Dietary supplements

NSF International Standard/ American National Standard

NSF/ANSI 173 – 2003

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for Dietary Supplements —

Dietary supplements

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Annexes

Foreword[2]

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.

[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. As such, 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.

[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 2000[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Astragalus Root*, 1999[4]

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

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Cohash root*, 2002[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Haw Bark*, June 2000[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Chaste Tree Fruit*, 2001[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cranberry*, 2002[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cramp Bark*, 2000[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Goldenseal*, 2002[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Berry*, June 1999[4]

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