



TruLabel™

Natural Products Association
LABEL REGISTRATION AND RANDOM TESTING PROGRAM





THE TRULABEL PROGRAM GUIDELINES

Label Registration and Random Testing

1.0 Introduction

TruLabel is the quality assurance program created and approved by the Board of Directors in July 1990. The Committee for Product & Label Integrity (ComPLI) administers the TruLabel program.

The major goals of the program are to:

- Create a high level of confidence on the part of retailers and consumers that products sold at retail in the industry are accurately labeled.
- Establish self-regulation as an ongoing process in the industry.
- Further demonstrate the maturity of the industry to legislators.
- Provide a database of products and ingredients available in the industry.

In 1995, the Board of Directors and membership adopted a by-law, which makes membership in TruLabel mandatory for supplier membership in the Natural Products Association. A brief synopsis of the requirements follows:

- 1.1 All suppliers of dietary supplement products sold to retail consumers shall enroll their product labels in TruLabel to maintain membership in the Natural Products Association.
- 1.2 Within 30 days of submission of new membership applications, companies joining the Natural Products Association must register TruLabel required products. Within 90 days of joining Natural Products Association, all product labels that may not have been available initially must be submitted.
- 1.3 New products must be registered within 90 days of introduction to the market.
- 1.4 Changes in product ingredients require updating of the product registration within 90 days of first marketing changed product.
- 1.5 The intent of the TruLabel requirement for the Natural Products Association membership is to assure that all labels bearing the name of a Natural Products Association supply member are registered with TruLabel.

2.0 The Program

2.1 Overview

TruLabel consists of a computerized database containing information on the label contents of products entered in the program. Products are periodically selected for laboratory analysis to confirm the label. Selection may occur through several mechanisms including:

- Selection of categories (such as vitamin C single ingredient) by ComPLI.
- Selection of best sellers, random selection of products.
- Selection based on complaints.

When discrepancies between label declarations and product content are found, the member company has two options: a) allow the failing test to be published in *Natural Products Association Now*; or b) enter the remediation process as defined in *Natural Products*

Association Policies and Procedures.

Laboratory results, which confirm the label claim, are published in *Natural Products Association Now*. Publication of adverse findings does not occur unless the discrepancy remains uncorrected or there is no cooperation from the label owner in resolving the discrepancy.

2.2 Label Entry

Labels are submitted with completed enrollment forms.

2.2.1 Form A provides general information about the registering company and must be signed by a Company officer.

2.2.2 Form B describes each specific product and must be submitted with an actual label attached.

2.2.3 The registration fee for each product label or change in product label is based on the number of components/ingredients for each label registered and must be paid at time of label registration as follows:

<u># of Ingredients</u>	<u>Fee per Label</u>
1-10	\$ 5.00
>10	\$10.00

There is a \$10.00 processing fee per Form A submitted. The registration fee for additional sizes of a product is \$2.00 per label.

2.2.4 Each product must be registered; including additional sizes and flavors of a product and those sold under different labels (different labels must be identified at time of submission). Products must be registered within 90 days of introduction to the market. Changes in product ingredients require updating of the product registration within 90 days of first marketing changed product.

2.2.5 TruLabel members are invoiced an annual maintenance fee of \$25.00 per company with an additional \$2.00 per currently registered label for the first 250 labels and \$1.00 per label over 250.

2.3 Label Review

The names, UPC numbers, and ingredients (including excipients and binders) of all products are entered into a computerized database. *Membership in TruLabel does not necessarily imply compliance with federal labeling laws.* The Natural Products Association does not review labels for compliance with federal labeling laws. It is the supplier's responsibility to ensure their labels and label claims are accurate and in compliance with all applicable regulations.

2.4 Testing

Products selected for testing are purchased from retail stores and/or distributors. Samples are encoded and submitted for analysis in unidentified form. The commercial laboratories used are selected based on their integrity, experience and reputation for the particular analysis required.

