

**Guidance for Industry:
Compliance With Regulations Restricting the
Sale and Distribution of Cigarettes and
Smokeless Tobacco to Protect Children and
Adolescents**

December 9, 2013

Office of Compliance and Enforcement
Center for Tobacco Products
U.S. Food and Drug Administration

Family Smoking Prevention and Tobacco Control Act

- President Obama signed into law on June 22, 2009
- The Food and Drug Administration (FDA) was given the authority to regulate tobacco products under the new law

Family Smoking Prevention and Tobacco Control Act

- Required FDA to re-issue certain regulations previously issued in 1996
- Authorizes FDA to contract with States, U.S. Territories, and Tribes to assist with inspections of tobacco product retailers

Guidance Document

- Guidance represents FDA's current thinking on the regulations regarding "Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents"
- Guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public

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Draft Guidance for Industry

Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents
[Revision to Draft Guidance]*

Document Issued: March 2011

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 are available from:

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Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850
(Tel) 240-276-1717

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>

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

* This revised draft guidance replaces the original FDA guidance "Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents," which FDA issued in June 2010. Revisions/Additions are noted by date.

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For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CIP-1373 (1-877-287-1373) Monday-Friday, 9:00 a.m. – 4:00 p.m. EDT.

Additional copies are available online at:
<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.
You may send an e-mail request to SmallBizTobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, 9200 Corporate Blvd., Rockville, MD 20850.

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

August 2013

21 C.F.R. 1140

- “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents”
- Applies to manufacturers, distributors, and retailers who manufacture, distribute, or sell cigarettes or smokeless tobacco
- Effective 6/22/10

Regulated Products

- **Cigarettes, including roll-your-own tobacco**
- **Cigarette Tobacco**
- **Smokeless tobacco**
 - e.g., moist snuff, snus, loose leaf chewing tobacco, and other products meeting the definition of a smokeless tobacco product

NOT covered by the Rule

- Cigars and pipe tobacco that do **not** meet the definition of cigarettes

Sale and Distribution Provisions

- Prohibits the sale of cigarettes or smokeless tobacco to people younger than age 18
- Requires retailers to verify that a person buying cigarettes or smokeless tobacco is at least 18 years old or older by means of photographic identification (photo ID) containing the bearer's date of birth for all individuals who are under the age of 27
- Requires all individuals who have access to a facility where no minors are present or permitted to enter to be at least 18 years old or older, including the sales clerk
- Prohibition of sale of regulated tobacco products to all minors, includes those attempting to purchase for an adult, e.g., parent

Examples of FDA recommended age verifying techniques

- Requiring employees to compare the date of birth on the photographic identification with a calendar
- Installing price scanners that require entering the purchaser's date of birth
- Requiring employees to scan all photographic identifications through an electronic age verification device

Sale and Distribution Provisions

- Prohibits the sale of cigarette packages with fewer than 20 cigarettes
 - May not sell individual cigarettes (often called “singles” or “loosies”) or any package with less than 20 cigarettes, or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use
 - Very limited exception for packaged, single cigarettes sold in vending machines in facilities where no person younger than 18 years of age is present or permitted to enter, at any time

Sale and Distribution Provisions

- Prohibits the sale of cigarettes and smokeless tobacco in vending machines, self-service displays, or other impersonal modes of sale, except in limited situations
- Prohibits use of electronic locks, tokens, remote operating mechanisms
- Discusses who is responsible for the self-service display, advertising, or labeling or other item

Sale and Distribution Provisions

- Prohibits free samples of cigarettes (except “buy one get one free”) and imposes strict requirements for the distribution of free samples of smokeless tobacco products

Marketing Provisions

- Prohibits non-tobacco gifts or other items in exchange for buying cigarettes or smokeless tobacco products or furnishing evidence of a tobacco purchase, such as credits, proofs-of-purchase, or coupons
 - Under enforcement discretion
- Prohibits tobacco brand name sponsorship of any athletic, musical, or other social or cultural event, or any team or entry in those events

Marketing Provisions

- Prohibits the sale or distribution of items, such as hats and T-shirts, with tobacco brands or logos
- Permissible forms of labeling and advertising without prior notice include: newspapers; magazines; periodicals or other publications (whether periodic or limited distribution); billboards, posters, and placards; non-point-of-sale promotional material (including direct mail); point-of-sale promotional material; and audio or video formats delivered at a point-of-sale
- For Electronic and online media, notification is required under 21 C.F.R. § 1140.30(a)(2)

For More Information

Visit:

<http://www.fda.gov/TobaccoProducts>