Small Entity Compliance Guide: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Availability

A Notice by the Food and Drug Administration on 12/16/2010

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Department of Health and Human Services
Food and Drug Administration
[Docket No. FDA-2010-D-0605]

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary (printed page 78716) Supplements—Small Entity Compliance Guide.” The small entity compliance guide (SECG) is being issued for a final rule and an interim final rule published in the **Federal Register** of June 25, 2007, and is intended to set forth in plain language the requirements of that final rule and interim final rule and to help small businesses understand the regulations. In addition, the SECG includes several recommendations made by FDA in that final rule so that the guidance in those recommendations will be readily accessible to small businesses.

DATES:

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

ADDRESSES:

Submit electronic comments to *http://www.regulations.gov (http://www.regulations.gov)*. 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 written requests for single copies of the SECG to the Division of Dietary Supplement Programs (HFS-810), Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT:

Bradford Williams, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1440.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 25, 2007 (72 FR 34752 (/citation/72-FR-34752)), FDA issued a final rule establishing current good manufacturing practice (CGMP) regulations for dietary supplements (21 CFR part 111 (https://www.ecfr.gov/current/title-21/part-111)) (the DS CGMP final rule). The DS CGMP final rule requires persons who manufacture, package, label, or hold a dietary supplement to establish and follow current good manufacturing practice to ensure the quality of the dietary supplement and to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record. In that same issue of the **Federal Register** (72 FR 34959 (/citation/72-FR-

34959)), FDA also issued an interim final rule (the identity testing interim final rule) that sets forth a procedure for requesting an exemption from a requirement for the manufacturer to conduct at least one appropriate test or examination to verify the identity of any dietary ingredient that is a component of a dietary supplement. The final rule and the identity testing interim final rule became effective August 24, 2007. The compliance date of the DS CGMP final rule and the identity testing interim final rule is June 25, 2008; except that for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009; and except that for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010.

FDA examined the economic implications of the DS CGMP final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612 (https://www.govinfo.gov/link/uscode/5/601)) and determined that the DS CGMP 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 (https://www.govinfo.gov/link/plaw/104/public/121)), FDA is making available this SECG stating in plain language the requirements of the regulations. We also examined the economic implications of the identity testing interim final rule as required by the Regulatory Flexibility Act and determined that the identity testing interim final rule would not have a significant economic impact on a substantial number of small entities. However, because the identity testing interim final rule revises the DS CGMP final rule, the SECG includes the provisions of the identity testing interim final rule.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2) (https://www.ecfr.gov/current/title-21/section-10.115#p-10.115(c)(2))).[1] The SECG restates, in simplified format and language, FDA's requirements for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, including the requirements for a Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients. In addition, the SECG includes several recommendations made by FDA in the DS CGMP rule so that the guidance in those recommendations will be readily accessible to small businesses.

The SECG represents FDA's current thinking on current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements. 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. We note, however, that the regulations that serve as the basis for this guidance document establish requirements for all covered activities. For this reason, we recommend that affected parties consult the regulations at 21 CFR part 111 (https://www.ecfr.gov/current/title-21/part-111) in addition to reading the SECG.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 (https://www.govinfo.gov/link/uscode/44/3501)). The collections of information in 21 CFR part 111 (https://www.ecfr.gov/current/title-21/part-111) have been approved under 0910-0606.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments on the SECG. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

IV. Electronic Access

Persons with access to the Internet may obtain the SECG at *http://www.fda.gov/FoodGuidances.html (http://www.fda.gov/FoodGuidances.html)* or *http://www.regulations.gov (http://www.regulations.gov)*.

Dated: December 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

Footnotes

1. We note that the American Herbal Products Association submitted a petition for reconsideration on July 25, 2007, under 21 CFR 10.33 (https://www.ecfr.gov/current/title-21/section-10.33), requesting reconsideration of certain provisions of the DS CGMP final rule. FDA is currently considering this petition and the SECG does not represent a response to such petition.
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