There is a maximum possible annual laboratory cost for any company entered in the program. The cost is based on the number of labels enrolled, as follows:

<u>Number of Registered Labels</u>	<u>Maximum Annual Laboratory Cost</u>
1 – 50	\$1,000
51 – 100	\$2,000
101 – 150	\$3,000

151 – 200	\$4,000
> 200	\$5,000

Initial testing costs and the cost of repeated testing required by discrepant results in first round analysis are paid for by the company up to the annual maximum. Invoices are payable upon receipt. Interest will be charged after 30 days. “Pass” reports will be withheld until payment is received. Failure to pay test costs within 30 days of receiving one notice of non-payment, will forfeit the right to have its passing result published in *Natural Products Association Now*, and the cost of the test will be added to the Supplier’s annual dues when such dues become next due.

Standards for testing used by TruLabel may be identical or similar to those adopted by the United States Pharmacopoeia (USP), and may include standards for variation from label claim, disintegration or dissolution time, microbial limits, etc. Other standards may be drawn from the United States Homeopathic Pharmacopoeia, the British Herbal Pharmacopoeia or the American Herbal Products Association’s Herbs of Commerce as deemed appropriate.

2.5 Data Reconciliation

When the laboratory results indicate compliance with label claim, a statement to that effect will be published in the Natural Products Association newsletter. When discrepancies between label declarations and product content are found, the member company has two options: a) allow the failing test to be published in *Natural Products Association Now*; or b) enter the remediation process as defined in the Natural Products Association Policies and Procedures. In the case of private label products where the actual manufacturer is not known, the company named on the label will be asked to have the manufacturer contact the Natural Products Association for remediation follow-up.

If the company successfully completes the remediation process, the successful remediation result will be published in *Natural Products Association Now*. If the company fails the remediation process, the initial failing test results, together with the remediation failure, will be published in *Natural Products Association Now*. In all cases, the published name will be the name on the label.

When analyses are performed, ComPLI will attempt to include all products enrolled in TruLabel which fall into the selected category and the fit the test criteria.

2.6 Data Update

- 2.6.1 An annual maintenance fee of \$25.00 per company with an additional \$2.00 per product is charged for up to 250 labels and \$1.00 per label over 250, for those labels which have not had revisions to product contents or label claims.
- 2.6.2 Members must notify the program within 90 days if a registered product has had revisions to either product content or label claim. Any product so revised must be re-submitted and registered as per 2.2 above.
- 2.6.3 Members must notify the program annually of any previously registered products, which have been discontinued for sale.
- 2.6.4 Members must notify the program within 90 days if a new product is released for sale. Any new product must be registered as in 2.2 above.

3.0 Additional Features

TruLabel is capable of additional services to the industry, which will be initiated under the direction of the Committee for Product & Label Integrity (ComPLI).

4.0 Public Relations

The public relations aspects of TruLabel are under development. Until enrollment was made mandatory, companies voluntarily enrolled in the program were allowed to use in their advertising, in trade publications only, statements such as “Member of Natural Product Association’s TruLabel Program”. This practice is now discontinued until the new mandatory program is firmly established.

5.0 Use of TruLabel Logo and Reference to TruLabel Program

Until further notice, the TruLabel logo and reference to the TruLabel program may not be used in any marketing material or by manufacturer representatives or others involved in marketing, sales or otherwise.

Revised September 2006

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The following is an excerpt from the current Natural Products Association Policies and Procedures that pertain to the TruLabel random testing and label registration program:

4. TruLabel and Good Manufacturing Practices

a. TruLabel: TruLabel is a random testing and label registration program, participation in which is mandatory for Natural Products Association Supplier members marketing dietary supplements. Rules and procedures for TruLabel shall be recommended by the Committee for Product and Label Integrity for Board approval and the program shall be administered by the Natural Products Association Scientific Affairs Department. Confidential probation and remediation, under Board-approved procedures, may be allowed for a Supplier failing a product test. Access to the TruLabel database will not be allowed without the express case-by-case approval of the Executive Committee after review by Natural Products Association legal counsel.

