



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1600]

Draft Guidance for Industry and Tobacco Retailers; Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent." This draft guidance provides information to tobacco retailers on FDA's enforcement policy regarding certain so-called provisional tobacco products that become subject to not substantially equivalent (NSE) orders issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229.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 may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to 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: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, email: [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov)

SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a draft guidance for tobacco retailers entitled "Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent." In this draft guidance, FDA provides information on its enforcement policy regarding so-called provisional tobacco products that become subject to NSE orders under the FD&C Act. The provisional products addressed by this draft guidance are tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, and for which a section 905(j) (21 U.S.C. 387e(j)) (or substantial equivalent) report was submitted no later than March 22, 2011. Because the FD&C Act permitted this specific group of products to remain on the market pending FDA's review of the report, there will very likely be products at retail locations within the United States when FDA issues an order finding a tobacco product NSE. This draft guidance explains that FDA does not intend to take enforcement action for at least 30 calendar days from

the date the NSE order issues for those products that are in the retailer's current inventory at a specific retail location on the date FDA issues the NSE order.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on "Enforcement Policy for Certain (Provisional) Tobacco Products That FDA Finds Not Substantially Equivalent." 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 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>.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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