and finished drug products, including numerous dietary supplements, manufactured by Westpro Labs, Inc. Mr. Bushong stated that Westpro Labs, Inc. did not have an adequate laboratory facility in order to test components, in-processed drugs, and finished products to assure their conformance with appropriate specifications of identity, safety, strength, quality, and purity.

8. Mr. Bushong also provided the following information:

   a. Westpro Labs, Inc. failed to obtain gurantees from the manufacturers or suppliers.

   b. Westpro Labs, Inc. had no labeling or labeling exemption agreements.

   c. Labels used for "Pro-Go Super Derma-E Balm" were provided by Pro-Go Products, Inc. However, Mr. H. O. Stanford, President of Pro-Go Products, Inc., stated in his letter, dated April 23, 1974, that "all labels were submitted to Dr. K. W. Donsbach for his review and approval <u>before</u> printing." (See Exhibit 27)

Westpro Labs, Inc.

Advised the management of Rich Life, Inc. to do the following immediately:

1. Rx-drugs, OTC drugs, dietary supplements, and cosmetic products previously manufactured by Westpro Labs, Inc. be voluntarily quarantined, and tested to assure their conformance with the appropriate standards of safety, identity, strength, quality, and purity prior to the distribution because Westpro Labs, Inc. failed to provide the appropriate laboratory controls.

2. Labels and all other labeling associated with the products previously manufactured by Westpro Labs, Inc. be reviewed to comply with the Fair Packaging and Labeling Act, and Amendments published in the Federal Register because nearly all products appeared to be misbranded to some degree by false and misleading claims.

The inspection of this date also revealed that numerous products were disintegrated or decomposed due to prolonged storage. Voluntary Condemnation and Destruction covered the destruction of these products listed as per attached. (See attached VC & D, dated March 21, 1974)

A follow-up inspection may be deemed necessary at this time.

744 P Street
Sacramento 95814
(916) 445-2264

1449 Temple Street
Los Angeles 90026
(213) 620-2965

30 Van Ness Avenue
San Francisco 94102
(415) 557-1860

STATE OF CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG
2151 BERKELEY WAY, BERKELEY 94704
(415) 843-7900

68 North Winchester
Santa Clara 95050
(408) 244-1353

5545 E. Shields Avenue
Fresno 93727
(209) 291-6676

31 E. Channel Street
Stockton 95202
(209) 464-6533

VOLUNTARY CONDEMNATION AND DESTRUCTION

Date MARCH 21st, 1974

Firm Name WESTPRO LABS, INC. License Number 40299

Address 12791 MAIN STREET, GARDEN GROVE, CA. 10422 STANFORD STREET, GARDEN GROVE, CA. City GARDEN GROVE, CA. 92640 GARDEN GROVE, CA. 92641

Person Interviewed MR. G. MACOMBER, PRES. - MR. UNG, Q.C. MR. WARD, CONT. - MR. J. BUSHONG MR. TURLEY - PRODUCTION MANAGER Position

I (We) hereby voluntarily agree to the condemnation and destruction of the following material:

HEMOTONE THERAPEUTIC TABLETS - LOT NO. 67177 - 9,500 TABLETS

ECTOVITE - 109027 (QUAL. CHEM.) - 24,965 TABLETS

125 Mg. CHEWABLE C - 202035 (QUAL. CHEM.) - 21,072 TABLETS

PRO-GO WAFERS - 21236 (BIRCH) - 21,250 TABLETS

CALCIUM WITHOUT PHOSPHORUS - 17249 (AUSTRA) - 23,275 TABLETS

BONE MEAL TABLETS - LOT NO. 18154 - 123,800 TABLETS

AQUA PLEX - LOT NO. 47201 - 87,320 TABLETS

DOLOMITE - LOT NO. 014170 - 31,944 TABLETS

ASCORBIC ACID 100 Mg. - LOT NO. 019209 - 28,107 TABLETS

NONCHEWABLE VITAMIN C 250 Mg. - LOT NO. 730926 - 3,414 TABLETS

said material being unfit for human consumption or otherwise in violation of the California Health and Safety Code, Division 21, Chapters 1 through 8, the disposition of which is provided for by Chapter 8, Article 3, Section 26837.

I (We) hereby release the California State Department of Public Health and its agents from any and all liability.

Date and Method of Destruction: Dumped into trash container and denatured with steam and water. on the date indicated above.

Witness: K.L.

(Authorized Agent)

WESTPRO LABS, INC.
(Name of Firm)

X M E Turley
(Authorized Representative of Firm)

12791 MAIN STREET, GARDEN GROVE, CA. 92640
(Address)

(City or Town)

744 P Street
Sacramento 95814
(916) 445-2264

1449 Temple Street
Los Angeles 90026
(213) 620-2965

30 Van Ness Avenue
San Francisco 94102
(415) 557-1860

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Santa Clara 95050
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5545 E. Shields Avenue
Fresno 93727
(209) 291-6676

31 E. Channel Street
Stockton 95202
(209) 464-6533

OFFICIAL SAMPLE RECEIPT

Date MARCH 21st, 1974

Firm Name WESTPRO LABS, INC. License Number 40299

Address 12791 MAIN STREET City GARDEN GROVE, CA. 92640

Person Interviewed MARSHALL TURLEY, JACOB BUSHONG, SIEU UNG Position PRODUCTION MANAGER, PRODUCTION MANAGER, QUALITY CONTROL

The following material was this day taken as official samples under provisions of the Health and Safety Code, Division 21, Chapter 2, Article 3, Section 26232. "An authorized agent of the department may secure any sample or specimen of any food, drug, device, or cosmetic. If the agent obtains any samples prior to leaving the premises, he shall leave a receipt describing any sample obtained."

Quantity	Size of Unit	Material	L.S. No.
Approx	35 Lbs.	Labeled as "Potassium, Magnesium and B-6", Lot #B1106	A-67724
1	180 Lbs.	Juvo Per, Lot # 730428	A-67727
1	100 Lbs.	Brand of Acetaminophen, Analgesic, Lot # 3230	A-6772
1	100 Lbs.	Pan Enz 500, Lot # 2702	A-67729
1	60 Lbs.	Juvo Per, Lot # 730618	A-67730
1	2 Oz.	Super Derma-E Balm, Lot # A50262	A-6773
1	250 Lbs.	Pan Enz. 500, Lot # 730534	A-67732
1	250 Lbs.	Enz., Lot # 731112	A-67733
1	250 Lbs.	Enzyid, Lot # 730934	A-67734
1	100 Lbs.	A-C Plus E., Lot # 2989	A-67735
1	100 Lbs.	Enz, Lot # 730807	A-67736

Remarks Duplicate sample not retained Compliance Sample. The products identified as I.S. No. A-67726, Sampled from bulk.

Receipt acknowledged by

X _____ Signature

X _____ Firm Name

By _____ Authorized Agent

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DEPARTMENT OF PUBLIC HEALTH

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Fresno 93727
(209) 291-6676

31 E. Channel Street
Stockton 95202
(209) 464-6533

OFFICIAL SAMPLE RECEIPT

Date [illegible] 21st, 1974

Firm Name WESTPR[illegible]   License Number [illegible]

Address 12791 [illegible]   City [illegible], CA. [illegible]

Person Interviewed [illegible]   Position [illegible] PRODUCTION MANA[illegible] / [illegible] CONTROL

The following material was this day taken as official samples under provisions of the Health and Safety Code, Division 21, Chapter 2, Article 3, Section 26232. "An authorized agent of the department may secure any sample or specimen of any food, drug, device, or cosmetic. If the agent obtains any samples prior to leaving the premises, he shall leave a receipt describing any sample obtained."

