- E19 Optimization of Safety Data Collection
- E8(R1) Revision on General Considerations for Clinical Trials
- E11A Pediatric Extrapolation
- E14/S7B Discussion Group on Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation
- M9 Biopharmaceutics Classification System-Based Biowaivers
- M10 Bioanalytical Method Validation
- S1(R1) Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals
- S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals
- Q3C(R7) Impurities: Guideline for Residual Solvents
- Q3D(R1) Guideline on Elemental Impurities

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by April 3, 2018. To register for the public meeting, please visit the following website: *https://ich_regional_consultation_2018.eventbrite.com.* 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 meeting must register by April 3, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 9:30 a.m.

The agenda for the public meeting will be made available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm592065.htm* approximately 2 weeks in advance of the meeting.

If you need special accommodations due to a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) no later than March 23, 2018.

Requests for Oral Presentations: If you wish to make a presentation during the public comment session, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) no later than March 23, 2018. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. All requests to make presentations must be received by the close of registration on April 3, 2018. If selected for presentation, any presentation materials must be emailed to Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) no later than April 3, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Sign-up for making a public comment will also be available between 9 a.m. and 10 a.m. on the day of the meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. To register to attend via webcast, please visit the following website: *https://ich_regional_consultation_2018.eventbrite.com.* If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: February 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04256 Filed 3–1–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0258]

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—Small Entity Compliance Guide; 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 ''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—Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is intended to help small entities comply with a final rule we issued in the **Federal Register** of May 27, 2016, 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.'' The final rule is designed to ensure that serving sizes are based on more recent consumption data and that consumers have serving size information on the Nutrition Facts label that will assist them in maintaining healthy dietary practices.

DATES: The announcement of the guidance is published in the **Federal Register** on March 2, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency 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–2004–N–0258 for ''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—Small Entity Compliance Guide.'' 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 SECG to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS–800), 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 SECG.

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

In the **Federal Register** of May 27, 2016 (81 FR 34000), we issued a final rule pertaining to serving sizes for food. The final rule amends the definition of a single-serving container; requires dual-column labeling for certain containers; updates, modifies, and establishes certain Reference Amounts Customarily Consumed (RACCs); amends the serving size for breath mints; and makes certain technical amendments to various aspects of preexisting serving size regulations. The final rule, which is codified at §§ 101.9 and 101.12 (21 CFR 101.9 and 101.12), became effective July 26, 2016, and has a compliance date of 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. On October 2, 2017, FDA published a proposed rule to extend the compliance dates by approximately 1.5 years—to January 1, 2020, for manufacturers with $10 million or more in annual food sales and to January 1, 2021, for manufacturers with less than $10 million in annual food sales—and explained that, pending completion of the rulemaking with respect to the compliance dates, we intend to exercise enforcement discretion with respect to the compliance dates announced in the final rule (82 FR 45753). A final determination regarding the compliance dates is pending.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rules on nutrition labeling, taken as a whole, will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG 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.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 101.9 and 101.12 have been approved under OMB control number 0910–0381.

III. Electronic Access

Persons with access to the internet may obtain the SECG 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.

[FR Doc. 2018–04284 Filed 3–1–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0688]

Standardization of Data and Documentation Practices for Product Tracing; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Standardization of Data and Documentation Practices for Product Tracing.'' The draft guidance elaborates on the standards for the interoperable exchange of transaction information, transaction history, and transaction statements (product tracing information)