

Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program and Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 16, 2011.

**Donald M. Berwick,**  
Administrator, Centers for Medicare & Medicaid Services.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–D–0277]

#### **Draft Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled “Draft Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.” This revised draft guidance replaces the original draft guidance published in the **Federal Register** of June 9, 2010 (75 FR 32791). The original draft guidance was revised to remove potential ambiguities and to address several issues not included in the original draft guidance. This revised draft guidance is intended to help small entities comply with the final rule entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.”

**DATES:** Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 23, 2011.

**ADDRESSES:** The draft guidance for industry entitled “Draft Guidance for Industry: Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” is available on the Internet at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>, or a paper copy may be ordered free of charge by calling 1–877–287–1373.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, [ctpcpliance@fda.hhs.gov](mailto:ctpcpliance@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31; 123 Stat. 1776) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act and providing FDA with the authority to regulate tobacco products. Section 102 of the Tobacco Control Act requires FDA to publish final regulations regarding cigarettes and smokeless tobacco, which are identical in their provisions to the regulations issued by FDA on August 28, 1996 (61 FR 44396), with certain specified exceptions. In the **Federal Register** of March 19, 2010 (75 FR 13225), FDA published a final rule entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.” The final regulations apply to manufacturers, distributors, and retailers who make, distribute, or sell cigarettes or smokeless tobacco products.

As of June 22, 2010, these Federal regulations, among other things, prohibit retailers from selling cigarettes, cigarette tobacco, or smokeless tobacco to persons under the age of 18, and require retailers to verify the age of all customers under the age of 27 by checking a photographic identification that includes the bearer’s date of birth.

FDA announced the publication of the original draft guidance document on June 9, 2010 (75 FR 32791). This revised draft guidance replaces the original draft

guidance. The original draft guidance was revised to remove potential ambiguities and to address several issues not included in the original draft guidance. This revised draft guidance is intended to help small entities comply with the final rule entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” published on March 19, 2010. FDA is soliciting comments on the revised draft guidance document which replaces the original draft guidance document. FDA may amend the guidance document periodically as a result of comments received.

##### **II. Significance of Guidance**

FDA is issuing this draft guidance document consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on “Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### **III. Comments**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>.

Dated: March 17, 2011.

**Leslie Kux,**  
Acting Assistant Commissioner for Policy.

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