1. Board of Directors shall establish a fee schedule for TruLabel membership maintenance activities. Members of TruLabel agree to bear the costs of random product testing up to a maximum amount approved the Board of Directors. At the discretion of the Executive Director, fees due to the Natural Products Association by Supplier members whose products have been tested under TruLabel, shall be collected under the following policy:
 - Invoices are payable upon receipt
 - Highest legally allowable interest rate to be charged after 30 days
 - “Pass” reports withheld until payment received
 - Membership formally suspended after 60 days overdue
 - Extreme measures taken as advisable and determined by the Executive Committee, including but not limited to publishing the names of delinquent members or turning the account over to a collection agency
2. A member company whose product fails a TruLabel test has two options:
 - (a) Cease production and distribution of particular product; or
 - (b) Enter the remediation process.
3. The remediation process initially requires the affected Supplier to allow the Natural Products Association to re-test the product.
 - (a) The re-test will utilize a reserve portion of the sample from which the initial failing test result was obtained. If the product passes the re-test, no further remediation is necessary, and the passing result may be published in Natural Products Association publications (as with all passing results).
 - (b) If the product fails the retest, the product will be re-tested using 1) a new sample of the same lot, 2) a new sample of a different lot, or 3) retained sample from the manufacturer.
4. If the product fails the re-test as noted in 3(b), the remediation process further requires the affected Supplier to:
 - (a) Recall the entire lot of product from which the two failing test results were obtained;
 - (b) Immediately conduct an internal product failure investigation;
 - (c) Assign a cause or plausible explanation;

- (d) Determine necessary appropriate corrective/preventive follow-up action;
 - (e) Implement corrective/preventative follow-up action;
 - (f) Within 6 months, notify the Natural Products Association of the results of internal investigation and follow-up action(s);
 - (g) If the internal investigations reveals product failure cannot be effectively addressed so as to manufacture the product to meet label claim, the company must re-label the product or cease manufacture and sale of the product;
 - (h) If the internal investigation and follow-up actions effectively address product failure, the company must provide the Natural Products Association with a date after which lots can be expected to conform to label claim (include lot number of next batch of product distributed after corrective/preventative action has been taken);
 - (i) Submit to test of product from new lot as noted in (h) above;
 - (j) Submit to re-test of retained sample if product fails test noted in (i) above;
 - (k) Failure of this re-test will result in loss of Natural Products Association membership.
5. If the affected member company successfully completes the remediation process, the successful remediation result may be published in Natural Products Association publications.
 6. If the affected member company does not conduct the recall referenced in subparagraph 4(a) above, or if the Supplier fails to complete any aspect of the remediation process as noted in 4(b-k), the Supplier will be deemed to have failed the remediation process, lose its Natural Products Association membership, and the initial failing test results, together with the remediation failure will be published in Natural Products Association publications.
 7. A company that has lost its Natural Products Association membership due to failure to complete the remediation process or failure of the follow-up product test(s) as referenced in subparagraph (4, a-k) above, is not eligible for reapply for Natural Products Association membership for a period of one year.
 8. Loss of Natural Products Association membership due to failure to complete the remediation process or failure of the follow-up product test(s) as referenced in subparagraph (4, a-k), shall not result in the refund of any membership dues.
 9. The costs of the remediation process will be borne by the affected Supplier, except the cost of the re-test prescribed in subparagraph 3 above will be borne by the Natural Products Association if the product passes the re-test.
 10. A Supplier whose product initially passes a TruLabel test, but who fails to pay the Natural Products Association's invoice for the cost of the test within 30 days after receiving one notice of non-payment, may forfeit the right to have its passing result published in Natural Products Association publications, and the cost of the test will be added to the Supplier's annual dues when such dues next become due.