Quantity	Size of Unit	Material	L.S. No.
Approx 35 Tabs		Labeled as "Potassium Magnesium and B-6" Lot#	
1	180 Tabs	[illegible] Lot # 730428	
1	100 Tabs	[illegible] Lot #	
1	100 [illegible]	[illegible] Lot # 770[illegible]	
1	60 [illegible]	[illegible] Lot # 7[illegible]61[illegible]	
1	2 oz.	[illegible] - [illegible] Lot # A50[illegible]	
1	250 Tabs	[illegible] 500, Lot # 730534	
1	250 Tabs	Enz. Lot# B1112	
1	250 Tabs	[illegible] Lot# 730934	
1	180 Tabs	A-C Plus E, Lot# 7989	
1	180 Tabs	[illegible] Lot # 730807	

Remarks [illegible] [illegible] [illegible] Complaint [illegible] the product identified as I.S. No. A-67726 [illegible]

Receipt acknowledged by

[signature]

Signature

Firm Name

By [signature]

Authorized Agent

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31 E. Channel Street
Stockton 95202
(209) 464-6533

OFFICIAL SAMPLE RECEIPT

Date MARCH 21st, 1974

Firm Name WESTPRO LABS, INC. License Number 40299

Address 12791 MAIN STREET City GARDEN GROVE, CA. 92640

Person Interviewed MARSHALL TURLEY, JACOB BUSHONG, SIEU UNG Position PRODUCTION MANAGER, PRODUCTION MANAGER, QUALITY CONTROL

The following material was this day taken as official samples under provisions of the Health and Safety Code, Division 21, Chapter 2, Article 3, Section 26232. "An authorized agent of the department may secure any sample or specimen of any food, drug, device, or cosmetic. If the agent obtains any samples prior to leaving the premises, he shall leave a receipt describing any sample obtained."

Quantity	Size of Unit	Material	L.S. No.
1	100 Tabs.	Enzy., Lot#731111	A-67737
1	90 Tabs.	Formula K, Lot # A7210	A-67738
1	60 Tabs.	Iron Pep, Lot # 730414	A-67739
1	Approx 30 Tabs.	Labeled as "Enz.", Lot # 730933	A-67740
1	100 Tabs.	Vitamin A+D, Lot #204032	A-67741
1	100 Tabs.	Soft-Tex, Lot #87165	A-67742
1	100 Tabs.	Vitamin A+D, Lot # 3054	A-67743
1	ea.	"Passport to Good Health"	A-67744
1	100 Caplets	Rheumaplex, Lot#730607	A-67745
1	100 Tablets	Enzaid, Lot # 730521	A-67746
1	Approx. 20 Tabs.	Labeled as "Lymgest", Lot#3065	A-67747

Remarks Duplicate samples not retained Compliance samples. The products identified as I.S. # A-67740 and A67747, sampled from bulk.

Receipt acknowledged by

X _____ Signature

_____ Firm Name

By _____ Authorized Agent

744 P Street
Sacramento 95814
(916) 445-2264

1449 Temple Street
Los Angeles 90026
(213) 620-2965

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STATE OF CALIFORNIA

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Santa Clara 95050
(408) 244-1353

5545 E. Shields Avenue
Fresno 93727
(209) 291-6676

31 E. Channel Street
Stockton 95202
(209) 464-6533

OFFICIAL SAMPLE RECEIPT

Date _____

Firm Name MEDPRO LABS, INC. License Number _____

Address 12791 MAIN STREET MARSHALL TURL City _____

Person Interviewed JACOB BUSHOS SIEU UNG Position _____

The following material was this day taken as official samples under provisions of the Health and Safety Code, Division 21, Chapter 2, Article 3, Section 26232. "An authorized agent of the department may secure any sample or specimen of any food, drug, device, or cosmetic. If the agent obtains any samples prior to leaving the premises, he shall leave a receipt describing any sample obtained."

Quantity	Size of Unit	Material	L.S. No.
1	100 Tabs.	Zoo. Lot # 73111	
1	90 Tabs.	Formula K Lot # 731	
1	60 Tabs.	Fem Lot # 731	
	Remove 30 Tabs.	Labeled as Vita Lot # 73	
1	100 Tabs.	Tri-Vites A + D Lot # 3	
1	100 Tabs.	Multi-Vit Lot # 7316	
1	100 Tabs.	Vitamin A + D Lot # 3154	
1	ea.	"Ways to Good Health"	
1	100 Cplts.	Niacinamide Lot # 73C607	
1	100 Tablets	Ferrous Lot # 73C521	
1	approx. 30 Tabs.	Labeled as "Lovast" Lot # 73C65	

Remarks Replicate samples not retained. Complete samples identified as L.S.# 6740 and 6741 sampled from bulk

Receipt acknowledged by

_____ Signature

_____ Firm Name

By _____ Authorized Agent

446-118 (REV. 12-70)

Westpro Labs, Inc.

12791 Main Street, and
10422-10428 Stanford Avenue,
Garden Grove, CA 92640

On March 15, 1974, the inspection of Westpro Labs, Inc., at 12791 Main Street, 10422 and 10428 Stanford Avenue, Garden Grove, was made as a follow-up.

Interviewed the following personnel on this date:

1. Gary Macomber, Vice President of Rich Life, Inc.
2. Marshall E. Turley, Production Manager of Rich Life, Inc.
3. Sieu Ung, Quality Control Manager of Rich Life, Inc., and an exemptee at Rich Life, Inc.
4. Jake Bushong

This inspection obtained the following information:

1. Mr. Macomber stated the following:
   a. The manufacturing facilities of Westpro Labs, Inc., except the manufacturing facility of cosmetic products at 12791 Main Street, 10422-10428 Stanford Avenue, Garden Grove, will be moved completely to Rich Life, Inc. in El Monte, somtime between March 29, and April 1, 1974.
   b. The manufacturing facility for cosmetic products will be remained at 12791 Main Street, Garden Grove, for at least next 2 to 3 months.
   c. Moxie Industries, Inc. had leased the building at 12791 Main Street, Garden Grove, from "Doctor" Donsbach for cosmetic product manufacturing.
   d. The buildings located at 10422 and 10428 Stanford Avenue, Garden Grove, will be vacated as soon as the manufacturing facilities and warehouse stocks be removed to Rich Life, Inc. in El Monte.
   e. Moxie Industries, Inc. had acquired the manufacturing facilities, brand names, the securities and all other escrow condition of Westpro Labs, Inc. as of December 28, 1974.
   f. Moxie Industries, Inc. had paid the sum of approximately $500,000.00 for the manufacturing facilities, brand names, the securities and escrow condition of Westpro Labs, Inc. Mr. Macomber thought that $500,000.00 was reasonable for Westpro Labs, Inc. with the annual gross sales of approximately $1,200,000.00 in 1973. (See Exhibit 6)
   g. Mr. Macomber stated that the versatile and energetic "Doctor" Kurt W. Donsbach has been well known to the health food industries, and that "Doctor" Donsbach will be employed by Rich Life, Inc. as a sales consultant to provide lectures extensively on nutrition and the practical application of nutrition to the conventions, church groups, social clubs and organizations.
   h. Moxie Industries, Inc. also had acquired the distributorship of "Passport to Good Health" written by "Doctor" Donsbach.
   Mr. Donsbach was an author of "Passport to Good Health", (Your Nutritional Guide to Good Living), which he extols the virtues of various

nutritional products in what he considered as Preventive Organic Medicine, which coincidentally, are being marketed by Westpro Labs, Inc. (See Exhibit 7, identified as I.S. No. A-67744)

i. Mr. Donsbach will retain the editing right of a book called "Passport To Good Health"

j. Mr. William W. Ward will be also employed by Rich Life, Inc.

