



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 16, 2014

Dear Manufacturer, Retailer, Distributor or Importer:

The Center for Tobacco Products at the Food and Drug Administration (FDA) is providing this reminder to manufacturers, distributors,¹ and retailers of the requirements under the “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,” (1996 Rule), reissued at Title 21 Code of Federal Regulations (C.F.R.) Part 1140 (Cigarettes and Smokeless Tobacco) which, among other things, governs the ability of manufacturers, distributors, and retailers to advertise cigarettes and smokeless tobacco. Specifically, FDA reminds regulated industry to submit notifications to FDA if they intend to disseminate advertising or labeling in a medium not listed under 21 C.F.R. § 1140.30(a)(1) (media listed under 21 C.F.R. section 1140.30(a)(1) include newspapers; magazines; periodicals or other publications (whether periodic or limited distribution); billboards, posters, and placards; nonpoint-of-sale promotional material (including direct mail); point-of-sale promotional material; and audio or video formats delivered at a point-of-sale), as required under section 1140.30(a)(2). Section 1140.30(a)(2) provides, in part:

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 notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age.

In the preamble to the 1996 Rule, FDA noted that online media are not included within the list of permissible outlets for advertising without prior FDA notification and that advertisers should notify the Agency prior to advertising on the Internet. See 61 Fed. Reg. 44,395, 44,502 (Aug. 28, 1996). FDA also stated that 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. See 61 Fed. Reg. 44,395, 44,501 (Aug. 28, 1996). However, 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. Some examples of such media include, but are not limited to:

- Internet websites

¹ “Distributor means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption”. 21 C.F.R. § 1140.3(c).

- Product placements in movies, music videos, and television, if done at the expense of tobacco manufacturers, distributors, or retailers
- Blogs or weblogs (e.g., Blogger, WordPress, Tumblr)
- Emails sent to consumers
- Microblogs (e.g., Twitter)
- Podcasts (e.g., audio sharing)
- Social networks and online communities (e.g., Facebook, MySpace, LinkedIn, Friendster)
- Smart phones
- Video sharing (e.g., YouTube, Blip tv, Vimeo)
- Widgets or window gadgets
- Wikis (e.g., Wikipedia)
- Applications for smart phones and tablet computers (e.g., iPhones, Androids, iPads)
- Text messaging
- Instant messaging
- Pop up or roll-over advertisements on websites
- Online banners

You must provide the notification required by 21 C.F.R. § 1140.30(a)(2) for each medium not listed under section 1140.30(a)(1) through which you plan to disseminate, or cause to be disseminated, advertising and labeling, at least 30 days prior to the use of such medium. The notification must be submitted to the following address:

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

FDA requests that your notification be accompanied by a cover letter that includes:

- Date of the notification;
- The following subject lines:
 "RE: § 1140.30(a)(2) Notification of Other
 Advertising and Labeling Medium";
- The official contact name, address, email, fax number and phone number of the person authorized to act as the FDA contact regarding the notification.
- The name of the most responsible individual of the regulated entity, if the submitter is an agent submitting on behalf of the regulated entity;
- An indication whether the notification is done by or on behalf of a manufacturer, distributor, or retailer of the tobacco products covered by the submission.

The notification should include the following information:

- A list of the tobacco products covered by notification;

- A detailed description of the advertising or labeling medium. FDA requests that this information include, as applicable, each website domain name, each Twitter handle (username), etc.;
- A discussion of the extent to which the advertising or labeling medium may be seen by persons younger than 18 years of age; and
- A discussion of any access restrictions, including restrictions for persons younger than 18 years of age to the advertising or labeling medium.

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).

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.

For additional discussion on sections 1140.30(a)(1) and (a)(2), please review the Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, published August 2013, which is available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM248241.pdf>.

In addition, on September 23, 2014, at 2:00 p.m. EST., FDA will hold a live webinar on other media notification requirements. This webinar will be available at <http://www.fda.gov/tobaccoproducts/resourcesforyou/breakthechain/ucm220111.htm>.

Please address any comments to:

Ele Ibarra-Pratt, RN, MPH
Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We look forward to hearing from you. If you have any questions about the content of this letter, please contact FDA at 1-877-CTP-1373 (1-877-287-1373).

Sincerely,

/s/

Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products
Food and Drug Administration