NSF/ANSI 173 – 2008

Dietary supplements

NSF International Standard/ American National Standard

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NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

Standard Developer

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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 (NSF/ANSI 173 – 2008) includes revisions to Section 8 (173i27). Section 8 contains requirements for Good Manufacturing Practices (GMPs), which prior to this revision was based on the GMPs submitted by industry to the U.S. Food and Drug Administration (USFDA) in November 1995.[3] Since the USFDA has published Good Manufacturing Practices in 21 CFR § 111, this document has been revised to be consistent with the USFDA's GMPs. Requirements for written recall procedures were maintained, as were the requirements for compliance to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Dietary Supplement and Non Prescription Drug Consumer Protection Act. Further clarification on the interpretation of these GMPs for certification to this Standard may be found in NSF's Certification Policies for Dietary Supplements Manufacturers and Contract Manufacturers GMP Registration.

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.

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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, 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