2. Westpro Labs, Inc. had regularly published an editorial called "Westpro-Gram", "As-It-Is" in which Westpro Labs, Inc. also extols the virtues of various information relative to nutrition and preventive organic medicine. (See Exhibit 8) Westpro Labs, Inc. had sold a copy of this editorial for ten cents directly to the consumers in conjunction with the Westpro Labs, Inc. products. (See Exhibit 1)

Mr. Macomber stated that Moxie Industries, Inc. also had acquired the distributorship of an editorial.

This inspection revealed the following on this date:

1. Westpro Labs, Inc. had moved the manufacturing facility of protein powder (mixing, packaging and labeling operation) to 10428 Stanford Avenue, Garden Grove. Mr. Bushong stated that this change had made to prevent the possibility of cross contamination caused by protein powder, and as the result of an inspection made on March 6, 1973.
2. Drug products were being manufactured on the premises without the benefit of registered pharmacists or exemptees as defined in Sections 4050, and 4050.5, Business and Professions Code, State of California. (See Attachment 2, and Exhibits 9 through 24)
3. Drug products, as defined in Section 26010, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, were being manufactured on the premises. (See Attachments 3,4, and 5, and Exhibits 9 through 24)

This inspection of Westpro Labs, Inc. at 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, California 92640, revealed the deviations from the Current Good Manufacturing Practice Regulations under the Federal Food, Drug, and Cosmetic Act, Part 133, Title 21, Code of Federal Regulations, as defined in Section 26209, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, for drugs, among others,as follows: (See Exhibits 1, and 9 through 24)

Section 133.3 Buildings.

1. The buildings not maintained in a clean and orderly manner.
2. The buildings failed to provide suitable storage conditions for drug components, in-process materials, and finished drug products.
3. The buildings failed to provide adequate ventilation facilities to minimize contamination of products by extraneous adulterants, including cross-contamination by dust or particles of ingredients arising from the manufacture, storage, or handling of another products.

Section 133.4 Equipment.

1. Equipment used for the manufacture, processing, packing, labeling, holding or control of drugs not maintained in a clean and orderly manner.
2. The equipment not adequately cleaned in that all surfaces that come into contact with a drug product not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, and purity of the drug or its components.
3. The equipment not adequately installed to facilitate adjustment, disassembly cleaning and maintenance to assure the reliability of control procedures uniformity of production and exclusion from the drugs of contaminants from previous and current operations that might affect the safety, identity, strength, quality, or purity of the drug.

Section 133.5 Personnel.

1. The personnel responsible for directing the manufacture and control of the drug not adequate in number.
2. The personnel responsible for directing the manufacture and control of the drug not adequate in background of education, training, and experience.

Section 133.6 Components.

1. All components and other materials used in the manufacture, processing, and packaging of the drug products not stored and handled in a safe, sanitary, and orderly manner.
2. Control of components failed to include adequate provision in order to take a representative number of component containers from each lot, and to have one or more tests to establish the specific identity.
3. Representative samples of components liable to contamination or microbial contamination not appropriately examined.
4. Representative samples of all components intended for use as an active ingredient not tested to determine the strength to assure conformance with appropriate specifications.
5. Components not retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality, and purity purport to possess.
6. Appropriate records failed to maintain the following:
    a. The identity and quantity of the component, the name of the suppliers, the supplier's lot number, and the date of receipt not accurate.
    b. Exmainations and tests not performed at all.
    c. An individual inventory and record for each component used in each batch of drug manufactured or processed not accurately retained.
7. An appropriately identified reserve sample of all active ingredients not retained.

Section 133.7 Master production and control records; Batch production and control records.

1. Master production and control records, and batch production and control records not adequately reviewed to assure the products meet the appropriate specifications, and failed to include the following:
    a. A specimen or copy of each label and all other labeling associated with

the products not included, and failed to review adequately by the person or persons responsible for approval of such labeling.

b. A description of the container, closures, and packaging and finishing materials not adequate.

c. Manufacturing and control instructions, procedures, specifications not adequately described.

2. The batch production and control record prepared for the batch that was not manufactured at all.
3. The batch production and control record failed to identify lot or control number assigned on the batch that was not manufactured at all.
4. A record of each significant step in the manufacturing, processing, packing, labeling, and controlling of the batch not checked adequately.

Section 133.8 Production and control procedures.

1. Production and control procedures failed to provide all reasonbale precautions, including the following to assure that the drugs produced have the safety, identity, strength, quality, and purity they purport to possess:
   a. Each significant step in the process, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, weighing, and measuring during various steps of the processing, and the determination of the finished yield not adequately checked by a competent and responsible individual.
   b. To minimize contamination and prevent mixups, the equipment, utensils, and containers not thoroughly and appropriately cleaned, and properly stored.
   c. Appropriate precautions not taken to minimize contamination or cross-contamination in the production.
   d. Adequate in-process controls and sampling procedures not established at all to assure the uniformity and integrity of the products.
2. Representative samples of all dosage form drugs not tested to determine their conformance with the specifcations for the products.
3. Adequate procedures not established to do the following:
   a. Review and approval of all production.
   b. A thorough investigation of any unexplained discrepancy or the failure of a batch to meet any of its specifications.
   c. A wrritten record of the investigation not made at all.

Section 133.9 Product containers and their components.

1. Suitable specifications, test methods, and procedures not used to assure that containers, closures, and other components are suitable for intended use.
2. Suitable specifications, test methods, and procedures not established to assure that containers, closures, and other components not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components.

Westpro Labs, Inc.

Section 133.10 Packaging and labeling.

Packaging and labeling operation not adequately controlled to assure that correct labels and labeling are used for the drugs, and failed to include the following:

1. The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual not made to assure that they are accurate regarding identity, content, and conformity with the approved copy.
2. Restriction of access to labels and packaging labeling only to authorized personnel.
3. Labeling controls failed to provide strict control of the package labeling issued for use with the drug.
4. The appropriate records failed to identify the labeling, and the quantities issued and used.
5. The appropriate records failed to reconcile any discrepancy between the quantity of drug finished, and the quantity of labeling issued.
6. The appropriate records failed to show the quantities of all excess package labeling bearing lot or control numbers being destroyed.
7. Packaging and labeling operations failed to provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations, and to prevent distribution of any batch until all specified tests have been met.

Section 133.11 Laboratory controls.

Laboratory controls failed to include the establishment of appropriate specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality, and purity as follows:

1. The establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers, and their components used in drug production and packaging and a description of the sampling and testing procedures used for them.
2. The establishment of master records containing specifications and a description of sampling and testing procedures for in-process drug preparations.
3. The establishment of master records containing a description of sampling procedures, and appropriate specifications for finished drug products.
4. Adequate provisions for checking the identity and strength of drug products for all active ingredients.
5. Adequate provisions for auditing the reliability, accuracy, precision,

and performance of laboratory test procedures and laboratory instruments used.

6. A properly identified reserve sample of the finished drug products (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the required tests not retained at all.

Section 133.12 Distribution records.

1. Finished goods warehouse control and distribution procedures failed to include a system by which the distribution of each lot of drug can readily determined to facilitate its recall if necessary.
2. Distribution records failed to include the appropriate lot or control numbers of the drugs.
3. Finished goods warehouse control failed to include a system whereby the oldest stock is distributed first whenever possible to assure the quality of the drug products.

Section 133.13 Stability.

The assurance of the stability of finished drug products not established at all.

Section 133.14 Expiration dating.

The drugs failed to have suitable expiration dates, if applicable, which relate to stability tests performed on the products to assure that drug products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use.

This inspection of Westpro Labs, Inc. at 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, California 92640, also revealed the deviations from the Fair Packaging and Labeling Act and Amendments published in Federal Register, Part 1, Title 21, Code of Federal Regulations, as defined in Section 26438, Division 21, Sherman Food, Drug, and Cosmetic Law, California Health and Safety Code, for drugs, among others, as follows: (See Exhibits 4, and 9 through 24)

Labels and all other labeling associated with drug products failed to include the following:

1. Adequate direction for use. (See Attachments 6 and 7)
2. Inconspicuous name of the products.
3. The quantities of all the active ingredients.
4. Appropriate warning or caution statement.
5. A qualifying phrase, such as "Distributed by...." or "Manufactured for and distributed by...."

