Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993, *CBERPublicEvents@fda.hhs.gov.* For questions email: *CBERPublicEvents@fda.hhs.gov* (Subject line: Tick-Borne Diseases and Blood Safety Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public workshop is to discuss tick-borne pathogens that continue to emerge as threats to blood safety, the effectiveness of current and potential mitigation strategies, and the general approach to decision making on blood safety interventions.

II. Topics for Discussion at the Public Workshop

The workshop will include presentations and panel discussions on the following topics: (1) Biology, epidemiology, and clinical burden of *Anaplasma phagocytophilum* (the etiologic agent of human granulocytic anaplasmosis) and other emerging tick-borne agents; (2) the performance characteristics of currently available diagnostic assays for agents of concern; (3) known and potential risks of transfusion transmission posed by emergent tick-borne agents; (4) current and potential mitigation strategies; and (5) considerations in decision making for safety interventions. The day will conclude with a roundtable discussion.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site at: *https://www.eventbrite.com/e/emerging-tick-borne-diseases-and-blood-safety-public-workshop-tickets-28654127266.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by March 23, 2017. Early registration is recommended because seating is limited. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Kimberly Jones or Pauline Cottrell by email sent to *CBERPublicEvents@fda.hhs.gov* at least 7 days in advance. Requests for sign language interpretation or Computer Aided Realtime Translation (CART)/captioning should be made 2 weeks in advance of the event, no later than March 23, 2017. A request for either interpreting or captioning is to be sent directly to the FDA Interpreting Services Staff email account: *interpreting.services@oc.fda.gov.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305) Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the Internet at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm525485.htm.*

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–32029 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–D–4098]

Reference Amounts Customarily Consumed: List of Products for Each Product Category; 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 ''Reference Amounts Customarily Consumed: List of Products for Each Product Category.'' The draft guidance, when finalized, will provide 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: 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 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–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 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.'' We 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 *https://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 *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, 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: 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 draft guidance for industry entitled ''Reference Amounts Customarily Consumed: List of Products for Each Product Category.'' 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 which products belong to product categories included in the tables of RACCs per Eating Occasion established in § 101.12(b) (21 CFR 101.12(b)). This draft guidance 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.

We intend for this draft guidance, when finalized, to help industry comply with the statutory requirement, under section 403(q)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the 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) to update or modify certain pre-existing RACCs, and to establish RACCs for new product categories.

The draft guidance, when finalized, will help manufacturers identify the appropriate food category to which their product belongs, on which information manufacturers will be able to base the label serving size. The RACCs established in § 101.12(b) are divided into two tables: One for infants and young children 1 through 3 years of age, and another for the general food supply (*i.e.,* individuals four years and older). The draft guidance, when finalized, will provide examples of products that belong to product categories for which a RACC has been established in § 101.12(b). The tables in the draft guidance are not meant to be an all-inclusive list of products that are available on the market for each product category.

II. 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.

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–32006 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–0567]

[Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comments.

DATES: The meeting will be held on March 6, 2017, from 8:30 a.m. to 5:30 p.m. and March 7, 2017, from 8:30 a.m. to 12 p.m. The deadline for submitting comments to the public docket is February 17, 2017. Comments received on or before February 17, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

ADDRESSES: The meeting will be held at DoubleTree by Hilton Hotel Washington DC—Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301–589–5200. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at *http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-washington-dc-silver-spring-DCASSDT/about/amenities.html.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the