Revised and approved by the Natural Products Association Board of Directors November 2000

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GUIDELINES

The TruLabel Program is a dietary supplement label registration and random-testing program adopted by the Natural Products Association in 1990 and made a requirement for Supplier membership in 1995. This internal oversight program was designed to create a high level of confidence on the part of retailers and consumers that products sold in the marketplace are accurately labeled; establish an ongoing self-regulatory process within the industry; demonstrate industry maturity to legislators; and provide a comprehensive industry product database. ***As this is an internal oversight program, any reference to TruLabel Program membership or use of the TruLabel logo in any product marketing activities and/or materials (including product labels) is prohibited.***

All suppliers of finished dietary supplement products sold to retail consumers shall enroll their labels in TruLabel to maintain membership in Natural Products Association. Within 30 days of submission of new membership applications, companies joining Natural Products Association must register TruLabel required products. Within 90 days of joining the Natural Products Association, all product labels that may not have been available initially must be submitted. The intent of the TruLabel requirement for Natural Products Association membership is to assure that all labels bearing the name of a Natural Products Association Supplier member are registered with TruLabel.

In order to maintain membership in Natural Products Association, TruLabel members are required to register **new** products within 90 days of introduction to the market, and pay an annual maintenance and processing fee for all **previously registered** products. Registrants must also update product registrations within 90 days of first marketing products with changes in ingredients.

Foods and homeopathics are not required to be registered in the TruLabel Member Program. Products that are not ingested or otherwise incorporated into the body are also not required to be registered in the TruLabel Member Program. These products include health & beauty aids, books, clothing and equipment, etc.

The one-time, per product, label registration fee, based on number of ingredients, is determined as follows:

Number of Ingredients	1-10	> 10
Fee	\$5.00	\$10.00

There is an additional processing fee of \$10.00 for each Form A submitted. The fee for additional sizes of a specific product is \$2.00 per label. See Form B.

To enroll in the TruLabel Member Program, fill out the enclosed Form A, make copies of Form B as needed, attach actual product labels to the Form B, and send to Natural Products Association with the appropriate fee.

Should a product fall into a category selected for random-testing, laboratory fees are to be paid by the label owner up to an annual maximum based on the number of labels in the program:

Number of Labels	1-50	51-100	101-150	151-200	> 200
Maximum Possible Annual Lab Test Fees	\$1000	\$2000	\$3000	\$4000	\$5000

If there are any discrepancies found in the testing, procedures exist for resolving the discrepancy (see attachment B of the TruLabel Program Registration Packet).

Please note: Membership in TruLabel does not imply compliance with federal labeling laws. It is the supplier's responsibility to ensure their labels and label claims are accurate and in compliance with all applicable regulations.

If you have a question about the TruLabel program, please write or call the Natural Products Association at 1773 T St. NW Washington DC, 20009. Phone (202) 223-0101, FAX (202) 223-0250.

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ENROLLMENT FORM (FORM A)

Date: _____

Please Return to:

Natural Products Association
1773 T St. NW
Washington, DC 20009
Phone: (202) 223-0101; Fax (202) 223-0250

Instructions:

Each Company enrolling in the TruLabel Member Program needs to do the following:

- 1. Complete page 1 & 2 of enrollment form A**
- 2. Fill out a label application (Form B) for each product**
- 3. Attach actual label(s) or PDF to each Form B**
- 4. Submit Form A & B with full payment to the Natural Products Association**

Member # _____ Company Name _____

TruLabel Contact Name _____ Email _____

Street _____

City _____ State _____ Zip _____

Telephone _____ FAX _____

Enrollment Fees:

NUMBER OF PRODUCTS	FEE	SUBTOTAL
Number of products with 1-10 ingredients _____	x \$ 5.00	= _____
Number of products with 11 or more ingredients _____	x \$10.00	= _____
Number of additional sizes _____	x \$ 2.00	= _____
Processing fee		= \$10.00
TOTAL NUMBER OF LABELS _____	TOTAL \$	_____

Amount of Enclosed Check or Authorized Credit Card Payment: \$ _____

Credit Card # _____

(Visa, MasterCard or American Express only)

CID Number (usually on back of card) _____ Expiration Date _____

Authorized Signature _____

Cardholder's Billing Address _____

Please complete page 2 of Form A and include with enrollment materials.

