GuidanceDocuments RegulatoryInformation/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: August 11, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation and Analysis.

[FR Doc. 2016–19492 Filed 8–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR part 101

[Docket No. FDA–2011–F–0171]

Calorie Labeling of Articles of Food in Vending Machines; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry, entitled ''Calorie Labeling of Articles of Food in Vending Machines.'' The draft guidance, when finalized, will help covered vending machine operators and industry to better understand and comply with the final rule entitled ''Food Labeling: Calorie Labeling of Articles of Food in Vending Machines.''

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 30, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–F–0171 for Calorie Labeling of Articles of Food in Vending Machines; Draft Guidance for Industry. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of the guidance to Food Labeling and Standards Staff, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Felicia B. Billingslea, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Calorie Labeling of Articles of Food in Vending Machines.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of December 1, 2014 (79 FR 71259), we issued a final rule entitled ''Food Labeling: Calorie Labeling of Articles of Food in Vending Machines'' (''the rule''). The rule is codified at 21 CFR 101.8. The rule requires vending machine operators who own or operate 20 or more vending

machines, or who voluntarily register with FDA to be covered, to declare calories for those vending machine foods for which the Nutrition Facts label cannot be examined before purchase or for which visible nutrition information is not otherwise provided at the point of purchase. Covered vending machine operators must comply with the rule by December 1, 2016. However, in the **Federal Register** of August 1, 2016 (81 FR 50303), we issued a final rule entitled ''Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date.'' This rule provides that the compliance date for type size front-of-pack labeling requirements (§ 101.8(b)(2) (21 CFR 101.8(b)(2))) and calorie disclosure requirements (§ 101.8(c)(2)) for certain gums, mints, and roll candy products in glass-front machines in the final rule published December 1, 2014 (79 FR 71259) is extended to July 26, 2018. The compliance date for all other requirements in the final rule (79 FR 71259) remains December 1, 2016.

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 21 CFR 101.8 have been approved under OMB Control No. 0910–0782.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* 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: August 11, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–19493 Filed 8–15–16; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2014–0213; FRL–9950–65–Region 7]

Approval and Promulgation of Implementation Plans; State of Iowa; Infrastructure State Implementation Plan (SIP) Requirements for the 1997 and 2006 Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS), and the Adoption of the 1997 $PM_{2.5}$ Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of two State Implementation Plan (SIP) submissions from the State of Iowa for the Infrastructure SIP Requirements for the 1997 and 2006 Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS). Infrastructure SIPs address the applicable requirements of Clean Air Act (CAA) section 110, which requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each new or revised NAAQS promulgated by the EPA. The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA. This action also approves the adoption of the 1997 $PM_{2.5}$ standard.

On September 8, 2011, EPA issued a Finding of Failure to Submit a Complete State Implementation Plan for several states, including Iowa. With respect to Iowa, the Finding of Failure to Submit included the following 2006 $PM_{2.5}$ NAAQS infrastructure requirements: 110(a)(2)(A)–(C), (D)(i)(II) (prong 3 only), (E)–(H) and (J)–(M). This approval of Iowa's infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS addresses the September 8, 2011 finding.

DATES: This final rule is effective on September 15, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2014–0213. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically at *www.regulations.gov* and at EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219. Please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7039, or by email at *Hamilton.heather@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. What is being addressed in this document?

The EPA is approving two submissions from the State of Iowa: The infrastructure SIP submissions for the 1997 and 2006 $PM_{2.5}$ NAAQS received on March 31, 2008 and July 29, 2013. The SIP submissions from Iowa addressed the requirements of CAA sections 110(a)(1) and (2) as applicable to the 1997 and 2006 $PM_{2.5}$ NAAQS. The March 31, 2008 SIP submission also included the state adoption of the 1997 $PM_{2.5}$ standard. The EPA is also approving the 1997 $PM_{2.5}$ standard in today's action.

For the 1997 $PM_{2.5}$ NAAQS, the EPA took previous action to address section 110(a)(2)(D)(i)(I)—prongs 1 and 2 for Iowa. (72 FR 10380, March 8, 2007, as revised in 76 FR 48208, August 8, 2011). Therefore, in this final action, we are not acting on these portions since they have already been acted upon by the EPA.

A Technical Support Document is included as part of the docket to discuss the details of this final action.

II. EPA's Response to Comment

The public comment period on EPA's proposed regulation opened June 23, 2016, the date of its publication in the **Federal Register**, and closed on July 25, 2016. 81 FR 40825. During this period, EPA received one comment that is addressed as follows:

Comment: The commenter stated that EPA must disapprove the Prevention of Significant Deterioration (PSD) portions of the infrastructure SIP, 110(a)(2)(C), (D)(i)(II) (prong 3) and (J), because the local air agencies in Iowa with their