

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Display Date 7-16-08
Publication Date 7-17-08
Certifier A. Corbin

[Docket No. FDA-1995-N-0054] (formerly Docket No. 1995N-0304)

Small Entity Compliance Guide: Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of February 11, 2004 (69 FR 6788), entitled "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk." This SECG is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments on the SECG 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 SECG to <http://www.regulations.gov>. Submit written requests for single copies of the SECG to the Division of Dietary Supplement Programs, Office of Nutrition, Labeling, and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301-436-2639. Send one self-

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addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 11, 2004, FDA issued a final rule declaring dietary supplements containing ephedrine alkaloids adulterated under the Federal Food, Drug, and Cosmetic Act because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use. This final rule became effective April 12, 2004.

FDA examined the economic implementation of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-602) and determined that the final rule would have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), FDA is making available this SECG stating in plain language the requirements of the regulation.

FDA is issuing this SECG as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on this subject. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this SECG.

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. The SECG and 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>*.

III. Electronic Access

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

Dated: 7/10/08
July 10, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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

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