DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

February 21, 2014

Letter to Industry on Certain Tobacco Products Found to be Not Substantially Equivalent

Dear Retailer, Manufacturer, Importer, or Distributor:

The Food and Drug Administration (FDA) is providing this notice to inform tobacco product retailers, manufacturers, importers, and distributors that it has begun issuing Not Substantially Equivalent (NSE) Decisions for certain tobacco products that are currently on the market and has made some information about these products public. FDA is issuing this letter to remind you of your responsibility to comply with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

When an NSE order is issued, the tobacco product is immediately misbranded under section 903(a)(6) and adulterated under section 902(6)(A) of the FD&C Act, and it is illegal to sell or distribute the product in interstate commerce or import the product into the United States.

Where is there a list of tobacco products that FDA has found to be "Not Substantially Equivalent" (NSE)?

A list of certain NSE products can be found by visiting FDA's website at www.fda.gov/tobacco and searching for "Misbranded and Adulterated NSE Tobacco Products" using the search box. The list contains the product name and, when available, other information such as lot numbers or manufacturing codes or dates.

FDA is making this information available so that everyone will know which tobacco products can no longer be sold or distributed in interstate commerce or imported into the United States. This website will be updated as additional NSE orders are issued for tobacco products that are already on the market.

Additional Information for Retailers, Manufacturers, Importers and Distributors

What does this mean to Retailers?

When an NSE Order is issued for a tobacco product, any of that product that retailers have in their inventory becomes adulterated and misbranded and may be subject to seizure. It is illegal to sell or distribute that product across state lines. It is also illegal for retailers to buy or receive in interstate commerce for further distribution or sale any more tobacco products that are the subject of an NSE Order.

However, FDA recognizes that retailers may have limited options for disposing of products found NSE that are in their current inventories. FDA has published a draft guidance titled, "Enforcement Policy for Certain ("Provisional") Tobacco Products that FDA Finds Not Substantially Equivalent." In this draft guidance, FDA announced that it does not intend to take enforcement action for 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 policy extends only to tobacco products that are already in a retail store that offers the products for sale directly to consumers. During this time, 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.

Manufacturers

Upon issuance of an NSE order, it is illegal for you to sell or distribute the product in interstate commerce or import the product into the United States. Manufacturers may choose to request that these products be returned to them. Manufacturers who wish to export these products outside the United States should consult section 801(e) of the FD&C Act and 21 C.F.R. 1.101 for information specific to exports. FDA encourages manufacturers who receive an NSE order to work with your customers to ensure that your misbranded and adulterated product is not further distributed, imported, or sold in the United States by others.

Importers

Upon issuance of an NSE order, it is illegal for you to import the product in to the United States or to introduce the product into interstate commerce. We encourage you to contact your supplier to discuss possible options for the misbranded and adulterated product that you may have in your current inventory.

Distributors

Upon issuance of an NSE order, it is illegal for you to sell or distribute the product in interstate commerce. We encourage you to contact your supplier to discuss possible options for the misbranded and adulterated product that you may have in your current inventory.

How can anyone report a potential tobacco-related violation of the FD&C Act?

If you would like to report a potential tobacco-related violation of the FD&C Act, including possible misbranded and adulterated tobacco products that are being sold or distributed in interstate commerce or imported into the United States, you can use the Potential Tobacco Product Violation Reporting Form found at https://www.accessdata.fda.gov/scripts/ptvr/index.cfm. The information provided will be reviewed by FDA, and FDA will determine what follow-up action, if any, is appropriate.

Please free to contact us with any questions by email at ASKCTP@fda.hhs.gov, by phone at 1-877-287-1373, or by mail at:

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville MD 20850-3229

Sincerely,

/s/
Ann Simoneau
Director, Office of Compliance and Enforcement
Center for Tobacco Products
U.S. Food and Drug Administration