4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2015-N-1514]

RIN 0910-AH24

Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the regulation of "tobacco products" subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and restrictions regarding the sale and distribution of such tobacco products. Specifically, this ANPRM is seeking comments, data, research results, or other information that may inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. In April 2014, FDA published a proposed rule seeking to deem products meeting the

statutory definition of "tobacco product," except accessories to proposed deemed tobacco products, to be subject to the FD&C Act, as amended by the Tobacco Control Act. Specifically, the proposed rule seeks to extend the Agency's "tobacco product" authorities to those products that meet the statutory definition of "tobacco product," prohibiting the sale of "covered tobacco products" to individuals under the age of 18, and requiring the display of health warnings on certain tobacco product packages and in advertisements. The deeming rulemaking does not address the issues raised in this ANPRM.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-N-1514 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional

information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bryant M. Godfrey, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1-877-CTP-1373, bryant.godfrey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31). Specifically, section 101(b) of the Tobacco Control Act amends the FD&C Act by adding a new chapter that provides FDA with authority over tobacco products. Section 901 of the FD&C Act (21 U.S.C. 387a), as amended by the Tobacco Control Act, states that the new chapter in the FD&C Act (chapter IX--Tobacco Products) (21 U.S.C. 387 through 387u) applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to this chapter. Accordingly, in the Federal Register of April 25, 2014 (79 FR 23142), FDA published a proposed rule seeking to deem all products meeting the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except accessories to those products, to be subject to chapter IX of the FD&C Act.

FDA has evaluated data and science (including all of the evidence submitted to the docket of the proposed "deeming" rule cited below) related to the risks, especially to infants and children, from accidental exposure to nicotine, including exposure to liquid nicotine and nicotine-containing e-liquid(s), which are primarily used with electronic nicotine delivery systems (ENDS), such as electronic cigarettes. Recent increases in calls and visits to both poison control centers (see, e.g., CDC's Morbidity and Mortality Weekly Report, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm) and emergency rooms in the United States involving liquid nicotine poisonings and exposures has increased the public health concerns of these exposure risks. As a result of FDA's evaluation and these recent trends, FDA is considering whether, based on the acute toxicity of nicotine (up to and including nicotine poisoning), it would be appropriate for the protection of the public health to warn the public about the dangers of nicotine exposure, especially due to inadvertent nicotine exposure in infants and children, and/or require that some tobacco products be sold in child-resistant packaging. Comments submitted in response to FDA's proposed rule seeking to deem all tobacco products to be subject to the FD&C Act support such actions, and many request that FDA take prompt action to mitigate nicotine exposure risks (see Docket No. FDA-2014-N-0189, http://www.regulations.gov).

As previously discussed, the FD&C Act provides FDA with authority to regulate tobacco products. Sections 906(d)(1) and 910(c)(1)(B) of the FD&C Act provide FDA the authority to, by regulation or in a marketing authorization order, require restrictions on the sale and distribution of a tobacco product. The restrictions on the sale and distribution of a tobacco product may include restrictions on the access to, and the advertising and promotion of, the tobacco product, if FDA determines such restrictions would be appropriate for the protection of

the public health. The FD&C Act also provides FDA with authority to adopt a tobacco product standard under section 907 of the FD&C Act if the Secretary finds that it is appropriate for the protection of the public health.

In making such a finding under either section 906(d)(1) or section 907 of the FD&C Act, the Secretary must consider: (1) The risks and benefits to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

FDA intends to use the information submitted in response to this ANPRM to further inform its thinking about options for issuing potential regulations that would require nicotine exposure warnings and/or child-resistant packaging for some tobacco products, as articulated in this document. For the purposes of the questions in this ANPRM:

- "Liquid nicotine and nicotine-containing e-liquid(s) (liquid nicotine combined with colorings, flavorings, and/or potentially other ingredients)" are generally referred to as liquid nicotine.
- "Liquid nicotine" (as used throughout this document) refers to liquid nicotine that is made or derived from tobacco and intended for human consumption.
- "Novel tobacco products" (as used throughout this document) refers to products such as dissolvables, lotions, gels, and drinks.

II. Requests for Comments and Information

FDA is seeking comments, data, research results, and other information related to the following questions. Please explain your responses and provide any evidence or other information supporting your responses to the following questions:

A. Nicotine Exposure Warnings

1. Should FDA consider requiring nicotine exposure warning(s) text on liquid nicotine? If so, why?
2. Should FDA consider requiring nicotine exposure warning(s) text on tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products? If so, which products and why?
3. On what basis (e.g., physical characteristics or appearance of the product or packaging, product risks, form of marketing, route of exposure, type of packaging) should FDA determine which products should be required to carry the warning(s)? What data or information would be helpful to demonstrate the need for a warning or warnings?
4. If FDA were to require nicotine exposure warning(s) text for liquid nicotine, what issues should the warning(s) address and what wording should be used? Please consider: (a) Whether the warning(s) should be broad, or directed at specific dangers; (b) whether the warning(s) should specifically address oral, ocular, and dermal exposure dangers; (c) whether the warning(s) should focus exclusively on the risks to children and youth, or include the risks to vulnerable populations, such as pregnant women, adults with medical conditions, and pets; (d) whether the warning(s) should contain instructions to avoid the dangers altogether, such as "keep out of the reach of children"; (e) whether there are other dangers of liquid nicotine exposure that should be covered by the warning(s); and (f) whether information about what to do in the case of an accidental exposure to liquid nicotine should be included (e.g., when to seek medical attention, when to contact a Poison Control Center). Please submit data or evidence to support your position.

