requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based, harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency, International Federation for Animal Health—Europe, FDA, the U.S. Department of Agriculture, the U.S. Animal Health Institute, the Japanese Ministry of Agriculture, Forestry, and Fisheries, and the Japanese Veterinary Products Association.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health.

II. Draft Guidance on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods

The VICH Steering Committee held a meeting in June 2016 and agreed that the draft guidance document entitled ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods'' (VICH GL56) should be made available for public comment. This draft VICH guidance document is intended to provide study design recommendations which will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements in order to establish appropriate MRLs or other safe limits in honey following the treatment of honeybees with veterinary drug products, or to justify withdrawal periods in honey for registration purposes when an MRL already exists. Use of veterinary drug products in honeybee production is considered as a minor use in minor species in most jurisdictions.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Significance of Guidance

This level 1 draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents do not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

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 alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This draft 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 Action of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: December 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31998 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–4531]

Emerging Tick-Borne Diseases and Blood Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Emerging Tick-Borne Diseases and Blood Safety.'' 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. The workshop has been planned in partnership with AABB; America's Blood Centers; National Heart, Lung, and Blood Institute, National Institutes of Health (NIH); the U.S. Department of Defense; and the U.S. Department of Health and Human Services. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government agencies.

DATES: The public workshop will be held on April 6, 2017, from 8 a.m. to 5:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Natcher Auditorium, Natcher Conference Center, Bldg. 45, National Institutes of Health Campus, 9000 Rockville Pike, Bethesda, MD 20892. Entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center located adjacent to the Medical Center Metro, where routine security check procedures will be performed. Please visit the following Web site for NIH campus location, parking, security, and travel information *http://www.nih.gov/about/visitor/index.htm.* Please visit the following Web site for information on the Natcher Conference Center: *http://www.genome.gov/11007522.*

FOR FURTHER INFORMATION CONTACT: Kimberly Jones or Pauline Cottrell,

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