

Dietary supplements

**NSF International Standard/
American National Standard**

NSF/ANSI 173 – 2003



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NSF International Standard/
American National Standard
for Dietary Supplements —
Dietary supplements

Standard Developer
NSF International

Approved February 12, 2003
American National Standards Institute

Designated as an ANSI Standard
February 12, 2003
American National Standards Institute

Prepared by
The NSF Joint Committee on Dietary Supplements

Recommended for Adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
January 2003

Published by

NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

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Foreword²

The purpose of NSF/ANSI 173 – 2003 is to serve as an evaluation tool for analyzing dietary supplements. Certification to this Standard serves as a communication tool between manufacturers of ingredients and finished product, retailers, healthcare practitioners, and consumers. This Standard provides test methods and evaluation criteria to allow for the determination that a dietary supplement contains the ingredients claimed on the label, either qualitatively or quantitatively, and that it does not contain specific undeclared contaminants. In some instances, validated laboratory methods are not yet available for analyzing certain ingredients. In such cases, new methods will be added to this Standard as they become available.

NSF/ANSI 173 – 2003 was developed with participation from the dietary supplements industry, public health regulators, and distributors of dietary supplements. Participation and technical guidance was provided by representatives of the American Herbal Products Association, the American Pharmaceutical Association, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Institutes of Health, and the National Nutritional Foods Association.

Section 8 contains requirements for Good Manufacturing Practices (GMPs) based on the GMPs submitted by industry to the U.S. Food and Drug Administration (USFDA) in November 1995.³ When the USFDA publishes Good Manufacturing Practices, this document will be revised to be consistent with the USFDA's GMPs. Further clarification on the interpretation of these GMPs for certification to this Standard may be found in NSF's Certification Policies for Dietary Supplements.

NSF offers a certification program to this Standard. Products certified by NSF carry the NSF Mark, the leading mark in public health and safety certification around the world. The NSF Mark on a product gives consumers and retailers assurance that the product meets the requirements of the NSF Standard. For more information on the NSF certification program, please contact Kathy Pompliano at NSF International, P.O. Box 130140, Ann Arbor, Michigan 48113-0140 or at 1-734-769-8010.

Suggestions for improvement of this Standard are welcome. Comments should be sent to Chair, Dietary Supplements, c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140, USA.

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³ Federal Register, February 6, 1997 (Volume 62, Number 25), Docket No. 96 N-0417, 5699-5709

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NSF International Standard for Dietary Supplements —

Dietary supplements

1 General

1.1 Purpose

This Standard provides test methods and evaluation criteria for dietary supplement products to allow for the determination that the ingredients in the product are accurately identified and that the product contains the quantity of dietary ingredients and marker constituents declared on the product label and that the product does not contain unacceptable quantities of contaminants.

This Standard also provides criteria for determining that Good Manufacturing Practices were adhered to in the production of dietary supplements.

1.2 Scope

This Standard contains requirements for dietary supplements that bear or contain one or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. This Standard does not include products represented for use as conventional foods.

Products and ingredients deemed a hazard to public health or safety by a regulatory agency having jurisdiction shall be excluded from the scope of this document. Conventional foods shall be excluded from the requirements of this Standard.

2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this Standard. At the time this Standard was written, the edition indicated was

valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent edition of the document indicated below.

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Ashwagandha Root*, April 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Astragalus Root*, 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Bilberry fruit*, 2001⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Cohash root*, 2002⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Haw Bark*, June 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Chaste Tree Fruit*, 2001⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cranberry*, 2002⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cramp Bark*, 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Goldenseal*, 2002⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Berry*, June 1999⁴

⁴ American Herbal Pharmacopoeia, PO Box 5159, Santa Cruz, CA 95063

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Leaf with Flower*, February 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Reishi Mushroom*, September 2000⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *St. John's Wort*, July 1997⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Schisandra Berry*, October 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Valerian Root*, April 1999⁴

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Willow Bark*, December 1999⁴

AHPA, American Herbal Products Association, *Herbs of Commerce*, 2nd Edition, 2000⁴

AOAC International, Food and Drug Administration, *Bacteriological Analytical Manual*, eighth edition (1998)⁵

AOAC International, Official Methods of Analysis, 16th ed.⁵

BHP, British Herbal Medicine Association, British Herbal Pharmacopoeia, 1996⁶

Code of Federal Regulations, Title 40, (40 CFR) Part 141, National Primary Drinking Water Regulations⁷

