Proposed Rules

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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 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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) entitled ''Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products'' that appeared in the **Federal Register** of July 1, 2015. In the ANPRM, FDA requested comments, data, research results, or other information, that may inform regulatory actions that 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. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the ANPRM published July 1, 2015 (80 FR 37555). Submit either electronic or written comments by September 30, 2015.

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 ''Requests for Comments and Information'' 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: Bryant M. Godfrey or Courtney S. Smith, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1–877–CTP–1373, *CTPRegulations@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 1, 2015 (80 FR 37555), FDA published an ANPRM with a 60-day comment period to request comments, data, research results, or other information, that may inform regulatory actions that 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.

The Agency has received several comments requesting an extension of the comment period for the ANPRM. These comments convey concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful responses to questions raised in the ANPRM.

FDA has considered the requests and is extending the comment period for the ANPRM for 30 days, until September 30, 2015. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential regulatory action on these important issues.

II. Requests for Comments and Information

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: August 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20759 Filed 8–21–15; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0489; FRL–9932–74–Region 9]

Revision to the California State Implementation Plan; San Joaquin Valley; Demonstration of Creditable Emission Reductions from Economic Incentive Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a demonstration of creditable emission reductions submitted by California for approval into the San Joaquin Valley (SJV) portion of the California State Implementation Plan (SIP). This SIP submittal demonstrates that certain state mobile source incentive funding programs have achieved specified amounts of reductions in emissions of nitrogen oxides (NO_X) and fine particulate matter ($PM_{2.5}$) in the SJV area by 2014. The effect of this action would be to approve these amounts of emission reductions for credit toward an emission reduction commitment in the California SIP. We are taking comments on this proposal and plan to follow with a final action.

DATES: Written comments must be received on or before September 23, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R09–OAR–2015–0489, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *Email: steckel.andrew@epa.gov*

3. *Mail or deliver:* Andrew Steckel (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. Deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or email. *http://www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Idalia Perez, EPA Region IX, *perez.idalia@epa.gov,* (415) 972–3248.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we'', ''us'' and ''our'' refer to EPA.

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I. Background

On July 18, 1997, EPA established new national ambient air quality standards (NAAQS) for particles less than or equal to 2.5 micrometers (μm) in diameter ($PM_{2.5}$), including an annual standard of 15.0 micrograms per cubic meter (μg/m^3) based on a 3-year average of annual mean $PM_{2.5}$ concentrations, and a 24-hour (daily) standard of 65 μg/m^3 based on a 3-year average of 98th percentile 24-hour $PM_{2.5}$ concentrations.[1] EPA established these standards after considering substantial evidence from numerous health studies demonstrating that serious health effects are associated with exposures to $PM_{2.5}$ concentrations above these levels.

Following promulgation of a new or revised NAAQS, EPA is required under Clean Air Act (CAA) section 107(d) to designate areas throughout the nation as attaining or not attaining the NAAQS. On January 5, 2005, EPA published initial air quality designations for the 1997 annual and 24-hour $PM_{2.5}$ NAAQS, using air quality monitoring data for the three-year periods of 2001–2003 and 2002–2004.[2] These designations became effective April 5, 2005.[3] EPA designated the San Joaquin Valley (SJV) area[4] as nonattainment for both the 1997 annual $PM_{2.5}$ standard (15.0 μg/m^3) and the 1997 24-hour $PM_{2.5}$ standard (65 μg/m^3).[5]

Between 2007 and 2011, California made six SIP submittals to address nonattainment area planning

[1] 62 FR 36852 (July 18, 1997) and 40 CFR 50.7. Effective December 18, 2006, EPA strengthened the 24-hour $PM_{2.5}$ NAAQS by lowering the level to 35 μg/m^3. 71 FR 61144 (October 17, 2006) and 40 CFR 50.13. Effective March 18, 2013, EPA strengthened the annual $PM_{2.5}$ NAAQS by lowering the level to 12 μg/m^3. 78 FR 3086 (January 15, 2013) and 40 CFR 50.18. In this preamble, all references to the $PM_{2.5}$ NAAQS, unless otherwise specified, are to the 1997 24-hour standard (65 μg/m^3) and annual standard (15.0 μg/m^3) as codified in 40 CFR 50.7.

[2] 70 FR 944 (January 5, 2005).

[3] *Id.*

[4] The SJV area encompasses over 23,000 square miles and includes all or part of eight counties in California's central valley: San Joaquin, Stanislaus, Merced, Madera, Fresno, Tulare, Kings, and Kern. For a precise description of the geographic boundaries of the San Joaquin Valley nonattainment area, see 40 CFR 81.305.

[5] 40 CFR 81.305.