

OTHER MEDIA NOTIFICATIONS

COMPLIANCE TRAINING AND EDUCATION FOR RETAILERS AND SMALL BUSINESSES



FDA

CENTER FOR
TOBACCO
PRODUCTS

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MISSION STATEMENT

The mission of FDA's Center for Tobacco Products (CTP) is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

OVERVIEW

1. Legal authority
2. Notification requirements
3. Guidance for Industry information

LEGAL AUTHORITY

TITLE 21 C.F.R. PART 1140

Title 21 C.F.R. Part 1140

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

21 C.F.R. §1140.30(a)(1)

Permissible forms of advertising without prior notification:

A manufacturer, distributor, or retailer may, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in:

21 C.F.R. §1140.30(a)(1)

- Newspapers
- Magazines
- Periodicals or other publications
- Billboards, posters, and placards
- Nonpoint-of-sale promotional material
- Point-of-sale promotional material
- Audio or video formats delivered at a point-of-sale

21 C.F.R. §1140.30(a)(2)

- Other media notification requirements:

A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall:

21 C.F.R. §1140.30(a)(2)

- Notify Agency 30 days prior to the use of such medium
- Describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age

1996 RULE

- Preamble stated that online media are not included within the list of permissible outlets for advertising without prior notice to FDA
- Preamble also stated product placements in movies, music videos, and television, if not done at the expense of tobacco manufacturers, distributors, or retailers would not be affected by the rule

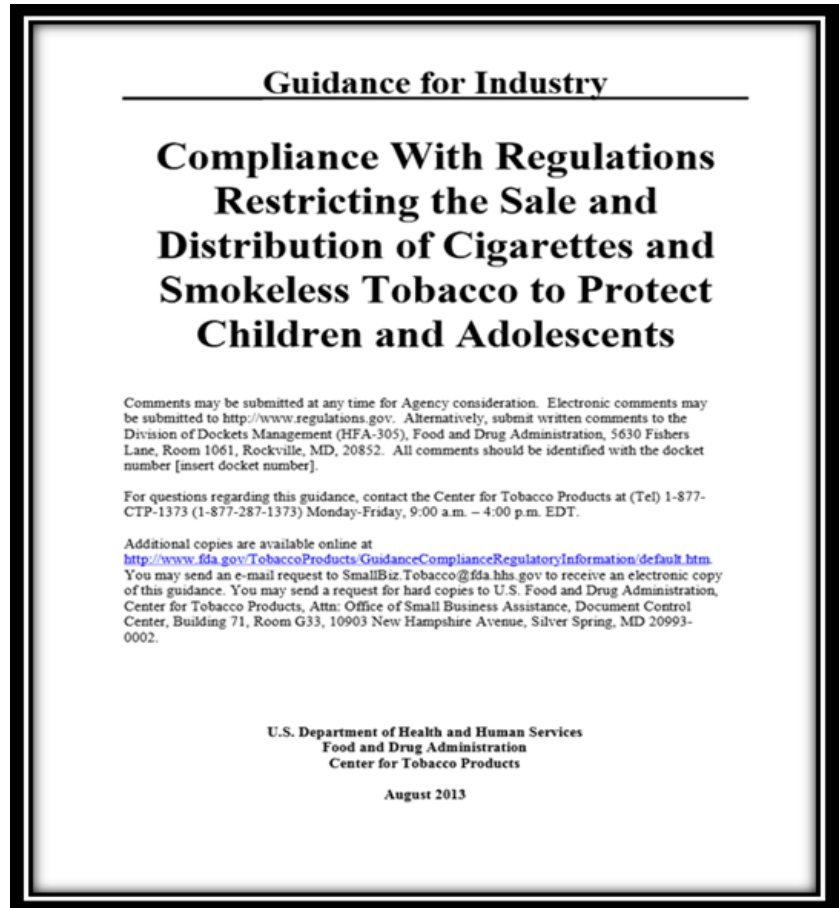
1996 RULE

- FDA does require prior notification for product placements in movies, music videos, and television, when such placements are done at the expense of tobacco manufacturers, distributors, or retailers
- Since 1996, many forms of electronic and online media have come into existence or become more prevalent