Westpro Labs, Inc.

No attempt was made during this inspection to provide the Report of Observations since the management stated that the manufacturing facilities of Westpro Labs, Inc. will be moved to Rich Life, Inc. in El Monte. However, the aforementioned deviations were verbally discussed with the management.

Management stated the following relative to the deviations cited:

1. All the drug products, including dietary supplements, previously manufactured by Westpro Labs, Inc. will be volutarily quarantined, and tested to assure the safety, identity, strength, quality, and purity of the products purport to possess prior to the distribution as soon as the manufacturing facilities of Westpro Labs, Inc. are relocated.
2. Numerous deviations from the Current Good Manufacturing Practice Regulations will be corrected to comply. (See Attachment 7)
3. Labels and all other labeling associated with the Westpro Labs, Inc. products will be reviewed immediately to comply.
4. Ms. Nana Kraus, complainant, will be contacted immediately. (See Attachment 8)

Management was requested to provide the following: (See Exhibits)

1. A copy of Drug Manufacturing License retained by Westpro Labs, Inc. at 12791 Main Street, Garden Grove, California 92640, that had expired on January 17, 1974.
2. A copy of application for consent to transfer securities subject to legend or escrow condition, and certification from the Secretary of Westpro Labs, Inc.
3. Appropriate master production and control records.
4. Appropriate batch production and control records.
5. Appropriate packaging and labeling records.
6. Representative samples.
7. Appropriate inventory records.
8. Appropriate distribution records.
9. Appropriate laboratory control records, if any.
10. Appropriate gurantees issued by the suppliers, if any.
11. Appropriate labeling or labeling exemption agreements, if any.
12. Appropriate labels and all other labeling associated with the products to be sampled.
13. Brochures, catalogs, circulars, or price lists, if any.
14. A book called "Passport To Good Health" written by Kurt W. Donsbach.
15. A copy of an editorial called "Westpro-Gram", "As-It-Is", published by Westpro Labs, Inc.

Mr. Bushong stated that all the records as listed above will be photocopied, and ready in approximately two to three days.

A follow-up inspection was tentatively scheduled to be made on Thursday, March 21, 1974.

LIMITED INSPECTION REPORT

KEYPUNCH: Punch Code 5 in Column 1, and Punch Code 3 in Column 2.

Phase of Inspection *(Col. 3)*
(0) ☒ Original

Entry Number *(Col. 4)*
(1) ☒ Add New Record
(3) ☐ Modify Record
(5) ☐ Delete - Remove Record

Firm File No. *(Col. 5 - 9)* 2 0 1 2 6

Date of Inspection *(Col. 10 - 15)* 0 3 | 1 3 | 7 4 (Mo. Day Yr.)

Firm Name: Westpro Labs, Inc.

Firm Address: 12791 Main Street, Garden Grove, California 92640

ACTIONS TAKEN	Col. No.	(0) NO	(1) YES	FOLLOW-UP ACTIONS NEEDED	Col. No.	(0) NO	(1) YES
V. C. AND D.	16	x		General Inspection	26		x
EMBARGO	17	x		Embargo Disposition	34	x	
EMBARGO DISPOSITION	18	x		Lab Chem. Anal.	36	x	
CITATION	19	x		Lab Micro. Anal.	38	x	
LAB SAMPLE	20	x		Adm. Rev. Label	40	x	
LABEL	21	x		Obtain Sample	42		x
ADVERTISING	22	x		Letter	44	x	
OTHER EVIDENCE	23	x		Hearing	46	x	
NONE	24	x		Citation	48	x	
OTHER	25		x	Other	50		x

file
6/21/71

COMMODITIES COVERED BY ACTIONS TAKEN:

Name	Col. No.	Commodity Code		
1. Drug Manufacturing License	52-54	9	1	1
2.	55-57			
3.	58-60			
4.	61-63			
5.	64-66			
6.	67-69			

See attached report.

Inspector's Name Ky Stephen Suh Inspector's I.D. No. 0 4 7 *(Col. 70-72)*

Joint Inspector's Name _____ Joint Inspector's I.D. No. _____ *(Col. 73-75)*

Original: L.A.
c: Sacramento

(Rev. 7/72) Form 446-140

Westpro Labs, Inc.

12791 Main Street, and
10422-10428 Stanford Avenue,
Garden Grove, CA 92640

On March 13, 1974, at approximately 10:00 hours, this inspection was made as the result of an "Assignment Memorandum", dated January 30, 1974. (See Attachment 1)

Westpro Labs, Inc. had manufactured products at three separate buildings located at 12791 Main Street, 10422 and 10428 Stanford Avenue, Garden Grove, California. (See Exhibit 1)

1. The building located at 12791 Main Street, Garden Grove, primarily consisted of the following:
    a. Office
    b. Component storage
    c. Weighing room
    d. Granulation process
    e. Drying process
    f. Tableting or compressing process
    g. Coating process
    h. Packaging and labeling operation
    i. Cosmetic product manufacturing process
    j. Finished product storage
    k. Shipping and receiving
2. The building located at 10422 Stanford Avenue, Garden Grove, consisted of the following:
    a. Office (warehouse control and sales)
    b. Labeling storage
    c. Finished goods warehouse
    d. Returned goods warehouse
    e. Shipping and receiving
    f. Cosmetic goods warehouse
3. The building located at 10428 Stanford Avenue, Garden Grove, consisted of the following:
    a. Component storage
    b. Protein powder packaging and labeling operation
    c. Shipping and receiving

Westpro Labs, Inc. was registered as a California Corporation. Products had been marketed under the Westpro Labs, Inc., the Metabolic Products, Star Brand, and Exquisite (cosmetic products) labels. This firm was also a private-label manufacturer, and had distributed products under numerous other labels. (See Exhibits 2, 3, and 4)

Westpro Labs, Inc.

Interviewed the following personnel on this date at 12791 Main Street, Garden Garden Grove:

1. Mrs. Elyse M. Donsbach, formerly Vice President of Westpro Labs, Inc.
2. William W. Ward, formerly Secretary and Treasurer of Westpro Labs, Inc., and currently with Rich Lfe, Inc., a subsidiary of Moxie Industries, Inc.
3. Jake Bushong, formerly Production Manager of Westpro Labs, Inc., and currently with Rich Life, Inc., a subsidiary of Moxie Industries, Inc.

The inspection at 12791 Main Street, Garden Grove, obtained the following information:

