By the Commission.

Dated: October 1, 2018.

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2018–24128 Filed 11–2–18; 8:45 am]

**BILLING CODE 8011–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 101

**[Docket No. FDA–2016–D–4414]**

## Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals; 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 guidance for industry entitled ''Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals; Guidance for Industry.'' This guidance is intended for conventional food and dietary supplement manufacturers. The guidance finalizes the draft guidance we issued in January 2017, which provides questions and answers (Q&A) on topics related to compliance with the Nutrition Facts and Supplement Facts label and Serving Size final rules, the labeling of added sugars, declaration of quantitative amounts of vitamins and minerals, and format issues on the Nutrition Facts and Supplement Facts labels.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 5, 2018.

**ADDRESSES:** You may submit either electronic or written comments on FDA guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2016–D–4414 for ''Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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.'' We will review this copy, including the claimed confidential information, in our 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, 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:** Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450.

**SUPPLEMENTARY INFORMATION:**

### I. Background

We are announcing the availability of a guidance for industry entitled ''Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals.'' This guidance is intended to help industry determine when manufacturers must comply with the two final rules on Nutrition and Supplement Facts labels and serving size, and how their products will need to comply with these rules. We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current

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.

Dated: October 30, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–24125 Filed 11–2–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

**[190A2100DD/AAKC001030/A0A501010.999900 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.*

**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.