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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1083]

Guidance for Industry and Food and Drug Administration Staff; Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.” This guidance provides information in response to questions that FDA has received regarding the issuance of civil money penalties for violations of regulations issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to tobacco products in retail outlets.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions” 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 information on 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, email: gerie.voss@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions.” In this guidance, FDA addresses questions regarding the issuance of civil money penalties for violations of tobacco product regulations. In the Federal Register of February 8, 2013 (78 FR 9396), FDA announced the availability of the draft guidance of the same title. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance 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 statute and regulations.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see

ADDRESSES). 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, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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