

Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

54. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

55. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VII. Document Availability

56. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (<http://www.ferc.gov>) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

57. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

58. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

By direction of the Commission.

Kimberly D. Bose,
Secretary.

[FR Doc. 2013-17730 Filed 7-23-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 118

[Docket No. FDA-2000-N-0190 (formerly Docket No. 2000N-0504)]

Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers With Outdoor Access); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled "Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access)" (the draft guidance). The document provides guidance to egg producers on certain provisions contained in FDA's final rule entitled, "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation" concerning the management of production systems that provide laying hens with access to the outdoors. Laying hens are provided outdoor access in some production systems, including certified organic production systems governed by the U.S. Department of Agriculture's National Organic Program regulations. **DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by September 23, 2013.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301-436-2632. Send one self-addressed adhesive label to assist

that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Nancy Bufano, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1493.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 2009 (74 FR 33030), FDA issued a final rule requiring shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the final rule and to register with FDA. The final rule became effective September 8, 2009, with a compliance date of July 9, 2010, for producers with 50,000 or more laying hens. For producers with fewer than 50,000, but at least 3,000 laying hens, the compliance date was July 9, 2012. The compliance date for persons who must comply with only the refrigeration requirements was July 9, 2010. The final rule is codified at 21 CFR part 118.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on how to interpret the requirements in the final rule with regard to production systems that provide laying hens with access to the outdoors, including questions and answers on coverage; definitions; SE prevention measures; and environmental sampling for SE. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in §§ 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910-0660.

III. 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. 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>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: July 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-17750 Filed 7-23-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA-2013-N-0521]

Menthol in Cigarettes, 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 potential regulation of menthol in cigarettes. FDA is also making available its preliminary scientific evaluation of public health issues related to the use of menthol in cigarettes. The preliminary scientific evaluation indicates there is likely a public health impact of menthol in cigarettes. This ANPRM is seeking comments, including comments on FDA's preliminary evaluation, and data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes.

DATES: Submit either electronic or written comments by September 23, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0521, 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 or CD-ROM 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 Agency name and Docket No. FDA-2013-N-0521 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, 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:

Annette L. Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act, enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provides FDA with the authority to regulate tobacco products (Pub. L. 111-31, 123 Stat. 1776). Among other things, section 907(e) of the FD&C Act (21 U.S.C 387g(e)) requires FDA's Tobacco Products Scientific Advisory Committee (TPSAC) to submit a report and recommendations to the Secretary of Health and Human Services (the Secretary of HHS) on the impact of the use of menthol in cigarettes on the

public health, including use among children, African Americans, Hispanics, and other racial/ethnic minorities.

TPSAC has submitted the report to HHS, available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>. In addition, the nonvoting industry representatives of TPSAC submitted a separate document reflecting the industry perspective, available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf>. Two cigarette manufacturers have challenged FDA's ability to rely on TPSAC's menthol report, and that case is currently pending (*Lorillard, Inc. v. FDA*, No. 11-440 (D.D.C.)).

Experts within FDA's Center for Tobacco Products (CTP) also initiated an independent evaluation of the available science related to the impact of the use of menthol in cigarettes on public health including peer-reviewed literature, secondary data analyses, and independent CTP analyses of relevant large data sets. This preliminary independent evaluation is entitled "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes" (the evaluation) (Ref. 1). The evaluation has been peer reviewed, and the peer review report is available on FDA's Web site at <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>. FDA is also making available an addendum with articles published since the evaluation was submitted for peer review in 2011 (Ref. 2).

As discussed previously, the FD&C Act provides FDA with authority to regulate tobacco products. This includes authority to adopt a tobacco product standard under section 907 of the FD&C Act if the Secretary of HHS finds that a tobacco product standard is appropriate for the protection of public health and includes authority to amend an existing product standard. In making such a finding, the Secretary of HHS must consider scientific evidence concerning: (1) The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the product standard; (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. The FD&C Act also provides FDA with authority to, by