1. On the above date, at approximately 10:30 hours, Mrs. Elyse M. Donsbach stated that Westpro Labs, Inc. had been legally acquired by Moxie Industries, Inc. as of December 28, 1973. She further stated that Mr. John P. King, Jr., of Nagel, Regan & Davidson Inc., at MacArthur Plaza, 4299 MacArthur Boulevard, Newport Beach, California 92660, (Telephone: (714) 833-8151), was an attorney and had involved in the preparation of an application for consent on transfer of the securities or escrow condition of Westpro Labs, Inc.
   Mrs. Donsbach was quite receptive to this inspection, and stated that she was not certain at this time as to whether the cosmetic products previously manufactured and the brand name used by Westpro Labs, Inc. had been acquired by Moxie Industries, Inc.
   Mrs. Donsbach also stated that she did not have anything to do with Westpro Labs, Inc. any more, and Mrs. Donsbach had left the premises at approximately 11:00 hours. (See Exhibit 2)
2. Mr. Jake Bushong stated that Mr. Sieu Ung was an exemptee, State Board of Pharmacy Exemption Certificate # 1106, of Rich Life, Inc., and actually working at Rich Life, Inc., 4441 North Baldwin Avenue, El Monte, California 91734, and that Mr. Ung occasionally, probably once every two to three days, came to Westpro Labs, Inc. since Moxie Industries, Inc. had acquired the manufacturing facilities of Westpro Labs, Inc. in December last year.
   This information was also obtained directly from both Mr. Marshall E. Turley, Production Manager, and Mr. Sieu Ung, Quality Control Manager of Rich Life, Inc. when they were contacted by phone.
   This information was, however, quite contrary to what the application, submitted to Food and Drug Section on January 18, 1974 by Moxie Industries, Inc., had indicated in that Mr. Ung was as an exemptee, and a person responsible for drug manufacturing operation at Westpro Labs, Inc., 12791 Main Street, Garden Grove, California 92640. (See Exhibit 5 and Attachment 1)
3. Mr. Bushong also stated that Moxie Industries, Inc. was a parent corporation of Rich Life, Inc., and that the manufacturing facilities of Westpro Labs, Inc. at 12791 Main Street, and 10422-10428 Stanford Avenue, Garden Grove, except the manufacturing facility of cosmetic products, will be moved to Rich Life, Inc., 4441 North Baldwin Avenue, El Monte, sometime between March 29, 1974

and April 1, 1974.
In the view of this situation, no attempt was made during this inspection to provide the Report of Observations nor to verify any of the improvements which management claimed to have made in production procedures at this time.

4. Mr. William W. Ward was a former corporate Secretary and Treasurer of Westpro Labs, Inc., and currently joined Rich Life, Inc. in Whi ttier Office as a part of business transaction between Rich Life, Inc., a subsidiary of Moxie Industries, Inc. and Westpro Labs, Inc. Mr. Ward stated that he did not have any corporate position or title with Rich Life, Inc. at this time, but that he had owned approximately ten per cent of stocks in both Westpro Labs, Inc. and the building located at 12791 Main Street, Garden Grove.
Mr. Ward further stated that as far as he knew as a Corporate Secretary and Treasurer of Westpro Labs, Inc., there was no corporate or corporate officer changes had been made until Moxie Industries, Inc. had acquired the manufacturing facilities of Wespro Labs, Inc. on December 28, 1973. (See Exhibits 2, and 3)
A certified copy of statement by domestic corporation, provided by Secretary of State of the State of California, indicated that Westpro Labs, Inc. had the following corporate officers, (See Exhibit 3), as of January 25, 1973:
    1. Kurt W. Donsbach, President
    2. Elyse M. Donsbach, Vice President
    3. William W. Ward, Secretary and Treasurer
5. Mr. Ward also stated that the manufacturing facilities of Westpro Labs, Inc., except the manufacturing facility of cosmetic products, will be moved to Rich Life, Inc. in El Monte, and that Rich Life, Inc. had leased the building located at 12791 Main Street, Garden Grove, temporarily from "Doctor" Donsbach for cosmetic product manufacturing.

A follow-up inspection may be deemed necessary at this time.

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67746

Obtained on March 21, 1974, at 1630 p.m.

Sold as OTC drug

Label (copied in part) ENZAID, A digestive Aid, 100 tablets, Lot No. 730521, Distributed by Metabolic Porducts 12975 Main St., Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc./ Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor own
Name (Make three copies of Invoice and attach)

Address ditto above City

Inventory on Hand Undetermined Amount Sampled a bottle, 100 tablets/btl.

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ----

Where Stored ----

NOTIFIED JUN 12 1974

Dow 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9294 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sink L.A.

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 66451

Obtained on March 6, 1973, at 1300 ~~a.m.~~ p.m.

Sold as Dietary supplement

Label (copied in part) Formula LB. "Food for special dietary uses", 200 tablets, Lot No. 127157, Westpro Labs. Inc. Garden ~~Grove~~ Grove, Calif. 92640

Dealer Westpro Laboratories, Inc. Legal Status Corp.

Address 12791 Main St., and/or 10422-10428 Stanford Ave. City Garden Grove 92640

License No. 40299 County Orange

Salesman Kurt W. Donsbach Price Paid None. Payment Refused r.g.

Guarantor ~~xxxxx~~ Linwilco Laboratories, Inc. (Name) See attached invoice No. 11941 (Make three copies of Invoice and attach)

Address ~~xxxxxxxxxxxxxx~~ 2148 Newport Blvd., City Costa Mesa, Calif. 92627

Inventory on Hand 1 bottle, 100 tabs./btl. Amount Sampled 1 bottle, 200 tabs./btl.
120 btls., 200 tabs./btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

MOTHER'S AUG 9 1973

(1) 3-12-73

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA 7999 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 200 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sick L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-4610

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 7999

I.S. No. A 66451

FOOD AND DRUG REPORT

Date Samples Received by Lab: 3/12/73 **Number of Samples Received:** 1

Sold as : Dietary Supplement

Label : Formula LB "Food for Special Dietary Uses", 200 Tablets, Lot # 127157
Westpro Labs., Garden Grove, California 92640

Dealer : Westpro Laboratories, Inc.
12791 Main Street and/or 10422-10428 Stznford Ave, Garden Grove, CA

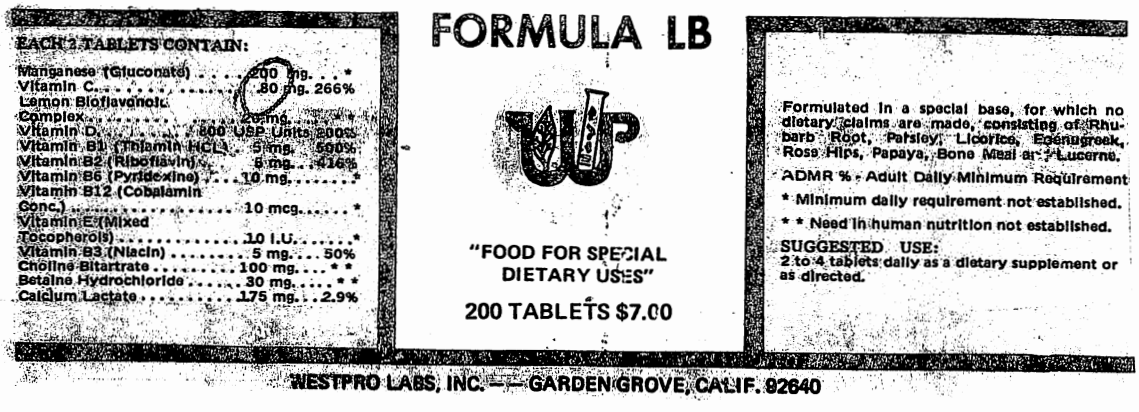
Inspector: K. Suh

Violative

Contents -	218 tablets
Vitamin B_1 -	3.2 mg/2 tablets - 64% of label
Vitamin C -	80.3 mg/2 tablets
Manganese	21.6 mg/2 tablets - 10% of label

Donald E. Paulsen
DEP:rj
7/26/73

8/13/73



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. Nº A 66456

Obtained on March 6, 19 73, at 1300 p.m.

Sold as Dietary supplement

Label (copied in part) One-Per, An all Natural Multiple Vitamin & Mineral Complex, 90 tablets, Lot No. 37218, Westpro Labs., Inc., Garden Grove, Calif. 92640

Dealer Westpro Laboratories , Inc. Legal Status Corp.

Address 12791 Main St., and/or 10422-10428 Stanford Ave., City Garden Grove 92640

License No. 40299 County Orange

Salesman Kurt W. Donsbach Price Paid None. Payment Refused r.g.

Guarantor Austra Chemicals, Inc. (Name) See attached Invoice No. 282 (Make three copies of Invoice and attach)

Address 18130 Mt. Washington, City Fountain Valley 92708

Inventory on Hand 97 btls., 30 tabs./btl. 69 btls., 90 tabs./btl. Amount Sampled 2 bottles, 90 tabs./btl.

