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 *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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling/Nutrition Programs Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–830), 5001 Campus Dr., College Park, MD 20740, 240–402–5429.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of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.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic.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 May 27, 2016, we issued a final rule entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (81 FR 33742). The final rule amends our 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 final rule 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). The final rule also revised the Nutrition Facts label to replace ''sugars'' with ''total sugars'' and to include the declaration of added sugars. The draft guidance is intended for conventional food and dietary supplement manufacturers and will, when finalized, provide questions and answers on topics related to compliance, labeling of added sugars, declaration of quantitative amounts of vitamins and minerals, and format.

II. Additional Issues for Consideration

We invite interested persons to comment on topics related to compliance, labeling of added sugars, declaration of quantitative amounts of vitamins and minerals, and format. However, we are particularly interested in responses to the following questions:

1. What, if any, concerns are there for manufacturers to use Brix values from 21 CFR 101.30 when calculating the added sugars content of products containing fruit juice concentrates?

2. For purposes of calculating the amount of added sugars, what, if any, concerns are there if we consider that all of the water in a formulation with fruit or vegetable juice concentrate is used to reconstitute the fruit or vegetable juice? To illustrate the issue, assume that fruit juice concentrate is added to a food and that the manufacturer also adds water to the food. We recognize that the water may reconstitute the fruit juice, but also recognize that some portion of the water may have other purposes or affect ingredients other than the fruit juice concentrate. Nevertheless, to calculate the amount of added sugars, we would consider that all of the water goes towards reconstituting the fruit juice.

3. What, if any, concerns are there if we consider that all of the water that has been removed from a product during processing contributes towards the concentration of juice added as an ingredient during the formulation of the product?

When responding to these questions, please explain your reasoning.

III. Paperwork Reduction Act of 1995

This 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 part 101 have been approved under OMB control number 0910–0813.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

V. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. U.S. Department of Health and Human Services. 2015 Dietary Guidelines for Americans. Accessed online at *http://www.health.gov/dietaryguidelines/dga2005/document/default.htm.*

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–32005 Filed 1–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0586]

Food and Drug Administration Tribal Consultation Policy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the FDA Tribal Consultation Policy. The purpose of the FDA Tribal Consultation Policy is to further the government-to-government relationship between FDA and American Indian and Alaskan Native Tribes (Indian Tribes) and facilitate tribal consultation with FDA. The FDA Tribal Consultation Policy provides background on FDA's mission and organizational structure and elaborates on the principles and guidelines in the U.S. Department of Health and Human Services (HHS) Tribal Consultation Policy. This policy finalizes the draft FDA Tribal

Consultation Policy issued in February 2016.

ADDRESSES: 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sarah Walinsky, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, (240) 402–4075.

SUPPLEMENTARY INFORMATION:

I. Background

Under Executive Order 13175 of November 6, 2000, executive departments and Agencies are charged with engaging in regular and meaningful consultation and collaboration with Indian tribal governments in the development of Federal policies that have tribal implications and are responsible for strengthening the government-to-government relationship between the United States and Indian Tribes. The HHS Tribal Consultation Policy, revised on December 14, 2010, further clarifies that each HHS Operating and Staff Division must have an accountable consultation process to ensure meaningful and timely input by tribal officials in the development of policies that have tribal implications. The FDA Tribal Consultation Policy, which finalizes the draft FDA Tribal Consultation Policy issued in February 2016, is based on the HHS Tribal Consultation Policy and includes Agency-specific consultation guidelines that complement the Department-wide efforts.

The purpose of the FDA Tribal Consultation Policy is to further the government-to-government relationship between FDA and Indian Tribes and facilitate tribal consultation with FDA. The policy provides background on FDA's mission and organizational structure and elaborates on the principles and guidelines in the HHS Tribal Consultation Policy. We consulted with Indian Tribes on the FDA Tribal Consultation Policy, which is intended to serve as a platform for the Agency to create consistent and meaningful tribal consultation across FDA Centers and Offices. A copy of the final policy has also been shared with Indian Tribes in a letter to tribal leaders.

II. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/tribal* or *https://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the document.

Dated: December 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31951 Filed 1–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0118]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA regulations requiring that the Agency receives prior notice before food is imported or offered for import into the United States.

DATES: Submit either electronic or written comments on the collection of information by March 6, 2017.

ADDRESSES: You may submit comments 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):* 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–2010–N–0118 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' 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 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