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Guidance for Industry

Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products

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

June 2010

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

Additional Copies

Additional copies are available from: Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, (Tel) 1-877-287-1373, http://fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.

Guidance for Industry[1]

Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products

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. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

This guidance document is intended to provide information related to FDA's enforcement policy concerning Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by Section 204 of the Family Smoking Prevention and Tobacco Control Act. Section 204 of the Tobacco Control Act amended Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the "Smokeless Tobacco Act," 15 U.S.C. 4402), to prescribe new requirements for health warning labels that must appear on smokeless tobacco product packages and advertising, and to require that rotational warning plans for packaging and advertising for smokeless tobacco products be submitted to FDA, rather than to the Federal Trade Commission (FTC).

Definition of "smokeless tobacco" under the Smokeless Tobacco Act

"Smokeless tobacco" is any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity. 15 U.S.C. 4408(1).

Background

The new warning labels required by Section 3 of the Smokeless Tobacco Act must begin to rotate in advertising for smokeless tobacco products beginning on June 22, 2010, and

[1] This guidance has been prepared by the Center for Tobacco Products at the U.S. Food and Drug Administration.

must be distributed and displayed on the packaging of smokeless tobacco products manufactured on or after June 22, 2010, as set forth in Section 3(b)(3) of the Smokeless Tobacco Act. Section 204(b) of the Tobacco Control Act; Section 3(b)(3) of the Smokeless Tobacco Act. In addition, on or after July 22, 2010, manufacturers may not introduce any smokeless tobacco product into domestic commerce unless its packaging complies with Section 3 of the Smokeless Tobacco Act. Id. Among the requirements in Section 3(b)(3) is that the rotation of label statements on packaging and advertising for each brand of smokeless tobacco must be "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA. Id.

FDA Enforcement Policy

At this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that a smokeless tobacco manufacturer, distributor, importer, or retailer must have an FDA-approved rotational warning plan so long as a rotational warning plan has been submitted to FDA by July 22, 2010. FDA believes that allowing additional time for the review of rotational warning plans will permit an orderly transition of regulatory authority from the FTC to FDA to review and approve rotational warning plans. During such transition between June 22, 2010, and July 22, 2010, affected companies may wish to contact FDA to discuss the submission of their rotational warning plans in order to make the subsequent approval process more orderly and efficient. FDA intends to provide further public notice prior to revising or rescinding this enforcement policy after the transition from FTC to FDA has been accomplished for the submission and review of rotational warning plans. This enforcement policy pertains only to the requirement that smokeless tobacco manufacturers, distributors, importers, or retailers must have an FDA-approved rotational warning plan. FDA expects compliance with regard to all other requirements of Section 3 of the Smokeless Tobacco Act, including the requirements relating to size, formatting, location, and use of required warning statements.

Where to submit rotational warning plans

Written rotational warning plans should be directed to:

Office of Compliance
Center for Tobacco Products
Document Control Center
9200 Corporate Boulevard
Rockville, MD 20850