INA, *Allicin by High-Performance Liquid Chromatography*⁸

⁵ AOAC International, 481 Frederick Avenue, Suite 500, Gaithersburg, MD 20877

⁶ British Herbal Medicine Association, P.O. Box 304, Bournemouth, Dorset, BH7 6JZ, England

⁷ U.S. Government Printing Office, Washington, DC 20402

⁸ Institute for Nutraceutical Advancement (INA), c/o NSF International, 789 Dixboro Road, Ann Arbor, MI 48105

INA, *Black Cohosh Assay by ELSD*⁸

INA, *Catechins and Gallic Acid in Green Tea by HPLC*⁸

INA, *Fatty Acid Content in Saw Palmetto by Gas Chromatography*⁸

INA, *Ginkgo Flavonol Glycoside Assay by HPLC*⁸

INA, *Ginkgoterpenoid Assay by HPLC*⁸

INA, *Kavalactone Assay by HPLC*⁸

INA, *Phenolics in Echinacea by HPLC*⁸

INA, *St. John's Wort Assay by HPLC*⁸

INA, *Sterols Content in Saw Palmetto by Gas Chromatography*⁸

International Code for Botanical Nomenclature (St. Louis Code), 2000⁹

ISO/IEC 17025: 1999 *General requirements for the competence of testing and calibration laboratories*¹⁰

The Merck Index: An Encyclopedia of Chemicals, Drugs and Biologicals (Annual)¹¹

NSF International White Book of NSF Registered and USDA Authorized Proprietary Substances and Nonfood Compounds¹²

USEPA Methods for the Determination of Metals in Environmental Samples – Supplement, 1 – EPA/600/R-94-111 – May 1994¹³

⁹ Sixteenth International Botanical Congress, St. Louis, Missouri, July-August 1999. Publ. 2000, Koeltz Scientific Books.

¹⁰ International Organization for Standardization (ISO), 1, rue de Varembe, Case postale 56, CH-1211, Geneva 20, Switzerland

¹¹ Merck & Company, Whitehouse Station, NJ

¹² NSF International, 789 North Dixboro Road, Ann Arbor, MI 48105

¹³ USEPA, Office of Water, Washington, DC 20460

USEPA *Microwave Assisted Acid Digestion of Sediments, Sludges, Soils and Oils*, EPA Method 3510- September 1994¹³

USEPA *National Primary Drinking Water Regulations* (40 CFR part 141)¹³

USFDA, *Bacteriological Analytical Manual*, eighth edition, 1998¹³

USFDA, *Dietary Supplements Health and Education Act of 1994*, (an amendment to the Federal Food, Drug and Cosmetic Act): Public Law 103-417 – October 25, 1994¹⁴

USFDA, *Pesticide Analytical Manual*¹⁴

USFDA, *Food Code 2001 Recommendations of the United States Public Health Service Food and Drug Administration*¹⁴

USFDA, *Determination of Aristolochic Acid in Traditional Chinese Medicines and Dietary Supplements*¹⁵

USP, United States Pharmacopeia, USP 25-NF 20, Supplement 3¹⁶

WHO, World Health Organization Monographs on Selected Medicinal Plants, Volume 1¹⁷

WHO Guidelines for Drinking-Water Quality¹⁷

3 Definitions

Terms used in this Standard that have special technical meaning are defined here.

3.1 active ingredient: Principle ingredient identified in product name or on the principle display panel.

3.2 adulteration: As defined by the Federal Food and Cosmetic Act, §402, adulterated food is defined in Title 21, USC §342.

3.3 batch or lot: A specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and/or is produced according to a single manufacturing order during the same cycle of manufacture.

3.4 botanical ingredient: An ingredient of plant species or form.

3.5 chewable: A supplement intended to be reduced through mastication.

3.6 Class I: added nutrients.

3.7 Class II: naturally occurring (indigenous) nutrients.

3.8 dietary ingredient: An ingredient intended for use or used in a dietary supplement that is a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, or extract.

3.9 dietary supplement¹⁴: A product (other than tobacco) that:

- is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;
- is intended for ingestion in pill, capsule, tablet, powder, or liquid form;
- is not represented for use as a conventional food or as the sole item of a meal or diet;
- is labeled as a “dietary supplement;”
- includes an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351, of the Public

¹⁴ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-0001

¹⁵ USFDA Forensic Chemistry Center, Cincinnati, OH

¹⁶ United States Pharmacopeia, 121601 Twinbrook Parkway, Rockville, MD 20852-1790

¹⁷ World Health Organization, 1211 Geneva 27, Switzerland