Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent

Guidance for Industry and Tobacco Retailers

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2013-D-1600.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

September 2015

Contains Nonbinding Recommendations

Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent

---

Guidance for Industry and Tobacco Retailers[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

FDA is issuing this guidance to provide information on its enforcement policy to retailers regarding so called "provisional" tobacco products that become subject to not substantially equivalent orders issued under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The "provisional" tobacco products addressed by this 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 905(j) (or substantial equivalence) report was submitted no later than March 22, 2011. Under the FD&C Act, tobacco products meeting these criteria were permitted to remain on the market pending FDA's review of such report. If FDA issues an order finding the product not substantially equivalent (NSE), the product is adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act; 21 U.S.C. 387b(6)(A), 387c(a)(6)). This means that, effective immediately upon issuance of an NSE order, it is a prohibited act to sell or distribute the product in interstate commerce, to import such products into the United States, or to receive from interstate commerce and sell or offer to sell or otherwise deliver products. In addition, a tobacco product that is the subject of an NSE order is subject to seizure at any time.

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. 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

[1] This guidance was prepared by the Office of Compliance and Enforcement and Office of Regulations in the Center for Tobacco Products at FDA.

the date FDA issues the NSE order. This policy extends only to tobacco products that are already in a retail store that offers the products for sale directly to consumers. FDA encourages retailers to contact their supplier or manufacturer to discuss possible options for the misbranded and adulterated product that they may have in their current inventory.

FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.