

Overview of Warning Letters *and Common Violations on the Internet*

November 7, 2012

Sangeeta Vaswani Chatterjee

Team Leader

Promotion, Advertising, and Labeling Group

Office of Compliance and Enforcement

Center for Tobacco Products

Mission Statement

- The mission of FDA's Center for Tobacco Products (CTP) is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

Overview

- CTP conducts routine surveillance of sales, distribution, marketing, and advertising activities related to regulated tobacco products on the Internet.
- CTP has issued Warning Letters to regulated tobacco industry for violations found on this medium.

Agenda

- Warning Letters
- Compliance Actions
- Common Violations
- Examples
- Questions

Warning Letters

- Warning Letters are issued for violations of regulatory significance observed during compliance checks
- Warning Letters are issued to:
 - Achieve voluntary compliance, and
 - Establish notice prior to enforcement actions
- Circumstances may require sequential or concurrent FDA enforcement actions

Compliance Actions

- Failure to comply may result in FDA initiating enforcement actions such as recall, seizure, injunction, administrative detention, civil money penalties, no tobacco sale orders, and/or prosecution.
- For example:
 - Adulterated or misbranded tobacco products that are sold or held for sale in the United States are subject to **seizure** under section 304 of the FD&C Act
 - Tobacco products imported into the United States that are, or appear to be, adulterated, are subject to **refusal of admission** under section 801(a)

Common Violations

- Flavor Ban
- Modified Risk Tobacco Products
 - “Light”, “Mild”, or “Low”
 - Other MRTPs
- Sponsorship

Flavor Ban

- **Section 907(a)(1)(A)**
 - Prohibits a cigarette or any of its component parts (including the tobacco, filter, or paper) from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice that is a characterizing flavor of the tobacco product or tobacco smoke.

Banned Flavors

- **907(a)(1)(A)** includes, but is not limited to, these characterizing flavors:
 - Strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee
 - Other flavorings also may be considered characterizing flavors

Tobacco Products Covered by the Flavor Ban

- **907(a)(1)(A)** applies to:
 - Cigarettes
 - Loose tobacco for use in cigarettes or as roll-your-own (RYO) tobacco
 - Flavored cigarette papers
 - Flavored cigarette filters
- Refer to Guidance for Industry and FDA Staff:
<http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183228.htm>

Flavor Ban – Adulteration, Misbranding & Prohibited Acts

- **Section 902(5)**
 - A tobacco product is adulterated if it is, or purports to be or is represented as, a tobacco product which is subject to section 907, unless it is in all respects in conformity with such standard.
- **Section 301(q)(1)(A)**
 - Failure or refusal to comply with any requirement prescribed under section 907 is a prohibited act.
- **Section 903(a)(1)**
 - A tobacco product is deemed misbranded if its labeling is false or misleading in any particular
- **Section 301(a)**
 - The introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded is a prohibited act

Warning Letter

(Example 1)

- **Recipient:** <http://www.low-price-cigarettes.com>
- **Issue Date:** 5/11/2012
- **Charge:** Section 902(5) of the FD&C Act [Flavor Ban]; or Section 903(a)(1) of the FD&C Act [Misbranding]



KISS SUPER SLIMS FRESH APPLE

1-2 cartons	20.95 USD
3 and more cartons	20.45 USD

Quantity:

Price: 20.95 USD

ADD TO CART

Kiss Super Slims Fresh Apple

10 hard flip top packs, 200 filtered cigarettes, Slims box. (Tar 5mg, Nicotine 0.5mg) Made in Europe

Warning Letter

(Example 2)

- **Recipient:** Classica Trading Center – <http://www.shopping-heaven.com>
- **Issue Date:** 5/11/2012
- **Charge:** Section 902(5) of the FD&C Act [Flavor Ban]; or Section 903(a)(1) of the FD&C Act [Misbranding]



Doina Lux Premium

10 packs, 200 filtered cigarettes with aromatizator, King Size Box. (Tar - 15mg, Nicotine - 1.3mg) Made by Tutun CTC. Made in Moldova.

CHOCOLATE Flavour

Price: \$12.99

Qty:

ADD TO CART

Modified Risk Tobacco Products (“MRTPs”)

- **Section 911(a)**
 - No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product without an FDA order in effect, issued pursuant to section 911(g).

M RTP – Definition

- **Section 911(b)(1)**
 - **M RTP** is defined as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”

MRTPs – What are they?

- **“Light”, “Mild”, or “Low”** – label, labeling, or advertising uses “light”, “mild”, “low”, or similar descriptors.
- **Other MRTPs** – label, labeling, or advertising represents explicitly or implicitly that:
 - a) Lower Risk or Less Harmful
 - b) Reduced Level or Exposure to a Substance
 - c) Does Not Contain or Free of a Substance
- Any product where the manufacturer "has taken any action . . . that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful"

MRTPs – Effective Dates

- “Light”, “Mild”, or “Low”
 - As of June 22, 2010, manufacturers are **prohibited** from manufacturing these products
 - As of July 22, 2010, manufacturers and importers of finished tobacco products are **prohibited** from introducing these products into domestic commerce.
 - Distributors, wholesalers, and retailers are **permitted** to sell such products **only if** those products were manufactured before June 22, 2010, and introduced into domestic commerce by the manufacturer, which includes an importer of finished tobacco products, before July 22, 2010.

MRTPs – Effective Dates

- **Other MRTPs**

- As of June 22, 2009, all regulated entities are **prohibited** from introducing these products into domestic commerce.

- Refer to Guidance for Industry and FDA Staff:
<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm214597.htm>

MRTPs – Adulteration & Prohibited Acts

- **Section 902(8)**

- A tobacco product is adulterated if it is in violation of section 911.