5. With preceding question 4 in mind, should there be multiple textual warnings that randomly display to convey different dangers, or should there be a single, consistent textual warning that covers all of the different dangers? Please submit data or evidence to support your position.
6. If FDA were to require nicotine exposure warning(s) text for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, what issues should the warning(s) address and what wording should be used? Please consider: (a) Whether the warning(s) should be broad, or directed at specific dangers; (b) whether the warning(s) should specifically address oral, ocular, and dermal exposure dangers; (c) whether the warning(s) should focus exclusively on the risks to children and youth, or include the risks to vulnerable populations, such as pregnant women, adults with medical conditions, and pets; (d) whether the warning(s) should contain instructions to avoid the dangers altogether, such as "keep out of the reach of children"; (e) whether there are other dangers of nicotine exposure that should be covered by the warning(s); and (f) whether information about what to do in the case of an accidental exposure to liquid nicotine should be included (e.g., when to seek medical attention, when to contact a Poison Control Center). Please submit data or evidence to support your position.
7. With preceding question 6 in mind, please respond to the following questions: Should there be multiple textual warnings that randomly display to convey different dangers, or should there be a single, consistent textual warning that covers all of the different dangers? Should different types of tobacco products carry different warnings? If so, which type(s) of tobacco products should carry what warning(s) and what is the reasoning for different warnings for different types of tobacco products? Please submit data or evidence to support your position.

8. If FDA were to require nicotine exposure warning(s) text for liquid nicotine, should FDA consider requiring color(s) or graphic elements, such as symbols, as part of the warning(s)? If so, what color or graphic elements should FDA consider?

   (a) Are there data on graphic elements and/or colors that would be most effective in communicating the dangers associated with nicotine exposure? If so, please provide these data.

   (b) Would a graphic element alone (as opposed to text alone or any combination of text, color, or graphic elements) be sufficient to effectively communicate the dangers associated with nicotine exposure? Please provide data or evidence to support your position.

   (c) How could the warning(s) text and graphic image(s) add to or detract from each other?

9. If FDA were to require nicotine exposure warning(s) text for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, should FDA consider requiring color(s) or graphic elements as part of the warning(s)? If so, what color or graphic elements should FDA consider?

   (a) Are there data on graphics and/or colors that would be most effective in communicating the dangers associated with nicotine exposure? If so, please provide these data.

   (b) Would a graphic image alone be sufficient to effectively communicate the dangers associated with nicotine exposure? Please provide data or evidence to support your position.

   (c) How could the warning(s) text and graphic image(s) add to or detract from each other?

(d) Should different tobacco products carry different color or graphic elements? If so, what criteria should FDA use to determine which type of tobacco products should carry what color or graphic elements?

10. If FDA were to require a nicotine exposure warning(s) (text and any applicable color or graphic element) for liquid nicotine, should FDA adopt a different nicotine exposure warning(s) requirement based on the packaging/containers (e.g., a brief/abbreviated warning(s) for liquid nicotine in small packaging/containers, omit the warning(s) if the tobacco product is in a child-resistant package)? If so, how should the warning(s) differ? Please submit data or evidence to support your position.
11. With respect to tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, if FDA were to require a nicotine exposure warning(s) (text and any applicable color or graphic element), should FDA adopt a different nicotine exposure warning(s) requirement based on the packaging/containers (e.g., a brief/abbreviated warning(s) for tobacco products in small packaging, omit the warning(s) if the tobacco product is in a child-resistant package)? If so, how should the warning(s) differ? Please submit data or evidence to support your position.
12. Are you aware of data or information that would support any required font sizes, formatting, and display considerations for nicotine exposure warnings (textual and/or graphic)? If so, please provide that evidence.
13. Should FDA require the inclusion of the American Association of Poison Control Centers' telephone number on the container labeling and/or packaging of liquid nicotine and tobacco products other than liquid nicotine? Why or why not?

14. Are there any nicotine exposure warnings (textual and/or graphic) for liquid nicotine required by authorities at the local, State, or Federal (i.e., other agencies) level, or by foreign governments that you particularly would like to highlight? If so, which ones and why? Are there any data regarding the effectiveness or utility of these warnings? If so, please provide these data.
15. Are there any nicotine exposure warnings (textual and/or graphic) for tobacco products other than liquid nicotine required by authorities at the local, State, or Federal (i.e., other agencies) level, or by foreign governments that you particularly would like to highlight? If so, which ones and why? Are there any data regarding the effectiveness or utility of these warnings? If so, please provide these data.
16. Are you aware of any existing evidence regarding whether warnings (text and any applicable color or graphic element) are effective for mitigating the risks of nicotine exposure? If so, please provide that evidence.

