thinking of 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 alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

In the Federal Register of May 27, 2016, FDA issued two final rules entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (81 FR 33742; the “Nutrition Facts label final rule”) and the “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (81 FR 34000; the “Serving Size final rule”). The Nutrition Facts label final rule amends the regulations for the nutrition labeling of conventional foods and dietary supplements to provide updated nutrition information and to improve how the nutrition information is presented to consumers. The Nutrition Facts label final rule also revised the Nutrition Facts label to replace “sugars,” with “total sugars” and to include the declaration of added sugars. The Serving Size final rule amended the definition of a single-serving container, required dual-column labeling on certain packages, and amended several reference amounts customarily consumed that are used by manufacturers to determine their label serving size. The two final rules provided two compliance dates distinguishing between manufacturers with $10 million or more in annual food sales (July 26, 2018) and manufacturers with less than $10 million in annual food sales (July 26, 2019). As discussed below, FDA extended the compliance dates for these final rules.

In the Federal Register of January 5, 2017 (82 FR 1347), we made available a draft guidance for industry entitled “Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals; Draft Guidance for Industry; Availability” and gave interested parties an opportunity to submit comments by March 6, 2017, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance primarily related to compliance dates and labeling requirements for added sugars and have modified the final guidance where appropriate in response to the comments. Changes to the guidance include new Q&A(s) regarding added sugars, which include examples for calculating added sugars in certain products. The guidance notes that, although the Nutrition Facts label and Serving Size final rules became effective on July 26, 2016, their compliance dates (originally scheduled to be July 26, 2018, for manufacturers with $10 million or more in annual food sales and July 26, 2019, for manufacturers with less than $10 million in annual food sales) have not been realized yet. In the Federal Register of October 2, 2017 (82 FR 45753), however, we proposed to extend the compliance date for manufacturers with $10 million or more in annual food sales from July 26, 2018, to January 1, 2020, and the compliance date for manufacturers with less than $10 million in annual food sales from July 26, 2019, to January 1, 2021. We finalized the changes to the compliance date in the Federal Register of May 4, 2018 (83 FR 19619).

In addition, we made editorial changes to the draft guidance language to improve clarity. The guidance announced in this notice finalizes the draft guidance dated January 2017.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/FoodGuidances or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.


Leslie Kux,
Associate Commissioner for Policy.

FURTHER INFORMATION CONTACT: Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action, (202) 273-4680; elizabeth.appel@bia.gov.

SUPPLEMENTARY INFORMATION: ICWA requires, in any involuntary proceeding, the party seeking foster-care placement of, or termination of parental rights to, an Indian child must notify the parents, Indian custodians, and child’s Tribe and send a copy to the appropriate BIA Regional Director. This notice updates the addresses for two of the Regional Director offices. ICWA also requires that any State court entering a final adoption decree or order in any Indian child adoptive placement furnish a copy of the decree or order to BIA Chief of Human Services at BIA’s Central Office. This rule also updates the mail stop for Central Office in Washington, DC, because the mail stop has moved.

Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The Department has developed this rule in a manner consistent with these requirements.

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A21100DD/AACK001030/ A0A501010.999990 253G]

25 CFR Part 23
RIN 1076–AF42
Change of Address; Indian Child Welfare Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule; technical amendment.

SUMMARY: The Bureau of Indian Affairs (BIA) is amending its regulations to reflect a change of addresses for filing copies of Indian Child Welfare Act (ICWA) notices to the Alaska Regional Director and Midwest Regional Director, and to update the mail stop for BIA’s Central Office in Washington, DC for filing ICWA adoption notices. This rule is a technical amendment that corrects the addresses for filing ICWA documents with the Alaska Regional Director, Midwest Regional Director, and Central Office in Washington, DC.

DATES: Effective November 5, 2018.

For further information contact: Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action, (202) 273-4680; elizabeth.appel@bia.gov.
B. Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.). The rule is administrative in nature and affects only mailing addresses.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. It will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year. The rule’s requirements will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. Nor will this rule have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the U.S.-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 et seq.) is not required.

E. Takings (E.O. 12630)

Under the criteria in Executive Order 12630, this rule does not affect individual property rights protected by the Fifth Amendment nor does it involve a compensable “taking.” A takings implication assessment is therefore not required.

F. Federalism (E.O. 13132)

Under the criteria in Executive Order 13132, this rule has no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule corrects BIA mailing addresses.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule meets the criteria of section 3(b)(1) requiring all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation and meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175)

The Department strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department’s consultation policy and under the criteria in Executive Order 13175 and have determined there are no potential effects on federally recognized Indian Tribes and Indian trust assets.

I. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., prohibits a Federal agency from conducting or sponsoring a collection of information that requires OMB approval, unless such approval has been obtained and the collection request displays a currently valid OMB control number. Nor is any person required to respond to an information collection request that has not complied with the PRA. This rule does not contain any information collections requiring approval under the PRA; however, OMB has approved the information collection requirements related to this rule under OMB Control No. 1076-1086.

J. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment because it is of an administrative, technical, and procedural nature. See, 43 CFR 46.210(i). No extraordinary circumstances exist that would require greater review under the National Environmental Policy Act.

K. Effects on the Energy Supply (E.O. 13175)

This rule does not impose a major Federal action significantly affecting the quality of the human environment because it is of an administrative, technical, and procedural nature. See, 43 CFR 46.210(i). No extraordinary circumstances exist that would require greater review under the National Environmental Policy Act.