- **Section 301(pp)**

- Prohibits the introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

Warning Letter

(Example 1)

- **Recipient:** – <http://www.cigarettes-com.net>
- **Issue Date:** 9/14/2012
- **Charge:** Section 902(8) of the FD&C Act [“Light”, “Mild”, or “Low”]

CAMEL Lights

JT International



10 packs, 200 cigarettes. King size. Hard box. Nicotine: 0.7; tar: 8. Made in Ukraine.



\$25.95
~~\$26.95~~

3 cartons: \$80.85
6 cartons: \$155.70
12 cartons: \$308.40

Куріння призводить до серцево-судинних захворювань та раку легень

ADD TO CART

CAMEL Lights

Warning Letter

(Example 2)

- **Recipient:** <http://www.cigs365.com>
- **Issue Date:** 7/24/2012
- **Charge:** Section 902(8) of the FD&C Act [“Light”, “Mild”, or “Low”]

The screenshot displays two cigarette products side-by-side. At the top, the text "Lights Cigarettes" is circled in red. Below it, two red boxes highlight the product names: "Bond Special Selection" and "Camel Blue".

Product Name	Nicotine	Tar	Price	Minimum Order
Bond Special Selection	0.6 mg	6 mg	\$ 23.30	3 cartons minimum
Camel Blue	0.7 mg	8 mg	\$ 21.60	3 cartons minimum

Additional details for each product include a "view details" link and a "+ Add to Cart" button. A warning in Ukrainian is present at the bottom of each product image: "Куріння призводить до серцево-судинних захворювань та раку легень" (Smoking leads to cardiovascular diseases and lung cancer).

Warning Letter

(Example 3)

- **Recipient:** Mysnus AB – <http://www.mysnus.com>
- **Issue Date:** 3/12/2012
- **Charge:** Section 902(8) of the FD&C Act [Other MRTP]

All products are pasteurized, with low levels of Nitrosamines....

V2 Tobacco is an independent and privately owned Snus factory started in 2006 by Marc Vogel and Patrick Vogel, located in Silkeborg, Denmark. It produces several variants of Swedish Snus. All products are pasteurized with low levels of Nitrosamines. Their production philosophy and concept is driven by their passion for Snus, for excellence and the benefits you enjoy from small batch smokeless tobacco making. Today they are manufacturing the brands Thunder, Phantom, Offroad, BaccOff, FellInn and Nordströmmen.

Warning Letter

(Example 4)

- **Recipient:** <http://www.bestcigaretteshop.com>
- **Issue Date:** 10/31/2011
- **Charge:** Section 902(8) of the FD&C Act [Other MRTP]

Kent takes out more nicotine and tars than any other leading cigarette – the difference in protection is priceless...

Kent cigarettes were created in 1952 by small tobacco manufacturers, P. Lorillard Company. It was a great boom, as Kent cigarettes were the first cigarettes, which had a filter to drastically reduce tar and nicotine. In 1954 Kent cigarettes got a new filter and a new slogan: "Kent takes out more nicotine and tars than any other leading cigarette - the difference in protection is priceless", since that time these cigarettes are popular all over the world.

Violations of Regulations Prescribed under 906(d)

- **21 CFR Part 1140 – Cigarettes and Smokeless Tobacco**
 - Applies to:
 - Cigarettes, Cigarette Tobacco, Smokeless Tobacco
 - Manufacturers, Distributors, Retailers

Violations of 906(d) Regulations – Misbranding

- **903(a)(7)(B)**

- A tobacco product is misbranded if it is sold or distributed in violation of regulations prescribed under 906(d).

Sponsorship

- **21 CFR 1140.34(c)**

- No manufacturer, distributor, or retailer may sponsor any:

- athletic,
 - musical,
 - artistic, or
 - other social or cultural event, or
 - any entry or team in any event,

in the brand name (etc.) identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Sponsorship Exception

- EXCEPTION: Manufacturers, distributors, and retailers may use corporate names, so long as:
 - Corporate name was registered and in use in the United States before January 1, 1995, *and*
 - Corporate name *itself* does not use the brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of the product identification identical or similar to, or identifiable with, those used for any cigarette or smokeless tobacco brand.

Warning Letter

(Example 1)


- **Recipient:** Cherokee Brands, LLC
- **Issue Date:** 12/14/2010
- **Charge:** Section 903(a)(7)(B) of the FD&C Act [Sponsorship]

Halifax VA County Fair 100th Anniversary sponsors Page 1 of 3



Live Musical Entertainment! 1910 2010
100th Anniversary Celebration
October 5-9

Premiere Sponsors:



HOME ABOUT US SCHEDULE MUSIC SPONSORS

100th Anniversary Sponsors

Sponsors of the Halifax County Fair place their brand at the center of the industry. Sponsor presence enriches the Fair experience and helps Halifax County.


District levels of sponsorship of the Halifax County Fair present opportunities for a range of corporate participation. To become a sponsor or to receive more information, please contact Donnell Corneil, Coordinator of the Halifax County Fair 100th Anniversary. Phone: 434.517.1551 - Email: donnell@halifaxfair.com

All contributions are made to the Friends of Halifax County Fair, a 501(c)(3) non-profit organization, for defensible.

Premiere Sponsors:



Major Sponsors:



<http://www.halifaxcountyfair.com/sponsors.html> 10/18/2010

Warning Letter

(Example 2)

- **Recipient:** Santa Fe Natural Tobacco Co.
- **Issue Date:** 8/26/2011
- **Charge:** Section 903(a)(7)(B) of the FD&C Act [Sponsorship]

