

Dom

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 1-2-09  
Publication Date 1-5-09  
Certifier J.D.

Food and Drug Administration

[Docket No. FDA-2004-D-0303] (formerly Docket No. 2004D-0466)

**"Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act;"**

**Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act." The guidance describes the amount, type, and quality of evidence that FDA recommends a manufacturer have to substantiate a claim under this section of the Federal Food, Drug, and Cosmetic Act (the act).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

cf0837

FDA.2004.D.0303

NAD

Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Robert Moore, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1441.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of November 9, 2004 (69 FR 64962), FDA made available a draft guidance entitled “Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act” and gave interested parties an opportunity to submit comments by January 10, 2005. FDA considered received comments as it finalized this guidance.

This guidance describes the amount, type, and quality of evidence FDA recommends a manufacturer have to substantiate a claim under section 403(r)(6) of the act (21 U.S.C. 343(r)(6)). This final guidance document is limited to issues pertaining to substantiation under section 403(r) of the act; it does not extend to substantiation issues that may exist in other sections of the act.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents FDA’s current thinking on the substantiation for dietary supplement claims made under section 403(r)(6) of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

---

An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## **II. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in the guidance was approved under OMB Control No. 0910–0626.

## **III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

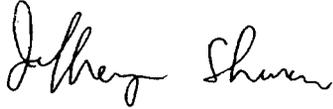
## **IV. Electronic Access**

Persons with access to the Internet may obtain the guidance document at *<http://www.cfsan.fda.gov/guidance.html>*.

**DEC 23 2008**

Dated: \_\_\_\_\_

December 23, 2008.

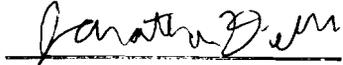


\_\_\_\_\_  
Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

  
\_\_\_\_\_