Quarantine Established None. (Amount, size of container and codes)

NOTIFIED JUL 18 1973

Reason for Quarantine ---

Where Stored ---

(D) Ok 3-12-73

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA7984 Chief's Citation No.

Amount of Sample Submitted 2 btls.,90 tabs./btl Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentrations of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sack L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-4610

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 7984

I.S. No. A 66456

FOOD AND DRUG REPORT

Date Samples Received by Lab: 3/12/73 Number of Samples Received: 2

Sold as : Dietary Supplement
One-Per, An All Natural Multiple Vitamin & Mineral Complex - 90 Tablets

Label : Lot # 37218 Westpro Labs., Inc., Garden Grove, California 92640

Dealer : Westpro Laboratories
12791 Main Street, and/or 10422-10428 Stanford Avenue, Garden Grove, CA

Inspector: K. Suh

Vitamins

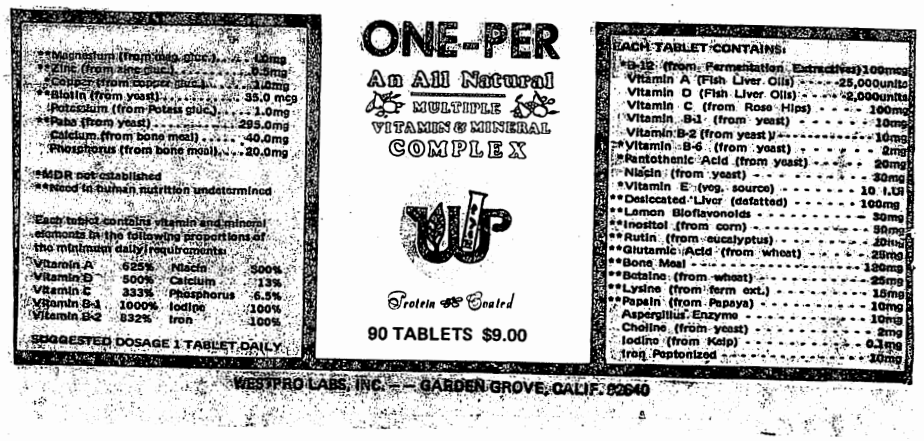
Contents -	90 tablets (2 chipped)
Vitamin A -	19,000 USP units per tablet - 74%
Vitamin C -	74 milligrams per tablet — 74%
Iron -	2.5 milligrams per tablet — 25%

Donald E. Paulsen
Mary L. Wanless
DEP-FEK-WRS-MAW:rj
6/29/73

of Food Lab

4-8/23/73

37218



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 66459

Obtained on March 6, 19 73, at 1300 ~~a.m.~~ p.m.

Sold as Dietary supplement

Label (copied in part) Complete food supplement, 180 caplets, Lot No. 214202, Westpro Labs., Inc., Garden Grove, Calif. 92640

Dealer Westpro Laboratories, Inc. Legal Status Corp.

Address 12791 Main St., and/or 10422-10428 Stanford Ave., City Garden Grove 92640

License No. 40299 County Orange

Salesman Kurt W. Donsbach Price Paid None. Payment Refused r.g.

Guarantor Linden Laboratories, Inc. (Name) See attached Invoice No. 59345 (Make three copies of Invoice and attach)

Address 5353 Grosvenor Blvd., City L.A., Ca. 90066

Inventory on Hand 26 btls., 360 caplets/btl. ~~70 btls., 180 caplets/btl.~~ Amount Sampled 1 btl., 180 caplets/btl.

Quarantine Established None. (Amount, size of container and codes) NOTIFIED JUL 18 1973

Reason for Quarantine ---

Where Stored ---

Dalle 3-12-73

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA7987 Chief's Citation No.

Amount of Sample Submitted 1 btl., 180 caps./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentrations of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sack (Inspector) L.A. (District)

(9-1-52) FORM 446-202 ATTACH ADDITIONAL DATA IF NECESSARY 65915-450 8-72 2M TRIP ② OSP

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-4610

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 7987

I.S. No. A 66459

FOOD AND DRUG REPORT

Date Samples Received by Lab: 3/12/73 Number of Samples Received: 1

Sold as : Dietary Supplement

Label : Complete Food Supplement, 180 caplets - Lot # 214202 - Westpro Labs., Garden Grove, California

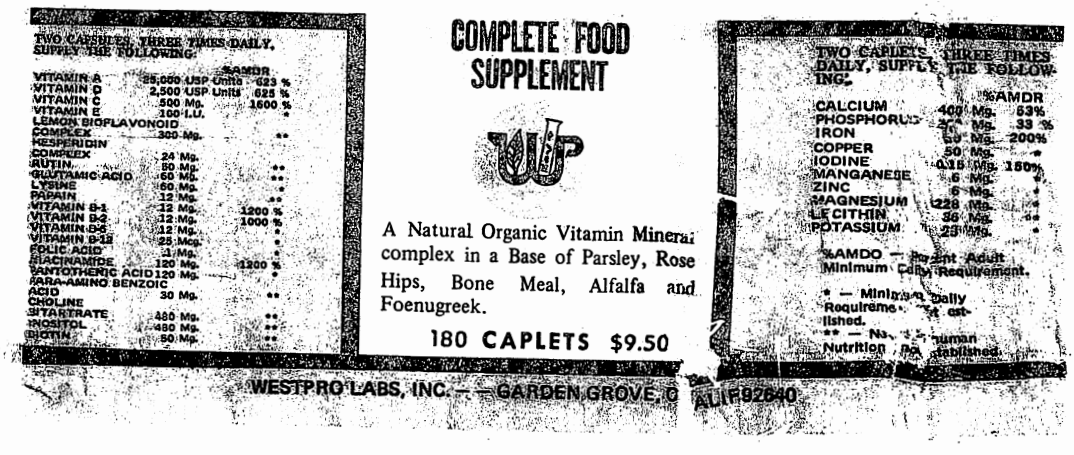
Dealer : Westpro Laboratories, Inc.
12791 Main Street, and/or 10422-10428 Stanford Avenue, Garden Grove, CA

Inspector: K. Suh

Contents - 179½ tablets
Iron - 28.5 mg/6 tablets
Vitamin A - 22,000 USP units/6 tablets
Vitamin C - 409 milligrams per 6 tablets

Mary A. Wallace F. E. Kirsham

WRS-FEK-MAW:rj
6/29/73



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 66463

Obtained on March 6, 19 73, at 1300 p.m.

Sold as Dietary supplement

Label (copied in part) All. 250 tablets. Lot No. 2614. Westpro Labs., Inc., Garden Grove, Calif. 92640

Dealer Westpro Laboratories, Inc. Legal Status Corp.

Address 12791 Main St., and/or 10422-10428 Stanford Ave., City Garden Grove 92640

License No. 40299 County Orange

Salesman Kurt W. Donsbach Price Paid None. Payment Refused r.g.

Guarantor own
Name (Make three copies of Invoice and attach)

Address ditto above City

Inventory on Hand 19 btls., 500 tabs./btl. 62 btls., 100 tabs./btl. Amount Sampled 1 bottle, 250 tabs./btl.

Quarantine Established None.
(Amount, size of container and codes)

NOTIFIED JUL 18 1973

Reason for Quarantine ---

Where Stored ---

(1) Ollie 3-12-73

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. CA7991 Chief's Citation No.

