NSF/ANSI 173 - 2005a

Dietary supplements

NSF International Standard/ American National Standard

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NSF/ANSI 173 - 2005a

NSF International Standard/ American National Standard for Dietary Supplements —

Dietary supplements

Standard Developer

NSF International

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Foreword²

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.

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.

This version (NSF/ANSI 173 – 2005 addendum) includes the following revisions:

- Section 2, Normative References, was updated to include the latest versions of referenced documents.
- Section 3, Definitions, has been revised to further clarify the definition of Dietary Supplement.
- Section 7, Test methods for detection of contaminants raw materials and finished products, has been revised to incorporate a protocol to detect the presence of *Escherichia coli* and identify the generic and pathogenic strains.
- Tables 3 and 4 have been revised to correct the references and to utilize a format that will ensure consistency between allowable levels in ingredients and finished products.

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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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, August 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, Cramp Bark, February 2000⁴
- AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, Cranberry, 2002⁴
- AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, Dang Gui Root, 2003⁴
- AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, Echinacea purpurea Root, 2004
- AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, Ginkgo Leaf, 2003⁴
- AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, Goldenseal, 2001⁴
- AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, Hawthorn Berry, June 1999
- 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

⁴ American Herbal Pharmacopoeia, PO Box 66809, Scotts Valley, CA 95067