List of Subjects in 25 CFR Part 23

Administrative practice and procedures, Child welfare, Grant programs—Indians, Grant programs—social programs, Indians, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Department of the Interior, Bureau of Indian Affairs, amends part 23 in title 25 of the Code of Federal Regulations as follows:

PART 23—INDIAN CHILD WELFARE ACT

1. The authority for part 23 continues to read as follows:


2. In § 23.11, revise paragraphs (b)(2) and (7) to read as follows:

§ 23.11 Notice. *
  * * * * *

(b) * * *

(2) For child-custody proceedings in Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio, or Wisconsin, notices must be sent to the following address: Minneapolis Regional Director, Bureau of Indian Affairs, 5600 American Blvd. W, Ste. 500, Bloomington, MN 55437. *
  * * * * *

(7) For child-custody proceedings in Alaska (except for notices to the Metlakatla Indian Community, Annette Island Reserve, Alaska), notices must be sent to the following address: Alaska Regional Director—Attn: Human Services, Bureau of Indian Affairs, 3601 C Street, Suite 1258, Anchorage, Alaska 99503. Notices to the Metlakatla Indian Community, Annette Island Reserve, Alaska, must be sent to the Portland Regional Director at the address listed in paragraph (b)(11) of this section. *
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DEPARTMENT OF THE TREASURY
Office of Foreign Assets Control

31 CFR Part 560 and Appendix A to Chapter V

Iranian Transactions and Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is amending the Iranian Transactions and Sanctions Regulations (ITSR) to implement further the President’s May 8, 2018 decision to cease the United States’ participation in the Joint Comprehensive Plan of Action (JCPOA) by making changes to reflect the re-imposition of sanctions pursuant to certain sections of Executive Order 13846 and changes to certain sanctions lists maintained by OFAC. OFAC is also amending an existing general license in the ITSR to authorize U.S. persons to sell personal property in Iran and transfer the proceeds to the United States.

DATES: Effective: November 5, 2018.


SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC’s website (www.treasury.gov/ofac).

Background

Implementing the President’s May 8, 2018 Decision by Reinstating Certain Authorities in the ITSR and Making Certain Technical and Conforming Changes

On May 8, 2018, the President issued National Security Presidential Memorandum-11 (NSPM–11), which set forth his decision to cease the United States’ participation in the JCPOA. In NSPM–11, the President directed the Secretary of State and the Secretary of the Treasury to immediately begin taking steps to reimpose all U.S. sanctions lifted or waived in connection with the JCPOA as expeditiously as possible, and in no case later than 180 days from the date of NSPM–11. In accordance with his decision, on August 6, 2018, the President issued Executive Order 13846 (83 FR 38939, August 7, 2018) (E.O. 13846) to, among other things, re-impose relevant authorities from certain Executive Orders that had been revoked previously. Today, OFAC is amending the ITSR, 31 CFR part 560, and appendix A to 31 CFR chapter V to take additional regulatory steps to implement the President’s May 8, 2018 decision.

Previously revoked authorities. On January 16, 2016, the President issued Executive Order 13716 (81 FR 3693, January 21, 2016) (E.O. 13716), which, among other things, revoked Executive Order 13622 of July 30, 2012 (77 FR 45897, August 2, 2012) (E.O. 13622) in connection with the JCPOA. In light of this revocation, on January 21, 2016, OFAC amended the ITSR to, among other things, remove regulatory provisions that implemented sections 5 and 6 of E.O. 13622, (See 81 FR 3330). In that rule, OFAC also made certain technical and conforming changes to the ITSR and appendix A to 31 CFR chapter V related to (1) the removal of certain individuals and entities from OFAC’s Specially Designated Nationals and Blocked Persons List (SDN List), the Foreign Sanctions Evaders List, and the Non-SDN Iran Sanctions Act List on January 16, 2016, and (2) the concurrent transfer of certain individuals and entities that OFAC had previously identified as blocked pursuant to E.O. 13599 of February 5, 2012, to a “List of Persons Identified for Conduct in the Caspian Sea” (E.O. 13599 List), which OFAC made available on its website on January 16, 2016.

Reinstating certain authorities and removing E.O. 13599 List references. In furtherance of the President’s May 8, 2018 decision and in light of the issuance of E.O. 13846, OFAC is now amending the ITSR and appendix A to 31 CFR chapter V by: (1) Reinstating the regulatory provisions implementing the authorities that were previously in sections 5 and 6 of E.O. 13622 and now are in sections 1 and 10 of E.O. 13846 by revising paragraph (c) of § 560.211 of the ITSR; and (2) removing references to the E.O. 13599 List by revising notes in §§ 560.211 and 560.304 of the ITSR, revising note 1 to § 560.324 of the ITSR, and revising a note to appendix A to 31 CFR chapter V.

Sections 1(a)(i) and 1(a)(ii) of E.O. 13846 authorize the Secretary of the Treasury to block all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person, including any foreign branch, of a person upon determining that: (i) On or after August 7, 2018, the person has materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, the purchase or acquisition of U.S. bank notes or precious metals by the Government of Iran, or (ii) on or after November 5, 2018, the person has materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, the National Iranian Oil Company (NIOC), the Naftiran Intertrade Company (NICO), or the Central Bank of Iran. Section 16 of E.O. 13846 defines the terms “NIOC” and “NICO” as including any entity owned or controlled by, or operating for or on behalf of, respectively, NIOC or NICO. Section 10 of E.O. 13846 provides that section 1(a) of the order, among other specified provisions, shall not apply to any person for conducting or facilitating a transaction involving a project described in subsection (a) of section 603 of the Iran Threat Reduction and Syria Human Rights Act of 2012 to which the exception under that section applies. Although it is not named in the section, section 10 of E.O. 13846 refers to the Shah Deniz natural gas field in Azerbaijan’s sector of the Caspian Sea and related pipeline projects to bring the gas from Azerbaijan to Europe and Turkey.

By separate action, effective November 5, 2018, OFAC is removing the E.O. 13599 List from its website and relisting on the SDN List, as