Draft Guidance for Industry and FDA Staff

The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act

DRAFT GUIDANCE

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For questions regarding this document contact Michele Mital at 301-796-4800.

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

Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This guidance is intended for manufacturers, retailers, importers, and FDA staff. The guidance describes FDA's current thinking regarding the scope of the provision prohibiting the marketing of a tobacco product in combination with another product regulated under the Federal Food, Drug, and Cosmetic Act (FDCA). It is not intended to be an exhaustive analysis of all activities that may or may not fall within the scope of the prohibition.

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.

II. Discussion

Section 201(rr)(4) of the FDCA, as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), states:

> A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement)

This guidance discusses certain activities that FDA believes do or do not fall within the scope of the prohibition. The guidance is not intended to be an exhaustive analysis of all activities that may or may not fall within the scope of the prohibition.

A. FDA believes the following activities are included within the scope of section 201(rr)(4) of the FDCA and, therefore, are prohibited:

A tobacco product and a non-tobacco product regulated under the FDCA are physically, chemically, or otherwise combined or mixed to produce a single entity that is marketed as containing both products. For example:

- Mouthwash (which may be a drug or a cosmetic under the FDCA) is added to the ingredients of a cigarette and the cigarette is identified as containing mouthwash.
- Compressed or powdered tobacco is added to candy or gum (which are foods under the FDCA) and the candy or gum is identified as containing a tobacco product.
- Nicotine that is derived from tobacco is added to water, juice, or soda (which are foods under the FDCA) and the water, juice, or soda is identified as containing a tobacco product.

A tobacco product and a non-tobacco product regulated under the FDCA are packaged together in a single package or as a unit. For example:

- A pack of cigarettes is shrink-wrapped or sold in a box, bag, or other container with a bottle of mouthwash.
- A pack of cigarettes is shrink-wrapped or sold in a box, bag, or other container with a skin cream.

A coupon for a discount on a specifically identified non-tobacco product regulated under the FDCA is offered contingent upon the purchase of a tobacco product. For example:

- A coupon for a 50 cent discount on a specifically identified mouthwash is offered contingent upon the purchase of a pack of cigarettes.

B. FDA believes the following activities are not included within the scope of section 201(rr)(4) of the FDCA and, therefore, are not prohibited under that section:

A tobacco product and a non-tobacco product regulated under the FDCA are advertised on the same store sign or in the same store circular. For example:

- Cigarettes and mouthwash are advertised on the same sign in a store window or in the same store advertising circular.

A tobacco product and a non-tobacco product regulated under the FDCA are sold in the same retail establishment or advertised in the same place. For example:

- Cigarettes and mouthwash are sold in the same store or are advertised in the same magazine.

Two or more tobacco products are packaged together in a single package or as a unit.

- A pack of cigarettes is sold in a box, bag, or other container with a package of pipe tobacco.