

Populations; E.O. 13045, Protection of Children from Environmental Health Risks; E.O. 13132, Federalism; E.O. 13175, Consultation and Coordination with Indian Tribal Governments; and E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, and Use; E.O. 12988, Civil Justice Reform Act.

This final rule amends TVA's regulations for the protection of archaeological resources by providing for issuance of petty offense citations by TVA's law enforcement agents for violations of ARPA or AA. The rule is not subject to Office of Management and Budget Review under Executive Order 12866. The rule contains no Federal mandates for State, local, or tribal government or for the private sector. TVA has determined that these amendments will not have a significant annual effect of \$100 million or more or result in expenditures of \$100 million in any one year by State, local, or tribal governments or by the private sector. Nor will the amendments have concerns for environmental health or safety risks that may disproportionately affect children, have significant effect on the supply, distribution, or use of energy, or disproportionately impact low-income or minority populations. Accordingly, this final rule has no implications for any of the referenced authorities.

#### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, TVA is required to prepare a regulatory flexibility analysis unless the head of the agency certifies that the proposal will not have a significant economic impact on a substantial number of small entities. TVA's Chief Executive Officer has certified that the amendments promulgated in this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. This determination is based on the finding that the amendments are directed toward Federal resource management to help prevent loss or destruction of archaeological resources, with no economic impact on the public.

#### C. Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act.

#### List of Subjects in 18 CFR Part 1312

Administrative practice and procedure, Historic Preservation, Indians—lands, Penalties, Public Lands,

Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 18 CFR part 1312 is amended as follows:

#### PART 1312—PROTECTION OF ARCHAEOLOGICAL RESOURCES: UNIFORM REGULATIONS

■ 1. The authority citation for Part 1312 is revised to read as follows:

**Authority:** Pub. L. 96–95, 93 Stat. 721, as amended, 102 Stat. 2983 (16 U.S.C. 470aa–mm) (Sec. 10(a) & (b)); 16 U.S.C. 831–831ee (2012). Related Authority: Pub. L. 59–209, 34 Stat. 225 (16 U.S.C. 432, 433); Pub. L. 86–523, 74 Stat. 220, 221 (16 U.S.C. 469), as amended, 88 Stat. 174 (1974); Pub. L. 89–665, 80 Stat. 915 (16 U.S.C. 470a–t), as amended, 84 Stat. 204 (1970), 87 Stat. 139 (1973), 90 Stat. 1320 (1976), 92 Stat. 3467 (1978), 94 Stat. 2987 (1980); Pub. L. 95–341, 92 Stat. 469 (42 U.S.C. 1996)

■ 2. In § 1312.1, a sentence is added at the end of paragraph (a) to read as follows:

##### § 1312.1 Purpose.

(a)\* \* \*. The regulations in this part also enable TVA's law enforcement agents to issue petty offense citations for violations of any provision of 16 U.S.C. 470ee or 16 U.S.C. 433.

\* \* \* \* \*

■ 3. In § 1312.2, paragraph (c) is added to read as follows:

##### § 1312.2 Authority.

\* \* \* \* \*

(c) Provisions pertaining to the issuance of petty offense citations are based on the duties and powers assigned to TVA's law enforcement agents under 16 U.S.C. 831–831ee.

■ 4. In § 1312.3, paragraph (j) is added to read as follows:

##### § 1312.3 Definitions.

\* \* \* \* \*

(j) *Director* means the Director of TVA Police and Emergency Management assigned the function and responsibility of supervising TVA employees designated as law enforcement agents under 16 U.S.C. 831c–3(a).

■ 5. Section 1312.22 is added to read as follows:

##### § 1312.22 Issuance of citations for petty offenses.

Any person who violates any provision contained in 16 U.S.C. 470ee or 16 U.S.C. 433 in the presence of a TVA law enforcement agent may be tried and sentenced in accordance with the provisions of section 3401 of Title 18, United States Code. Law enforcement agents designated by the

Director for that purpose shall have the authority to issue a petty offense citation for any such violation, requiring any person charged with the violation to appear before a United States Magistrate Judge within whose jurisdiction the archaeological resource impacted by the violation is located. The term “petty offense” has the same meaning given that term under section 19 of Title 18, United States Code.

Dated: August 8, 2016.

**Rebecca C. Tolene,**

*Deputy General Counsel and Vice President, Natural Resources.*

[FR Doc. 2016–19343 Filed 8–15–16; 8:45 am]

**BILLING CODE 8120–08–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0171]

#### Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry; Small Entity Compliance Guide; 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 guidance for industry entitled “Calorie Labeling of Articles of Food in Vending Machines—Small Entity Compliance Guide.” The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines.”

**DATES:** Submit either electronic or written comments on FDA guidances at any time.

**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—Small Entity Compliance Guide." 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 the Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition (HFS-305), 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:** Ashley N. Rulffes, 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

In the **Federal Register** of December 1, 2014 (79 FR 71259), we issued a final rule requiring vending machine operators who own or operate 20 or more vending machines, or who voluntarily register to be covered, to provide calorie declarations for those foods sold from vending machines 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 (the final rule). 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.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents our current thinking on calorie labeling for foods sold in vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines, or a person who voluntarily registers with FDA to be covered by the rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Paperwork Reduction Act of 1995

This SECG refers to collections of information described in FDA's final rule that published in the **Federal Register** of December 1, 2014, and that will be effective on December 1, 2016. As stated in the final rule, these collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in the final rule have been approved under OMB control number 0910-0782. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

##### III. Electronic Access

Persons with access to the Internet may obtain the SECG at either <http://www.fda.gov/Food/GuidanceRegulation/>

*Guidance Documents Regulatory Information/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.*

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**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>.

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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