GUIDANCE FOR INDUSTRY

“Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents”

(August 21, 2013)



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

EXAMPLES OF “OTHER MEDIA”

- Internet Websites
- Product placements in movies, music videos or television*
- Blogs, weblogs, microblogs
- Emails sent to consumers
- Podcasts
- Video sharing
- Pop up or roll-over advertisements on Websites
- Social networks and online communities
- Widgets or window gadgets
- Wikis
- Applications for smart phones and tablet computers
- Text messaging
- Instant messaging

*If done at the expense of tobacco manufacturers, distributors, or retailers

NOTIFICATION REQUIREMENTS

NOTIFICATION REQUIREMENTS

- Submit at least 30 days prior to use of medium
- Description of the advertising or labeling medium
- Discussion of the extent to which the advertising or labeling may be seen by persons younger than 18 years of age

GUIDANCE FOR INDUSTRY INFORMATION

Notification should include:

- List of the tobacco products covered by the notification
- Description of the advertising or labeling medium
- Discussion of the extent to which the medium may be seen by persons younger than 18 years of age; and
- Discussion of any access restrictions, including restrictions for people younger than 18 years

Notification Cover Letter

Cover letter including:

- Date of notification
- Subject line: “RE: § 1140.30(a)(2) Notification of Other Advertising and Labeling Medium”
- Official contact
- Company role (manufacturer, distributor, or retailer)
- Most responsible individual of the regulated entity, if submitter is an agent submitting on behalf of the regulated entity

Notification Submission Address

The notification must be submitted to:

Office of Compliance and Enforcement
Center for Tobacco Products
Food and Drug Administration
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitting Notifications

