

# **Guidance for Industry and FDA Staff**

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## **General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)\***

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

**\*This is a revision of the first edition of the FDA guidance “General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors,” which FDA issued on September 22, 2009. Revisions/Additions are noted by date.**

# **Preface**

## **Public Comment**

Written comments and suggestions may be submitted at any time for FDA consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by FDA until the document is next revised or updated.

## **Additional Copies**

Additional copies are available from the Internet at <http://www.fda.gov/flavoredtobacco>. You may also send an e-mail request to [May.Nelson@fda.hhs.gov](mailto:May.Nelson@fda.hhs.gov) to receive an electronic copy of the guidance.

# Guidance for Industry and FDA Staff<sup>1</sup>

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## General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)

*This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance document. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.*

### Introduction

The Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), establishes a tobacco standard special rule for cigarettes that is effective on September 22, 2009. This special rule for cigarettes 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, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. The issues identified in this guidance document represent those that we believe are frequently asked regarding the ban of cigarettes that contain certain characterizing flavors. In developing the guidance document, we carefully considered the relevant statutory criteria regarding the ban.

### General Questions and Answers:

1. What is the significance of today's announcement on flavored cigarettes?

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<sup>1</sup> This guidance has been prepared by the Center for Tobacco Products at the U.S. Food and Drug Administration.

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Smoking is the leading cause of preventable death in the United States, claiming over 400,000 lives each year. An important way to reduce the death and disease caused by smoking is to prevent children and adolescents from starting to smoke. Studies have shown that 17 year old smokers are three times as likely to use flavored cigarettes as are smokers over the age of 25. In addition to being more attractive to young people, flavored products make it easier for new smokers to start smoking by masking the unpleasant flavor of tobacco. Studies have also demonstrated that young people believe that flavored tobacco products are safer than unflavored tobacco products.

Flavored cigarettes are just as addictive and have the same types of harmful effects as regular cigarettes. Removing these flavored products from the market is important because it removes an avenue that young people can use to begin regular tobacco use. Congress specifically enacted the ban on sale of cigarettes and their component parts, such as filters and papers, which contain certain characterizing flavors. The removal from the market of cigarettes that contain certain characterizing flavors is an important step in the Nation's efforts to reduce the burden of illness and death caused by tobacco products as authorized by the FSPTCA, signed by President Obama on June 22, 2009.

### **2. What products are covered?**

Several key definitions in the law define which products are covered.

The ban applies to all tobacco products that meet the definition of a cigarette in section 900(3) of the FDCA even if they are not labeled as cigarettes or are labeled as cigars or as some other product.

Specifically, section 900(3) defines cigarettes as:

“(3) CIGARETTE.—The term ‘cigarette’—

“(A) means a product that—

“(i) is a tobacco product; and

“(ii) meets the definition of the term ‘cigarette’ in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

“(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

“(4) CIGARETTE TOBACCO.—The term ‘cigarette tobacco’ means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.”

This definition refers to a provision of the Federal Cigarette Labeling and Advertising Act which defines the term ‘cigarette’ as:

“(1) The term “cigarette” means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

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(B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).”

**3. Does the special rule for cigarettes in section 907(a)(1)(A) of the FDCA, banning cigarettes containing an artificial or natural flavor that is a characterizing flavor, apply to loose tobacco intended to be used in cigarettes or as roll-your-own tobacco?**

Yes. The special rule for cigarettes in section 907(a)(1)(A) of the FDCA bans all cigarettes containing an artificial or natural flavor that is a characterizing flavor. Section 900(3) of the FDCA defines “cigarette” as including “tobacco, in any form . . . that is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.” Loose tobacco intended to be used in cigarettes or as roll-your-own tobacco fits this definition of “cigarette” and therefore may not be flavored with a characterizing flavor.

**4. Does the special rule for cigarettes in section 907(a)(1)(A) of the FDCA, banning cigarettes containing an artificial or natural flavor that is a characterizing flavor, apply to rolling paper or filters intended for use in roll-your-own cigarettes?**

Yes. The special rule for cigarettes in section 907(a)(1)(A) of the FDCA prohibits the component parts of a cigarette (including the filter or paper) from containing an artificial or natural flavor that is a characterizing flavor. Section 900(3) of the FDCA defines “cigarette” as a tobacco product that “meets the definition of the term ‘cigarette’ under section 3(1) of the Federal Cigarette Labeling and Advertising Act,” which states that a cigarette is any wrapped roll of tobacco. A consumer rolled, roll-your-own cigarette is a cigarette under section 900(3) because it is a wrapped roll of tobacco. Rolling paper or filters intended for use in roll-your-own cigarettes are component parts of a rolled, roll-your-own cigarette and therefore may not be flavored with a characterizing flavor.

**5. Under what, if any, circumstances would FDA consider cigars, including little cigars, to be in violation of the ban in section 907(a)(1) of the FDCA?**

[Response updated December 23, 2009] The ban applies to all tobacco products with certain characterizing flavors that meet the definition of a “cigarette” in section 900(3) of the FDCA even if they are not labeled as “cigarettes” or are labeled as cigars or as some other product. If a product is labeled as a cigar or as some other tobacco product and the agency determines that the product meets the definition of cigarette in section 900(3), then consistent with its enforcement policy, a warning letter will be issued to the firm to provide it with notice of its violation of the FSPTCA. The warning letter provides the firm with 15 business days to respond prior to the agency’s initiation of further regulatory action against the firm and/or its tobacco product. The agency will follow this policy unless the evidence shows that the violation involves felonious intent or the agency has promulgated regulations under section 901(b) of the FSPTCA.

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We encourage members of the public to submit any information relevant to compliance with the prohibition of cigarettes containing characterizing flavors, including information concerning consumer perception of tobacco products not labeled as cigarettes, but because of their appearance, the type of tobacco used in the filler, or their packaging and labeling, are likely to be offered to, or purchased by, consumers as cigarettes. Please submit any information to Docket No. FDA-2009-N-0294.

### **6. Does the ban apply to bona fide pipe tobacco?**

No. The ban does not apply to bona fide pipe tobacco. However, as noted above in question 5, the ban applies to all tobacco products with certain characterizing flavors that meet the definition of a “cigarette” in section 900(3) of the FDCA. The definition of a “cigarette” includes “tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.”

We encourage members of the public to submit any information relevant to compliance with the ban of cigarettes containing characterizing flavors regarding any tobacco product that may meet the definition of a “cigarette.” Please submit any information to Docket No. FDA-2009-N-0294.

### **7. How will this ban be enforced?**

As of September 22, 2009, cigarettes and their component parts that contain characterizing flavors (other than tobacco or menthol) or an herb or spice are illegal. FDA has a range of enforcement and regulatory tools to address violations of the ban by, among others, manufacturers, importers, distributors, and retailers. Before taking enforcement action, it is the agency’s general practice to issue Warning Letters to firms to notify them that they or their products are in violation of the law and to give them the opportunity to come into compliance. As always, when circumstances are appropriate, FDA may take enforcement action to protect the public health without first issuing a Warning Letter.

### **8. Will FDA provide a comprehensive list of products that are illegal?**

No. All products that meet the description in section 907(a)(1)(A) of the FDCA below are banned. Section 907(a)(1)(A) states:

“...a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.”

The agency plans to make available Warning Letters it has issued and information about enforcement actions it has taken to notify the public about violative products.