B. Child-Resistant Packaging

1. Should FDA require child-resistant packaging for liquid nicotine? If so, why?
2. Should FDA require child-resistant packaging for liquid nicotine if the liquid nicotine product is not intended to be opened by the consumer (e.g., liquid nicotine in permanently sealed, prefilled, and/or disposable cartridges)? Please provide the reason for your response.
3. Should FDA consider requiring child-resistant packaging for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products? If so, which ones and why?

4. If FDA were to require child-resistant packaging for liquid nicotine (including for those products that are not intended to be opened by the consumer), what type of exposure risks (e.g., oral, ocular, dermal) should FDA seek to mitigate with the requirement?
5. If FDA were to require child-resistant packaging for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, what risks (e.g., oral, ocular, dermal) should FDA seek to mitigate with the requirement?
6. If FDA were to require child-resistant packaging for liquid nicotine, how should the requirement be articulated? Please consider: (a) Whether the requirement should be based on mandated physical characteristics of the packaging (e.g., must have a squeeze-to-turn lid, flow restrictor); (b) whether the requirement should be performance based (e.g., unable to be opened by 80 percent or more of 5-year-olds who try to open the package, and more than 90 percent of adults on average between the ages of 50-70 can successfully open the package); or (c) whether the requirement should be based on a combination of (a) and (b), or is there some other basis for the requirement that FDA should consider? Is your proposal technically feasible? Please submit data or evidence to support your position.
7. If FDA were to require child-resistant packaging for tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, how should the requirement be articulated? Please consider: (a) Whether the requirement should be based on mandated physical characteristics of the packaging (e.g., must have a squeeze-to-turn lid, child-resistant cap, blister packaging); (b) whether the requirement should be performance based (e.g., unable to be opened by 80 percent or more of 5-year-olds who try to open the package, and more than 90 percent of adults on average between the ages of 50-70 can successfully open the package); or (c) whether the requirement should be based on a combination of (a) and (b),

or is there some other basis for the requirement that FDA should consider? Is your proposal technically feasible? Please submit data or evidence to support your position.

8. Are there other factors FDA should consider to further prevent or discourage people (especially infants and children) from inadvertently consuming or being exposed to liquid nicotine? If so, please explain. Examples of other factors may include: attractiveness of the product or packaging (e.g., appealing images, fragrance, flavors), resemblance of packaging to food and drink items (e.g., candy, fruit), color of the product (e.g., resemblance to beverages such as juice), resemblance of packaging to that of medications (e.g., eye drops).
9. If FDA were to require child-resistant packaging, what should FDA consider and what actions should FDA take to mitigate the risk that users of products with child-resistant packaging will defeat the purpose of the packaging by leaving the packaging open, by disabling the protection mechanism, or by moving the product to a different container?

C. Other Actions and Considerations

1. With respect to liquid nicotine, should FDA require both nicotine exposure warnings (text and/or any applicable color or graphic element) and child-resistant packaging, or should only one and not the other be required? Please explain your reasoning and provide data or evidence to support your position.
2. With respect to tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, should FDA require both nicotine exposure warnings (text and/or any applicable color or graphic element) and child-resistant packaging, or should only one and not the other be required? Please explain your reasoning and provide data or evidence to support your position.

3. With respect to liquid nicotine and the dangers of nicotine poisoning, should FDA consider requiring any additional warnings beyond a nicotine exposure warning (text and/or any applicable color or graphic element)? If so, please describe the warning(s) (textual and/or graphic) and provide evidence or data to support your recommendation.
4. With respect to tobacco products other than liquid nicotine, including, but not limited to, novel tobacco products, and the dangers of nicotine poisoning, should FDA consider requiring any additional warnings beyond a nicotine exposure warning (text and/or any applicable color or graphic element)? If so, for which products? Also, please describe the warning(s) (textual and/or graphic) and provide evidence or data to support your recommendation.
5. Should FDA consider any additional measures to mitigate nicotine exposure risks for people (especially infants and children) beyond nicotine exposure warnings (text and any applicable color or graphic element) and child-resistant packaging? If so, what measures should FDA consider and why? Please provide evidence or data to support your recommendation.

III. Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at

http://www.regulations.gov. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on http://www.regulations.gov. This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field entitled "Category (Required)", on the "Your Information" page on http://www.regulations.gov; for this ANPRM, however, FDA will not be following this general practice. Instead, FDA will post on http://www.regulations.gov comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on http://www.regulations.gov if you include that information in the body of your comments. For electronic comments submitted to http://www.regulations.gov, FDA will post the body of your comment on http://www.regulations.gov along with your State/province and country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on http://www.regulations.gov, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

Dated: June 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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