NSF/ANSI 173 - 2005

Dietary supplements

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NSF/ANSI 173 - 2005

NSF International Standard/ American National Standard for Dietary Supplements —

Dietary supplements

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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 edition of the Standard (NSF/ANSI 173 – 2005) includes the following revisions:

- Section 2, Normative references, includes editorial changes and updates to current referenced documents as well as additional references.
- Additional language and requirements have been incorporated into section 5, Raw Materials, to include product requirements and evaluation associated with the types of common claims.
- An identification and quantitative quality assurance section has been added to section 6.
- A modification and additional language has been incorporated into sections 6 and 7 to support compliance with method validation requirements within the context of analysis for dietary supplements.
- A modification to the language in section 7.1, Test methods for metals, to more accurately reflect the evaluation(s) performed to measure contaminant levels of chromium (VI).
- Incorporate pentachlorophenol into the table in 7.2.2.
- Section 9, Records retention, has been reformatted to be included as a Good Manufacturing Practice and clarification of necessary label storage.
- Additional language has been added to sections 5 and 7 to set limits for peroxide used in dietary supplements oils.

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

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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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, 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

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