1. Certification of TruLabel Applicant

I HEREBY CERTIFY THAT I HAVE AUTHORITY TO ACT ON BEHALF OF
_____ AND TO BIND _____

(Company Name)

(Company Name)

TO ALL PROMISES SET FORTH HEREIN. I FURTHER CERTIFY THAT THE FOLLOWING STATEMENTS ARE TRUE WITH RESPECT TO THIS APPLICATION TO THE TRULABEL PROGRAM AND WITH RESPECT TO EACH PRODUCT SUBMITTED FOR TRULABEL TESTING HEREUNDER:

On behalf of _____ :
(Company Name)

1. I hereby apply to the Natural Products Association for enrollment in the Natural Products Association's TruLabel Program, in accordance with and subject to the procedures and regulations of the Natural Products Association and the TruLabel Program. I have read and agree to the conditions set forth in the TruLabel Program Registration Packet covering the administration of the TruLabel Program. I agree to disqualification from participation in the TruLabel Program and forfeiture of Natural Products Association membership, in the event that any information provided to the Natural Products Association or to the TruLabel Program is false or in the event of violation of any rules or regulations governing the TruLabel Program.

2. I understand that TruLabel is an internal oversight program and that any reference to TruLabel Program Membership or use of the TruLabel Logo in any product marketing or materials (including product labels) is strictly prohibited. I further understand that membership in the TruLabel Program does not imply compliance with federal, state or local labeling laws, and that it is the responsibility of the member company to ensure that all labels and label claims are accurate and in compliance with all applicable legal requirements.

3. I hereby agree to hold the Natural Products Association, its members, officers, directors, employees, and agents, harmless from any complaint, claim, or damage arising out of any action or omission by any of them in connection with the TruLabel Program, this application, the application process, the requirements of TruLabel Program, the results of any TruLabel tests of product(s), the publication of a failing test result, or the lack of publication of a passing result on a TruLabel test. I UNDERSTAND AND AGREE THAT THE DECISION AS TO WHETHER ANY PRODUCT(S) PASS A TRULABEL TEST RESTS SOLELY AND EXCLUSIVELY WITH THE NATURAL PRODUCTS ASSOCIATION AND THAT THE DECISION OF THE NATURAL PRODUCTS ASSOCIATION IS FINAL.

I HAVE READ AND UNDERSTAND THESE STATEMENTS AND I INTEND TO BE LEGALLY BOUND BY THEM.

Company _____

Name _____ Title _____

Signature _____ Date _____



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**LABEL APPLICATION
(FORM B)**

ONE FORM FOR EACH PRODUCT
(Attach labels for all sizes of the product to this form)

New Product Registration Yes _____ No _____

Revision of Registered TruLabel Product

(check all that apply)

Product Name _____ Product Formula _____
(need to reregister product below)

Label Design _____ Sku/UPC # _____
(replacing sku/UPC # _____)

Date: _____

Member Number: _____ Company: _____

Product Name: _____

Number of ingredients: (Including all excipients, binders, etc.) 1 – 10 [\$5.00] > 10 [\$10.00] = \$ _____

Number of additional sizes and of this product (labels attached) _____ @ \$2.00 each = \$ _____

If the following information is not on the attached product label, please provide below:

UPC/SKU Code: _____

PLEASE ATTACH LABEL(S) or PDF TO BOX BELOW OR TO BACK OF FORM

(FOR ADHESIVE BACKED LABELS – PLEASE REMOVE BACKING ATTACH LABEL DIRECTLY TO FORM)