



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2016-D-4098]

Reference Amounts Customarily Consumed: List of Products for Each Product Category;

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 "Reference Amounts Customarily Consumed: List of Products for Each Product Category." The guidance provides examples of products that belong to product categories included in the tables of Reference Amounts Customarily Consumed (RACCs) per Eating Occasion established in our regulations.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-4098 for "Reference Amounts Customarily Consumed: List of Products for Each Product Category." 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 the 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: Jillonne Kevala, 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 "Reference Amounts Customarily Consumed: List of Products for Each Product Category." 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.

This guidance is intended to help industry comply with the statutory requirement, under section 403(q)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)(1)(A)(i)), that food that is intended for human consumption and offered for sale bear nutrition information that provides a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure that is appropriate to the food. To

comply with this requirement, manufacturers must determine and label their food products with the appropriate label serving size based on the amount of the product customarily consumed.

In the *Federal Register* of May 27, 2016, we issued a final rule entitled “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 final rule amends our regulations in § 101.12(b) (21 CFR 101.12(b)) to update or modify certain pre-existing RACCs, and to establish RACCs for new product categories.

In the *Federal Register* of January 5, 2017 (82 FR 1344), we announced the availability of a draft guidance for industry entitled “Reference Amounts Customarily Consumed: List of Products for Each Product Category; Draft Guidance for Industry” 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 and have modified the content, where appropriate, for this final guidance. Changes to the guidance include the addition of flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored) as an example in the “Nut and seed butters, pastes, or creams” product category. In the *Federal Register* of November 2, 2016, we published a Request for Information and Comments requesting information and comments on the appropriate product category and RACC for flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored) (81 FR 76323). Based upon the information and comments received, and our own assessment, we have determined that flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored) are comparable to nut butters and belong in the “Nut and seed butters, pastes, or creams” product category with a RACC of two tablespoons. In addition to this and other clarifying substantive changes that we

made to the guidance, we made editorial changes to improve clarity and to help ensure consistency with § 101.12(b). 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: February 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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