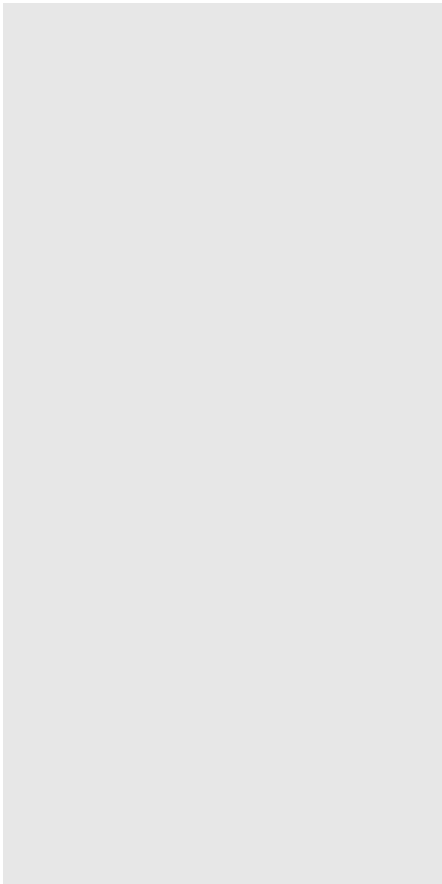
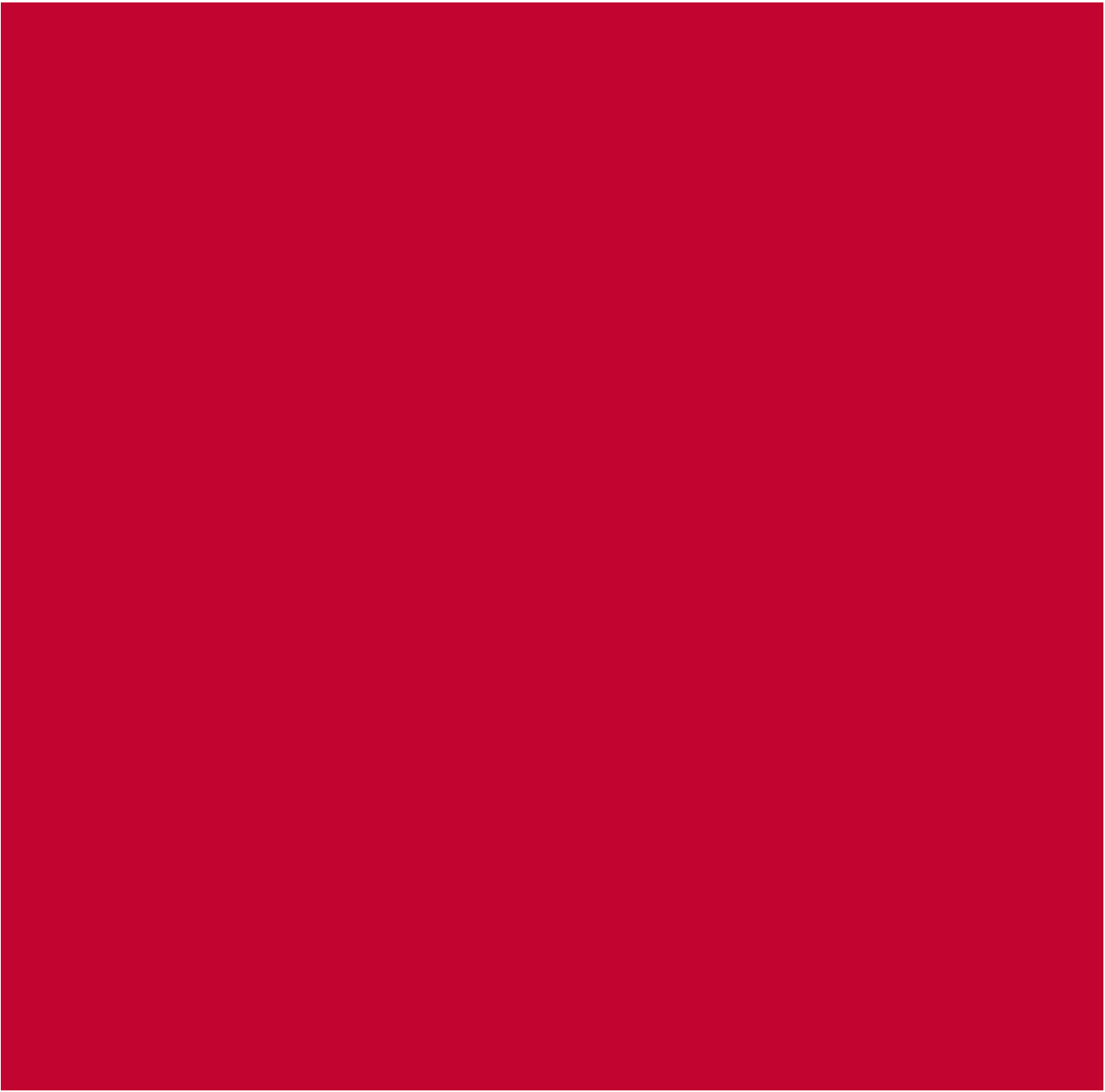
If you modify any previous access restrictions such that advertising or labeling previously unseen by persons younger than 18 years of age may then be seen by persons younger than 18 years of age, you should submit a new notification under section 1140.30(a)(2).

Submitting Notifications

If you currently disseminate cigarette or smokeless tobacco labeling or advertising in any media not listed in section 1140.30(a)(1), including but not limited to those discussed above, and have not already provided the notification required by 21 C.F.R. § 1140.30(a)(2), you should promptly do so.

QUESTIONS

- Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (August 21, 2013) at:
 - www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation
- Email FDA at: askctp@fda.hhs.gov
- Call FDA Toll-free at: 1-877-CTP-1373



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