Enforcement Policy for Certain Marketed Tobacco Products*

Guidance for Industry

DRAFT GUIDANCE

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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/Labeling/RulesRegulationsGuidance/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

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*When final, this guidance will supersede the guidance, "Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent," issued September 2015.

Enforcement Policy for Certain Marketed Tobacco Products[1]

Guidance for Industry[2]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 regarding FDA's enforcement policy for certain marketed tobacco products that become the subject of a not substantially equivalent (NSE) order. This policy primarily involves the so-called "provisional"[3] tobacco products that become subject to NSE orders issued under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This policy also extends to new tobacco products created by modifying the quantity of a provisional tobacco product in a pending substantial equivalence (SE) Report[4] that become subject to NSE orders. The guidance also provides information on FDA's enforcement policy for when FDA receives from the applicant a request for supervisory review under 21 CFR 10.75 within 30 calendar days of the issue date of the NSE order. FDA intends to offer copies of those final scientific reviews that supported the basis of the Agency's decision to the applicant concurrent with the NSE order for provisional tobacco products.

[1] When final, this guidance will supersede the guidance, "Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent," issued September 2015 (2015 guidance) (https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM386629.pdf). Here, as with the 2015 guidance, FDA indicates that it does not intend to take enforcement action against a retailer for certain marketed tobacco products for a certain period of time (see page 2 of this guidance for more information).

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

[3] 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.

[4] As described in Question and Response 8 of the guidance document, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)* (FAQs Guidance)*, http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf.

Upon issuance by FDA of an order finding the product 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, upon issuance of an NSE order, it is a prohibited act to introduce or deliver the product for introduction into 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 adulterated and misbranded is subject to seizure at any time.

However, because the FD&C Act permits a provisional tobacco product to remain on the market pending FDA's review of the SE Report for that product, the product is likely to be available to consumers at retail locations within the United States when FDA issues an NSE order, rendering the tobacco product adulterated and misbranded. Likewise, because FDA has previously stated that it does not intend to enforce the premarket requirements under sections 910 and 905(j) of the FD&C Act for those new tobacco products created by modifying the quantity of a provisional tobacco product subject to a pending SE Report, these products are also likely to be available to consumers at retail locations within the United States when FDA issues an order finding the tobacco product NSE. To provide time for sell-off of the products described in this paragraph that are in distribution, FDA does not intend to take enforcement action against a manufacturer, importer, or distributor of the product for at least 30 calendar days from the date of the NSE order.

In addition, should FDA receive a request for supervisory review of an NSE order from the applicant under 21 CFR 10.75 (appeal) within 30 calendar days from the issue date of the NSE order (i.e., date on the order letter), FDA does not intend to take enforcement action against the manufacturer, importer, or distributor based on the order until FDA makes a decision on that request. If the appeal results in a finding that the product is substantially equivalent, then commercial marketing of the product may continue. If the appeal results in FDA affirming the NSE order, then FDA does not intend to take enforcement action against a manufacturer, importer, or distributor for at least 30 calendar days from the date of FDA's decision on that appeal (i.e., date on the appeal denial letter).

FDA also does not intend to take enforcement action against a retailer for at least 30 calendar days from the date notice of the NSE order is posted on FDA's misbranded and adulterated NSE Tobacco Products website.[5] 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 inventory.[6]

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[5] FDA Misbranded and Adulterated NSE Tobacco Products website is located here: https://www.fda.gov/tobaccoproducts/labeling/tobaccoproductreviewevaluation/ucm371765.htm. In the event FDA receives an appeal from an applicant within 30 calendar days from the issue date of the NSE order, then FDA does not intend to post notice of the NSE order on its misbranded and adulterated NSE Tobacco Products website unless and until it affirms the order.

[6] The products discussed in this guidance document still may be subject to enforcement action at any time for other violations of the FD&C Act (i.e., violations of provisions besides the premarket requirements under sections 910(a)(2)(A)(i), 910(a)(2)(B), 910(a)(3), and 905(j)(1)–(2) of the FD&C Act).

FDA's guidance documents, including this guidance, 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.