Dietary supplements

NSF International Standard/ American National Standard

NSF/ANSI 173 – 2006
Addendum 1

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NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

Standard Developer

NSF International

Approved July 30, 2007
American National Standards Institute

Designated as an ANSI Standard
July 30, 2007
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
Addendum July 2007

Published by

NSF International
P. O. 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 – 2006, Addendum 1.”

Printed in the United States of America.

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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.

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 – 2006, Addendum 1) includes the following revisions:

- Section 1, General, was updated to include requirements for formulation submissions to demonstrate product compliance.
- A definition for "Major food allergen" was added to section 3, Definitions.
- Section 8, Good Manufacturing Practices, was revised to incorporate language on the handling and storage of raw materials in an effort to reduce cross-contamination from allergens.

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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Revisions to NSF/ANSI 173 – 2006 are shown in this addendum as ~~crossouts~~ for deletions and highlights for additions.

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