Amount of Sample Submitted 1 btl., 250 tabs./btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentrations of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Hall L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-4610

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 7991

I.S. No. A 66463

FOOD AND DRUG REPORT

Date Samples Received by Lab: 3/12/73 Number of Samples Received: 1

Sold as : Dietary Supplement

Label : All, 250 Tablets, Lot # 2614, Westpro Labs, Icn., Garden Grove, CA

Dealer : Westpro Laboratories, Inc.
12791 Main Street, and/or 10422-10428 Stanford Avenue, Garden Grove, CA

Inspector: K. Suh

Contents - 250 tablets
Vitamin C - 96 milligrams per 2 tablets
Iron - 23 mg/2 tablets
Vitamin A - 8000 USP units per 2 tablets

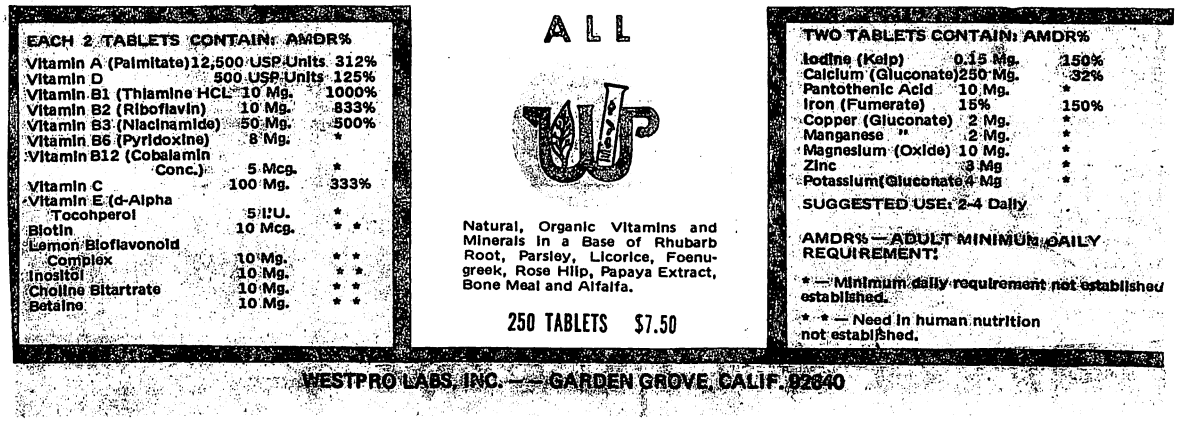
Deficiency

64% of Label

Mary A. Weadock J.E. Kirshaw

WRS-FEK-MAW:rj
6/29/73

8/13/73



STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. Nº A 66464

Obtained on March 6, 1973, at 1300 p.m.

Sold as OTC drug

Label (copied in part) Pan Enz 500, M P, 100 tablets, Lot No. 2702, Mx Metabolic Products, Division of Westpro Labs., Inc., Garden Grove, Calif. 92640

Dealer Westpro Laboratories, Inc. Legal Status Corp.

Address 12791 Main St., and/or 10422-10428 Stanford Ave., City Garden Grove 92640

License No. 40699 County Orange

Salesman Kurt W. Donsbach Price Paid None. Payment Refused r.g.

Guarantor own
Name (Make three copies of Invoice and attach)

Address ditto above City

Inventory on Hand 62 btls., 100 tabs./btl. ~~37 btls., 250 tabs./btl.~~ Amount Sampled 1 btl., 100 tabs./btl.

Quarantine Established None.
(Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

NOTIFIED JUN 7 1973

(1) Dan 3-12-73

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA7992 Chief's Citation No.

Amount of Sample Submitted 1 btl., 100 tabs./btl. Reseal and Hold for Evidence Mx Yes.

Reasons for Sampling Compliance sample. Check for the concentration of Pancreatin.

Adulteration x Misbranding x False Advertising

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sink L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-4610

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 7992

I.S. No. A 66464

FOOD AND DRUG REPORT

Date Samples Received by Lab: 3/12/73 Number of Samples Received: 1

Sold as : OTC Drug

Label : Pan Enz 500 - M P - 100 Tablets - Lot #2702 -Metabolic Products = Div. of Westpro Labs., Inc., Garden Grove, California 92640

Dealer : Westpro Laboratories
12791 Main Street and/or 10422-10428 Stanford Avenue, Garden Grove, CA

Inspector: K. Suh

Contents - 100 tablets/bottle
Lipase - 28 units/tablet
Amylase - 1900 units/tablet
Protease - 280 mg N.F. strength Pancreatin/tablet
Pancreatin - 280 mg N.F. strength Pancreatin based on the protease activity/tablet

Paul T. Clark
PTC:rj
5/31/73

Violation 602.1
Label Claim

Held K
7/3/73

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67726

Obtained on March 21, 1974, at 1630 a.m.
March 26, 1974 1630 p.m.

Sold as ~~Rx-drug~~ Rx-drug

Label (copied in part) Labeled as "Potassium, Magnesium and B-6", "Lot #731106", sampled from bulk, Manufactured by Westpro Labs, Inc., 12791 Main St., Garden Grove, CA 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marhsall Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand ~~161~~ bottles, 100 tabs./btl. Amount Sampled Approx. 35 tabs. on 3/21/74
2 bottles, 100 tabs./btl. on 3/26/74

Quarantine Established 161 bottles, 100 tablets/btl., Lot #731106. (Amount, size of container and codes)

Reason for Quarantine Adulterated and misbranded

Where Stored Westpro Labs, Inc.
12791 Main St., Garden Grove, CA 92640

(1) 4-12-74
(2) 4-15-74 (acct)

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

APR 25 1974

Laboratory No. LA 9275 Chief's Citation No.

Amount of Sample Submitted Approx. 35 tabs. and 2 bottles, 100 tabs./btl. Retained and Hold for Evidence Yes.

Reasons for Sampling Compliance samples. Check for the concentration of declared ingredients; K (elemental), Mg, and B-6.

Remark: According to the batch production and control records, one tablet consisted of 500 mg. of potassium bitartrate (Cream of Tartar).

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sak L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9275

I. S. NO. A 67726

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12 &4/15/74 Number of Samples Received: 1 and 2

Sold As : Rx-drug

Label : Labeled as "Potassium, Magnesium and B-6", Lot #731106, sampled from bulk, Manufactured by Westpro Labs, Inc.

Dealer : Westpro Labs, Inc., 12791 Main Street, Garden Grove, California 92640

Inspector: K. Suh

Small Bulk Bottle:	Potassium	425 mg/4 tablets (equivalent to 505 mg Potassium Bitartrate/tablets)
	Magnesium	205 mg/4 tablets
	Vitamin B-6	56 mg/4 tablets
Large Bottle of 100:	Potassium	415 mg/4 tablets (equivalent to 495 mg Potassium Bitartrate/tablets)
	Magnesium	205 mg/4 tablets
	Vitamin B-6	53 mg/4 tablets

Mary W. Claridge

WRS:MWC:dlj
4/25/74

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH

BUREAU OF FOOD AND DRUG

I. S. No. A 67727

Obtained on March 21, 19 74, at 1630 ~~a.m.~~ p.m.

Sold as [redacted] Drug

Label (copied in part) Two Per, 180 tablets, Lot # 730428, Star Brand, 10428 Stanford Ave., Garden Grove, CA 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall [redacted] Turley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached. (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 180 tabs./btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

(1) OAW 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9276 Chief's Citation No.

Amount of Sample Submitted 1 btl., 180 tabs./bt Reseal and Hold for Evidence Yes.

Reasons for Sampling [redacted] Compliance sample. Check for the concentration of declared ingredients which can readily determined.

