NATO News

*Critical News for Members on Tobacco Legislation, Litigation and Regulations*

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# Final FDA Guidance on the Free Sampling Ban

This month, the U.S. Food and Drug Administration has issued a final guidance document titled "The Prohibition of Distributing Free Samples of Tobacco Products." The FDA's Center for Tobacco Products releases a guidance document to explain the agency's recommendations on how retailers, distributors and manufacturers can comply with federal tobacco regulations. In January of this year, the FDA issued a draft guidance on this same topic and at that time NATO summarized the regulations regarding free tobacco samples in the January 10, 2017 NATO *News* bulletin.

The draft guidance issued in January and the final guidance issued this month are virtually identical. Below is a summary of the FDA regulations regarding the ban on free samples of tobacco products as contained in the final guidance document. A copy of the final guidance document titled "The Prohibition of Distributing Free Samples of Tobacco Products" also accompanies this bulletin.

**Background on Free Samples:** The Family Smoking Prevention and Tobacco Control Act, the federal law that authorizes the FDA to regulate tobacco products, prohibits the distribution of free samples of all tobacco products regulated by the FDA including cigarettes, roll-your-own tobacco, smokeless tobacco, cigars, pipe tobacco, e-cigarettes, e-liquids, vapor products, hookah tobacco, nicotine dissolvable products, nicotine gel products, and components and parts of tobacco products such as e-cigarette and vapor apparatus (i.e., atomizers). The law exempts the distribution of certain small quantities of smokeless tobacco in a "qualified adult-only facility" that meets a number of specific requirements.

**General Rule Prohibiting Free Samples:** Generally, the FDA regulations prohibit a retailer, distributor or manufacturer from distributing free samples of tobacco products to consumers except through a sales transaction that involves a consumer paying money for a tobacco product. Providing a free sample to a consumer in exchange for information such as an e-mail address or a telephone number is a prohibited free sample.

**Price Promotions, Discounts and Coupons:** The FDA guidance states that there are situations in which the sale of a tobacco product at less than full price does not violate the free sample ban. The FDA guidance includes the following examples:

1. "Buy one, get one," "two for the price of one," and any similar combination of buying one or more tobacco products to receive a free tobacco product as a part of the same transaction

do not violate the free sample ban and are allowed. This is the case because the consumer is paying money so that the free tobacco product is not really "free."

2. Buy one and receive a coupon redeemable later for a free tobacco product is prohibited unless the retailer, distributor or manufacturer has a method to verify that the person redeeming the coupon is the original purchaser that earned the coupon for a free tobacco product.

3. Tobacco products can be sold at a discounted price and do not violate the free sample ban.

4. Coupons can be redeemed that take dollars or cents off the price of the tobacco product allowing the tobacco product can be sold at a discount.

**Membership Loyalty Programs**

The FDA guidance document also explains how retailers can offer customers a membership or loyalty reward program. The following examples provided by the FDA apply to these membership or loyalty programs:

1. Tobacco product price discounts are allowed in both membership or loyalty programs.

2. Programs where consumers earn points or rewards for purchasing a certain number of tobacco products and then receiving a "reward" of a free tobacco product are allowed provided that the "reward" product is a part of a monetary transaction. For example, if a customer receives a reward of a free tobacco product after five products are purchased, the free reward product would need to be given to the consumer at the time the fifth product is bought or with the sixth or later purchase of a tobacco product. However, the FDA would allow the free reward product to be given free of charge to the consumer without a money transaction if the retailer, distributor or manufacturer has a method to verify that the consumer redeeming the reward is the original purchaser that earned the reward. One method of verification may be through the consumer's loyalty membership card.

**Business-to-Business Samples**

The FDA guidance also states that the agency does not intend to enforce the free product sample ban in a business-to-business transaction where free samples are distributed in limited quantities between a manufacturer and a distributor, a manufacturer and a retailer, and a distributor and a retailer. "Limited quantities" is defined as no more than necessary to achieve a business or marketing goal to make a business aware of a product in order to encourage the purchase of the product.

**Games of Chance**

Finally, the FDA guidance states that contests or games of chance are not prohibited under the free sample ban, but the prize cannot be a tobacco product unless the prize is given as a part of a tobacco product sales transaction involving an exchange of money. The FDA guidance does not clarify whether the purchase of a ticket for a chance to win a tobacco product would be allowed under the free sample ban. The FDA guidance does allow customers to enter into a drawing or raffle for a prize of either a discount in the price of a tobacco product or a coupon for a free

tobacco product at the time another tobacco product is purchased. Also, please note that there are other state and federal laws that retailers need to comply with regarding games of chance and a retailer should investigate these laws before conducting a game of chance.

