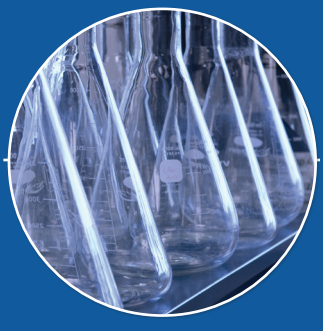
NSF International Standard /
American National Standard

NSF/ANSI 173 - 2009

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

Dietary supplements

Standard Developer

NSF International

American National Standards Institute

Designated as an ANSI Standard
April 8, 2009
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

Revised July 2005
Revised August 2006
Revised July 2007
Revised April 2008
Revised September 2008
Revised April 2009

Published by

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

For ordering copies or for making inquiries with regard to this Standard, please reference the designation "NSF/ANSI 173 – 2009."

Printed in the United States of America.

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Contents

Foreword[2]

The purpose of NSF/ANSI 173 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 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.

This version includes the following revisions:

– Incorporates NSF/ANSI 173 – 2008 Addendum, which includes issue 20, revisions to sections which address industrial contaminants; and

– Issue 24 modifications were added to the standard language to define the types of ingredients that are associated with the acceptable limits categories in tables and 6A and 6B.

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 the General Manager of Dietary Supplements, P.O. Box 130140, Ann Arbor, Michigan 48113–0140 or at 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.

[2] The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

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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, 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 followed in the production of dietary supplements.

1.2 Scope

This Standard contains requirements for dietary supplements that contain one or more of the following dietary ingredients: a vitamin, a mineral, an 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 are excluded from the scope of this Standard.

1.3 Formulation submission

The manufacturer shall submit, at a minimum, the following information for each product:

– complete formulation information, which includes the following:

  – the composition of the formulation (in percent or parts by weight for each ingredient in the formulation including excipients);

    NOTE – Ranges shall be considered acceptable.

  – the reaction process, if applicable;

  – the raw material ID number (if applicable), chemical/material name, trade name and supplier(s) for each chemical present in the formulation;

  – a list of known or suspected impurities associated with the finished product; and

– when available, an analytical method used to verify the claims listed on the label or certificate of analysis.

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 editions indicated were 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 2000[3]

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AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Bilberry fruit*, 2001[4]

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[3] American Herbal Pharmacopoeia, P. O. Box 66809, Scotts Valley, CA 95067 www.herbal-ahp.org

[4] American Herbal Products Association, 8484 Georgia Ave., Suite 370, Silver Spring, MD 20910 www.ahpa.org

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

AOAC International, *Official Methods of Analysis*, 18th edition (2005)[6]

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BHP, British Herbal Medicine Association, *British Herbal Pharmacopoeia*, 1996[7]

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Code of Federal Regulations, Title 21, Chapter 29, *Federal Food, Drug, and Cosmetic Act*[9]

Compliance Services International, *Analytical Method for the Determination of Quintozene and Its Degradates and Impurities in Ground Dried Ginseng Root by Gas Chromatography* Laboratory validation of analytical method number CSI-023-01, 1999[9]

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INA, *Allicin by High-Performance Liquid Chromatography*[11]

INA, *Black Cohosh Assay by ELSD*[12]

INA, *Catechins and Gallic Acid in Green Tea by HPLC*[12]

INA, *Fatty Acid Content in Saw Palmetto by Gas Chromatography*[12]

INA, *Ginkgo Flavonol Glycoside Assay by HPLC*[12]

INA, *Ginkgoterpenoid Assay by HPLC*[12]

INA, *Kavalactone Assay by HPLC*[12]

INA, *Phenolics in Echinacea by HPLC*[12]

INA, *St. John's Wort Assay by HPLC*[12]

INA, *Sterols Content in Saw Palmetto by Gas Chromatography*[12]

International Code for Botanical Nomenclature (St. Louis Code), 2000[12]

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[5] AOAC International, 481 Frederick Avenue, Suite 500, Gaithersburg, MD 20877 www.aoac.org

[6] AOCS, 2211 W. Bradley Ave., Champaign, IL 61821 www.aocs.org

[7] British Herbal Medicine Association, P. O. Box 304, Bournemouth, Dorset, BH7 6JZ, England www.bhma.info

[8] U. S. Government Printing Office, Washington, D. C. 20402 www.gpo.gov

[9] Compliance Services International, 1112 Alexander Avenue, Tacoma, WA 98421 www.complianceservices.com

[10] Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20401 www.gpo.gov

[11] Institute for Nutraceutical Advancement (INA), c/o NSF International, 789 Dixboro Road, Ann Arbor, MI 48105 http://www.nsf.org/business/ina/index.asp?program=INA

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

NTIS/IEC 17025: 1999 *General requirements for the competence of testing and calibration laboratories*[13]

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Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 USC 201[9]

USEPA *Methods for the Determination of Metals in Environmental Samples – Supplement*, 1 – EPA/600/R-94-111 – May 1994[16]

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USP, United States Pharmacopeia, USP 29-NF 24[19]

WHO, *World Health Organization Monographs on Selected Medicinal Plants*, Volume 1, 2 and 3[20]

WHO, *Guidelines for Drinking-Water Quality*[21]

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[13] National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 www.ntis.gov

[14] Merck & Company, One Merck Drive, Whitehouse Station, NJ 08889 www.merck.com

[15] NSF International, 789 North Dixboro Road, Ann Arbor, MI 48105 www.nsf.org

[16] USEPA, Office of Water, Washington, D. C. 20460 www.epa.gov

[17] U. S. Department of Commerce, Technology Administration, National Technical Information Services, 5285 Port Royal Road, Springfield, Virginia 22161 www.ntis.gov

[18] USFDA Forensic Chemistry Center, 1141 Central Pky, Cincinnati, OH 45202 www.fda.gov

[19] United States Pharmacopeia, 121601 Twinbrook Parkway, Rockville, MD 20852-1790 www.usp.org

[20] World Health Organization, 1211 Geneva 27, Switzerland www.who.int