Fe, I, Vit C

Adulteration x Misbranding x False Advertising

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Sak L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

(213) 620-3376

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
P. O. Box 30327, Terminal Annex
Los Angeles, California 90030

Lab. No. LA- 9276

I.S. No. A 67727

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 **Number of Samples Received:** 1

Sold as : Drug

Label : Two Per, 180 tablets, lot #730428, Star Brand

Dealer : Westpro Labs, Inc., 12791 Main St., and 10422-10428 Stanford Ave., Garden Grove, CA 92640

Inspector: K. Suh

Held per 6/21/74

Contents:	181 tablets
Vitamin C:	110 mg per 2 tablets
Iodine (as KI):	~~0.4~~ mg per 2 tablets
Iron:	~~6.6~~ mg per 2 tablets

300 lbs over

Paul T. Clark
Mary W Claridge

MWC:PTC:dlj
6/20/74

DIRECTIONS:
As a dietary supplement two tablets daily.
EACH TWO TABLETS CONTAINS:

Vitamin		M.D.R.
A (Water Sol.)	25000 USP Units	625%
D (Irr. Ergost.)	400 USP Units	100%
BALANCED B COMPLEX FACTORS:		
B-1 (Thiamine HCL)	25 mg.	2500%
B-2 (Riboflavin)	25 mg.	2083%
B-6 (Pyridoxine HCL)	25 mg.	**
B-12 (Cobal. Conc.)	50 mcg.	**
C (Ascorbic Acid)	150 mg.	500%
Inositol	250 mg.	*
Choline Bitartrate	150 mg.	*
Methionine dl	50 mg.	*
Rutin	25 mg.	*
Niacinamide	100 mg.	1000%
Pantothenic Acid	25 mg.	**
Vitamin E (Water Sol.)	12.5 I.U.	**
Citrus Bioflavonoid Com.	25 mg.	*
Para Amino Benzoic Add	25 mg.	*
Hesperidin Complex	5 mg.	*
Betaine HCL	25 mg.	*

TWO PER

180 TABLETS $9.50

STAR BRAND
10428 Stanford Avenue
Garden Grove, California 92640

Glutamic Acid	25 mg.	*
Bone Meal	87 mg.	*
Iron (Ferrous Fumerate) Buffered	5.7 mg.	57%
Magnesium (Oxide)	7.2 mg.	**
Manganese (Carbonat	6.1 mg.	**
Copper (Gluconate)	.25 mg.	**
Zinc (Gluconate)	.18 mg.	**
Iodine (Potassium Iodide)	0.1 mg.	100%
Phosphorus (Bone Meal)	13 mg.	1.7%
Calcium (Bone Meal)	29 mg.	3.8%
Folic Acid	0.1 mg.	**
Biotin	2 mcg.	*

In a base containing Alfalfa, Watercress, Parsley, Kelp and Lecithin.
M.D.R. - Minimum Daily Requisite.
* Need in human nutrition not established.
** M.D.R. not established.
A special sugar free coating, with excipients.

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67728

Obtained on March 21, 1974, at 1630 p.m.

Sold as OTC drug

Label (copied in part) Brand of Acetaminophen with Time release plus Vitamin C potassium, Magnesium, Zinc Analgesic, 100 tablets, Lot # 3230, Produced for Alacer Corp., Buena Park, Calif. 90620

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, Ca. 92640

License No. 40299 County Orange

Salesman Marshall Truley Price Paid None. Payment Refused r.g.

Guarantor Own (Name) See attached. (Make three copies of Invoice and attach)

Address Ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 tabs./btl.

Quarantine Established None. (Amount, size of container and codes)

NOTIFIED APR 25 1974

Reason for Quarantine ---

Where Stored ---

(i) Acct 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9277 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 tabs./Btl. Reseal and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of declared ingredients that can be readily determined.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Suk L.A.

STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH

SOUTHERN CALIFORNIA LABORATORY
1449 Temple Street, Room 101
(213) 620-3376 P. O. Box 30327m Terminal Annex
Los Angeles, California 90030

Lab. No. LA 9277

I. S. NO. A67728

FOOD AND DRUG REPORT

Date Samples Received by Lab: 4/12/74 Number of Samples Received: 1 (one)

Sold As : OTC Drug

Label : Brand of Acetaminophen with Time release plus Vitamin C potassium, Magnesium, Zinc Analgesic, 100 tablets, Lot #3230

Dealer : Westpro Labs, Inc., 12791 Main Street, and 10422-10428 Stanford Avenue Garden Grove, California 92640

Inspector: K. Suh

Held
6/21/74

Contents:	100 tablets
Vitamin C:	270 mg per tablet
Potassuim:	25 mg per tablet
Magnesium:	26 mg per tablet

Mary W. Claridge

MWC:WRS:dlj
4/24/74

PHEN

BRAND OF ACETAMINOPHEN WITH TIMED RELEASE VITAMIN C

Plus

Potassium, Magnesium, Zinc

ANALGESIC

Provides fast temporary relief for simple headache, minor muscular pains, and for pains of arthritis or rheumatism.

DOSE: Adults, 12 yrs and over—1-2 tablets. Children 5-11 yrs ¼-½ tablet. Dose may be repeated at 4 hr intervals—but not more than 3 times daily.

Produced for Abcer Corp. BUENA PARK, CALIF. 90620

100 tablets

Each tablet contains:		M.D.A.R.
Acetaminophen (3 grains)	325 mg.	None
Vitamin C (ascorbic acid)	250 mg.	833%*
Lemon Bioflavonoids	25 mg.	
Plus Minerals as		
(Potassium) Chloride	25 mg.	: : :
(Magnesium) Oxide	25 mg.	: : :
(Zinc) Carbonate	.5 mg.	

*National Research Council does not acknowledge any nutritional significance.
**Need in nutrition established but no minimum need determined.
M.D.A.R.: Minimum Daily Adult Requirement

NOTE:
VITAMIN C AND MINERALS ARE PRESENT AS FOOD SUPPLEMENTS ONLY. NO REPRESENTATION IS MADE THAT THEY EITHER MODIFY OR ENHANCE THE ACTION OF THE ANALGESIC, ACETAMINOPHEN.

CAUTION: If pain persists for more than 10 days, or redness is present, or in conditions affecting

WARNING: Do not give to children under 3 years of age or use for more than 10 days unless directed by physician.

Minerals present in tablet are chelated with Vitamin C (ascorbic acid) as dissolved in the intestinal tract.

Tablets are prepared under an exclusive process (U.S. Patent Pending) providing release of the Vitamin C present in the tablet into the body over a period of approximately 8 hours.

STATE OF CALIFORNIA—DEPARTMENT OF PUBLIC HEALTH
BUREAU OF FOOD AND DRUG

I. S. No. A 67729

Obtained on March 21, 19 74; at 1630 ~~a.m.~~ p.m.

Sold as OTC drug

Label (copied in part) Pan Enz 500, 100 tablets, Lot # 2702, Distributed by Metabolic Products Division of Westpro Labs, Inc., Garden Grove, Calif. 92640

Dealer Westpro Labs, Inc. Legal Status Corp.

Address 12791 Main St., and 10422-10428 Stanford Ave., City Garden Grove, CA 92640

License No. 40299 County Orange

Salesman Marshall E. Turley Price Paid None. Payment Refused r.g.

Guarantor own (Name) See attached (Make three copies of Invoice and attach)

Address ditto above City

Inventory on Hand Undetermined Amount Sampled 1 bottle, 100 tablets./btl.

Quarantine Established None. (Amount, size of container and codes)

Reason for Quarantine ---

Where Stored ---

JUN 6 1974

(1) Dell 4-12-74

MEMORANDUM TO LABORATORY OR FOR CHIEF'S CITATION

Laboratory No. LA9278 Chief's Citation No.

Amount of Sample Submitted 1 bottle, 100 tabs/Retained and Hold for Evidence Yes.

Reasons for Sampling Compliance sample. Check for the concentration of Pancreatin.

Adulteration x Misbranding x False Advertising x

Analysis Requested: Chemical x Microscopic Macroscopic

Insect Infestation Other Filth

Bacteriological Serological Organoleptic

Immediate Attention Yes. Product Is Perishable No.

Collected by K. Lark L.A.