The underlying theme of the FDA's position on whether a tobacco product is a free sample focuses on the payment of money by a consumer at the time the "free" sample product is provided to the consumer.

## Revised FDA Guidance for Retailers That Blend Pipe Tobacco, Blend E-Liquids, or Make Cigars

The FDA also issued another guidance document last week titled "Health Document Submission Requirements for Tobacco Products." This guidance document relates to those retailers who blend different pipe tobaccos together, blend e-liquids for electronic cigarettes or vaping apparatus, or make their own cigars. A copy of this guidance document accompanies this bulletin.

Please recall that the FDA required retailers that blend pipe tobaccos, mix e-liquids, or make their own cigars to register with the agency as a manufacturer by September 30, 2017. NATO issued a NATO *News* bulletin on September 6, 2017 as a reminder of this deadline with instructions on how to register with the FDA.

**Tobacco Health Documents:** Under the FDA tobacco regulations, manufacturers are required to file "tobacco health documents" with the agency on those tobacco products that are subject to the FDA deeming regulations that went into effect on August 8, 2016. These products include cigars, pipe tobacco, e-cigarettes and vapor products. The deadline for small-scale tobacco manufacturers to file "tobacco health documents" with the FDA is November 8, 2017. A "small-scale tobacco" manufacturer has up to 150 employees and annual total revenue of $5,000,000 or less. Also, the FDA has extended this November 8, 2017 deadline to May 8, 2018 for small-scale manufacturers impacted by recent natural disasters. Click on the link below for the areas determined by the FDA to be affected by natural disasters and therefore give until May 8, 2018 to file any tobacco health documents:

https://www.fda.gov/TobaccoProducts/NewsEvents/ucm579265.htm

Tobacco health documents are those documents developed by the manufacturer after June 22, 2009 that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents, including smoke constituents, ingredients, components and additives. The FDA interprets "health, toxicological, behavioral, or physiologic" to mean "cell-based, tissue-based, animal, or human studies, computational toxicology models, information on addiction, intentions to use, cognition, emotion, motivation, and other behavioral effects."

**File FDA Form 3743:** It is unlikely that retailers that blend pipe tobacco, mix e-liquids, or make cigars have developed such tobacco health documents. If not, then retailers that filed the appropriate manufacturer registration documents with the FDA by September 30, 20176 need to complete several portions of the accompanying FDA Form 3743 and mail it to the

FDA so the agency receives the form by November 8, 2017. Below are instructions on how to complete FDA Form 3743. In the event that a retailer, which registered as a manufacturer did develop any tobacco health documents, please review the accompanying guidance document for more detailed instructions on how to submit such tobacco health documents to the FDA.

**Instructions to Complete FDA Form 3743 If a Retailer Did Not Develop Any Tobacco Health Documents:** FDA Form 3743 is a seven page document that can be filled in on your computer screen by placing your cursor near the bottom of each appropriate box and clicking until a fill-in line appears.

In Section I, on Page 2, click on the box in front of the word "Manufacturer" and a ✔ should appear in the box. Then, fill in your company name, address, city, state, country and zip code (if you have not received a Company Headquarters DUNS Number or FEI Number, leave those boxes blank). Under the heading "Submitter Point of Contact," list your name, title, e-mail address, telephone and fax numbers.

Section II should not be filled in. In Section III, titled "Submission Format and Comments," in the area labeled "None," click on both of the boxes to confirm that you do not have any documents that relate to health, toxicological, behavioral or physiologic effects nor do you anticipate having any such documents in the future. Again, if you did develop any tobacco health documents, do not check either of these boxes but complete the applicable sections of the form.

In Section IV, titled "Confirmation of Statement," read the statement, check the box in front of "Agree" if you agree to the statement, then sign the form in the signature box, put your name and title in the box to the right of your signature, and include the date in the "Date" box. Immediately below your signature, check the box in front of "Submitter". Then, leave Sections, V, VI and VII blank.

You should make a copy of Form 3743 for your records and then mail Pages 1-4 of the form to the FDA so the agency receives the form by November 8, 2017 at the following address:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002