This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1211

[Document No. AMS–FV–11–0074; PR–A2 and PR–B2]

RIN 0581–AD24

Hardwood Lumber and Hardwood Plywood Promotion, Research and Information Order; Extension of Comment Period on Supplemental Notices

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Extension of comment period.

SUMMARY: Notice is hereby given that the comment period on a supplemental notice to amend the 2013 proposed rule for a Hardwood Lumber and Hardwood Plywood Promotion, Research and Information Order (Order) is extended. Under the proposed Order, assessments would be collected from hardwood lumber and plywood manufacturers and would be used to fund programs to promote hardwood lumber and plywood. The comment period is also extended for the supplemental notice to amend the 2013 proposed rule on procedures for conducting a referendum to determine whether issuance of a proposed Order is favored by manufacturers of hardwood lumber and hardwood plywood.

DATES: Comments must be received by September 7, 2015.

ADDRESSES: Interested persons are invited to submit written comments on the Internet at http://www.regulations.gov or to the Promotion and Economics Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., Room 1406–S, Stop 0244, Washington, DC 20250–0244; facsimile: (202) 205–2800; or email: Patricia.Petrella@ams.usda.gov.

SUPPLEMENTARY INFORMATION: The proposed rules on the Order and the referendum procedures were published in the Federal Register on November 13, 2013 (78 FR 68298 and 78 FR 67979, respectively). Those rules proposed the establishment of an industry-funded promotion, research and information program for hardwood lumber and hardwood plywood and referendum procedures. Those proposals provided for a 60-day comment period which ended on January 13, 2014. On January 16, 2014, a notice was published in the Federal Register that reopened and extended the comment period on the proposed Order until February 18, 2014 (79 FR 2805). A total of 939 comments were received during both comment periods. As a result of the extensive comments received, USDA published supplemental notices of proposed rulemaking on the proposed Order and the referendum procedures in the Federal Register on June 9, 2015 (80 FR 32493 and 80 FR 32488, respectively) to amend the 2013 proposed rules.

USDA received a request to extend the comment period to allow additional time for interested persons to review the proposals and submit comments. USDA is therefore extending the comment period an additional 60 days until September 7, 2015 to provide interested persons more time to review these rules, perform a complete analysis, and submit written comments.

Authority: This notice is issued pursuant to the Commodity Promotion, Research and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Dated: June 26, 2015.

Rex A. Barnes,
Associate Administrator.

[FR Doc. 2015–15184 Filed 6–30–15; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[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
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, particularly 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” (as used throughout this document) refers to liquid nicotine that is made or derived from tobacco and intended for human consumption.

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, 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.

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) 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/container(s) (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/container(s) (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 any existing 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...
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. 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).

8. 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.
DEPARTMENT OF THE TREASURY
Fiscal Service
31 CFR Parts 315, 353, and 360
[Docket No.: FISCAL–2015–0002]
RIN 1530–AA11
Regulations Governing United States Savings Bonds


ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Department of the Treasury, Bureau of the Fiscal Service, is proposing regulations governing United States savings bonds to address certain state escheat claims.

DATES: Comment due date: August 17, 2015.

ADDRESSES: The Bureau of the Fiscal Service invites comments on this proposed rule. Comments may be submitted through one of the following methods:
Electronically by submitting a comment at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Theodore C. Simms II, Senior Attorney, fiscal.treasury.gov.

I. Background

The Department of the Treasury has issued savings bonds since 1935 to raise funds for the operation of the Federal government, and to encourage savings by small investors. From the beginning of the savings bond program, savings bonds have been registered securities. Treasury has authorized several forms of registration, including registration to individuals, co-owners, fiduciaries, institutions, and beneficiaries. See 31 CFR 315.7, 353.7, and 360.6. Savings bonds generally are not transferrable and are payable only to the registered owner, except as described in Treasury regulations. See 31 CFR 315.15, 353.15, and 360.15. Detailed regulations describe when payment will be made to a person or entity that is not the registered owner.

Ownership of a savings bond is determined by Treasury's savings bond regulations. Federal and state courts, including the United States Supreme Court, have upheld these ownership rights against challenges by parties asserting claims under state law. See, e.g., Free v. Bland, 369 U.S. 663 (1962). The rights of registered owners and others described by Treasury regulations persist even for bonds that matured years ago, because Treasury does not require owners to redeem their paper savings bonds by a certain date.

In some cases, Treasury regulations determine who is entitled to payment based on state law. Treasury may look to state probate law, for example, to determine who is entitled to payment for savings bonds in a decedent's estate. See 31 CFR 315.71, 353.71, and 360.71. Treasury may also recognize certain state judicial proceedings that require payment to creditors, divorced spouses, and other claimants specifically listed in the regulations. See 31 CFR part 315, subpart E; Part 353, subpart E; part 360, subpart E. The touchstone for these claims, however, is Treasury's savings bond regulations.

Since at least 1952, Treasury has acknowledged circumstances when it will recognize a state's claim of title to savings bonds based on a judgment of escheat. "Escheat" describes a state's claim to property that has no owner. Many state probate laws allow a state to escheat the property of a person who dies without a will and without heirs. Treasury regulations do not specifically mention escheat, but they do provide that Treasury will pay a person entitled to the estate of a deceased savings bond owner in specified circumstances. When these circumstances are met, Treasury will pay a state that has title to savings bonds in the estate of a deceased owner. Like all claimants, the state must present the bonds to Treasury or otherwise meet Treasury's requirements for payment.

In recent years, states have submitted escheat claims to Treasury for savings bonds based on state unclaimed property laws, where there is no evidence that the savings bond owner has died. The first claims came from states whose escheat laws purported to give them custody, but not title, to certain unredeemed savings bonds. In 2012, the United States Court of Appeals for the Third Circuit upheld Treasury's position that states are not entitled to payment for savings bonds held only in their custody, because such claims interfere with the rights of registered owners and others under Treasury regulations. New Jersey v. U.S. Dept. of Treasury, 684 F.3d 382 (3rd Cir. 2012).

More recently, the State of Kansas submitted an escheat claim based upon a state court judgment that purported to convey title over certain unredeemed savings bonds. Kansas sought to redeem savings bonds in its possession, which had been turned over to the state as unclaimed property, and to redeem a much larger class of savings bonds that it did not possess. In this class are matured, unredeemed savings bonds...