Chattopadhyay, Kajal K. (DOR)

From: Althouse, Heather Rubino [redacted]
Sent: Thursday, February 15, 2018 4:37 PM
To: Chattopadhyay, Kajal K. (DOR)
Cc: Kabaria, Swati; Ibarra-Pratt, Ele; AskCTP
Subject: RE: Massachusetts Illegal Tobacco Task Force

Good afternoon!

Thank you for your letter to the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). Your letter discussed the State's consideration of a proposal to require smokeless tobacco products to bear a Massachusetts tax stamp. Your letter included six questions, some related to exhibits. We appreciate your desire to keep CTP apprised of your tobacco-related activities and discuss this new proposal with us.

Your questions are restated below in bold, followed by our responses:

1) **If a tobacco distributor were to open a five-pack sleeve (log) of smokeless tobacco product that it received from the manufacturer, place a tax stamp on the individual tins of the product, place the individual tins in a single clear bag solely to be used for transport such that the tins would be individually sold at the retailer and the clear bag discarded, would the distributor be considered a manufacturer or packager such that it would be required to submit a warning plan separate and apart from that already placed on record by the original manufacturer or importer of the product?**

   Under section 900(20) of the FD&C Act, a "tobacco product manufacturer" means "any person, including any repacker or relabeler, who—(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States.

   Engaging in activities included in the definition of a manufacturer under the Federal Food, Drug, and Cosmetic (FD&C) Act, such as removing products from the original manufacturer's packaging and repackaging or relabeling them, would subject you to the requirements pertaining to manufacturers. Tobacco product manufacturers must comply with applicable provisions of the FD&C Act and its implementing regulations including, but not limited to:
   - Registering domestic manufacturing establishment(s) and submitting product listings to FDA;
   - Reporting ingredients, and harmful and potentially harmful constituents;
   - Requiring premarket review and authorization of new tobacco products by the FDA;
   - Placing health warnings on product packages and advertisements

2) **In the same scenario described in question #1 above, would the clear bag into which the smokeless tobacco product is placed after it has been affixed with the tax stamp be required to have FDA required labels and warnings where the individual tins of the smokeless product bearing the required warnings and labels would be visible through the clear bag?**

   The product package must bear one of the required warning statements for smokeless tobacco products (15 U.S.C. 4402(a)(1)). Under chapter IX of the FD&C Act, the term "package" means "a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers."

   For shipping containers, section 920(a) of the FD&C Act provides that the label, packaging, and shipping containers of tobacco products...shall bear the statement "sale only allowed in the United States".

   See response to question #5 below for information regarding additional requirements.

3) **In Exhibit #2 (above), the bottom of the tax stamp covers a portion of the border surrounding the FDA required warning, but does not interfere with the actual text of the warning. As depicted in Exhibit #2, would the placement of the tax stamp be considered I n violation of any FDA statutes or regulations pertaining to required warnings for smokeless tobacco products?**

The required warnings cannot be obstructed.

Under Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) (15 U.S.C. 4402), as amended by section 204 of the Family Smoking Prevention and Tobacco Control Act, each smokeless tobacco product package and advertisement must bear one of four textual warning statements below. It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears one of the following required warning statements (15 U.S.C. 4402(a)(1)).

Section 903(a)(3) of the FD&C Act provides that a tobacco product is misbranded if any word, statement, or other information required by or under authority of chapter IX of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Section 903(a)(1) of the FD&C Act provides that a tobacco product is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act provides that in determining whether labeling or advertising is misleading, it "shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material . . . to consequences which may result from the use of the article to which the labeling or advertising relates . . . under such conditions of use as are customary or usual."

4) **As a follow-up to Question #3, if the tax stamp covered any part of the actual text of the FDA required warning (e.g., the top part of a letter), but the warning was otherwise unobstructed, would such placement of the tax stamp be considered in violation of any FDA statutes or regulations pertaining to required warnings for smokeless tobacco products?**

See the response to question 3.

5) **Please identify the specific statutory and regulatory provisions that specify the required labeling (e.g. warning labels, manufacturer identification, location of production, source of tobacco, etc.) for smokeless tobacco products?**

Provided below are provisions that you may find relevant to the questions you asked.

Under section 900(20) of the FD&C Act, a "tobacco product manufacturer" means "any person, including any repacker or relabeler, who—(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States.

Tobacco product manufacturers must comply with applicable provisions of the FD&C Act and its implementing regulations including, but not limited to:

- Registering domestic manufacturing establishment(s) and submitting product listings to FDA;
- Reporting ingredients, and harmful and potentially harmful constituents;
- Requiring premarket review and authorization of new tobacco products by the FDA;
- Placing health warnings on product packages and advertisements

Under Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) (15 U.S.C. 4402), as amended by section 204 of the Family Smoking Prevention and Tobacco Control Act, each smokeless tobacco product package and advertisement must bear one of four textual warning statements below. It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any

smokeless tobacco product unless the product package bears one of the following required warning statements (15 U.S.C. 4402(a)(1)):

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

Under chapter IX of the FD&C Act, the term "package" means "a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers."

The requirement for submission of warning plans for smokeless tobacco products and the specific requirements relating to random display of required warning statements on smokeless tobacco product packaging and quarterly rotation of required warning statements in smokeless tobacco product advertising appear at 15 U.S.C. 4402(b)(3). For information on "who submits a warning plan," please refer to FDA's draft guidance: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products (p. 8).

Section 903(a)(2) of the FD&C Act provides that a tobacco product is misbranded if in package form unless it bears a label containing--

(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;
(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;
(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and
(D) the statement required under section 920(a)..."

Note: In the draft guidance, entitled, Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops, FDA indicated that it intends to use enforcement discretion regarding section 903(a)(2)(c) of the FD&C Act for those products that are made or derived from tobacco. When the draft guidance is finalized it will represent FDA's current thinking on the issues contained therein.

Section 920(a) of the FD&C Act provides that the label, packaging, and shipping containers of tobacco products...shall bear the statement "sale only allowed in the United States".

Again, under chapter IX of the FD&C Act, the term "package" means "a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers."

Section 201(k) of the FD&C Act provides that a "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

As discussed in response to questions 3 and 4, section 903(a)(3) of the FD&C Act provides that a tobacco product is misbranded if any word, statement, or other information required by or under authority of chapter IX of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Section 903(a)(1) of the FD&C Act provides that a tobacco product is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act provides that in determining whether labeling or advertising is misleading, it "shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material . . . to consequences which may result from the use of the article to which the labeling or advertising relates . . . under such conditions of use as are customary or usual."

6) If Massachusetts moves forward with its proposal to require individual tins of smokeless tobacco product to bear a Massachusetts tax stamp, would the FDA be willing to review samples of individually stamped

tins and the clear bags into which they would be placed prior to implementation so that Massachusetts could obtain verification of compliance with applicable FDA regulations and statutory provisions?

Should you wish to contact us again about this issue, you can e-mail AskCTP@fda.hhs.gov. This allows us to track our correspondence.

For More Information

Not all legal requirements related to tobacco products are discussed in this response.

FDA continues to update its website to provide information designed to help industry and other stakeholders. Further, FDA posts Tobacco Compliance Webinars to our website and updates will be provided as additional webinars are available. We also encourage you to subscribe to FDA's "This Week in CTP." By subscribing, you'll receive updates about regulatory activities, retailer notices, upcoming events, and public education campaigns.

Thank you again for continuing to discuss this proposal with us.

-Heather

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