DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0121]

Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products–Small Entity Compliance Guide” for a final rule published in the Federal Register of February 2, 2012. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand and comply with the regulation.

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

ADDRESSES: Submit written requests for single copies of the SECG entitled “Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products – Small Entity Compliance Guide” to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.
Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 2, 2012 (77 FR 5171), FDA issued a final rule regarding further amendments to the general regulations of the FDA to incorporate tobacco products. FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the 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 legal requirements of the February 2, 2012, final rule, set forth in 21 CFR parts 1, 7, and 16, amending the FDA’s general regulations to ensure that tobacco products are subject to the same general requirements that apply to other FDA-regulated products.
FDA is issuing this SECG as 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 topic. 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) either electronic or written comments regarding this document. It is only necessary to send one set of 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm
or http://www.regulation.gov.


Leslie Kux,
Assistant Commissioner for Policy.

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