FDA will begin the meeting by soliciting feedback regarding how stakeholders, such as patients and health care providers, think about burden related to REMS. The meeting will then focus on strategies for anticipating and addressing REMS burden and access issues in several broad topic areas (including several areas identified in the key opinions and recommendations from stakeholders in the Standardizing and Evaluating REMS Report). Potential discussion topics are described in this document. For topics related to strategies for minimizing burden and barriers to patient access (topics 1–3), FDA will present ongoing and planned Agency initiatives, solicit feedback on these initiatives, and ask for feedback on other opportunities for anticipating and minimizing burden and patient access issues.

Potential topics for discussion include the following:

- *Topic 1: Understanding the stakeholder perspective.*

Discussion will focus on gaining a better understanding of how stakeholders, such as patients, health care providers, dispensers, and others, think about burden and access issues related to REMS—for example, understanding the different dimensions of burden (*e.g.,* administrative, logistical, workflow) and better understanding the different types of patient access issues that are implicated by REMS.

- *Topic 2: Improved communication about the existence of a REMS and about what is required of stakeholders under that REMS.*

Discussion will focus on strategies to improve communications about REMS, including communications about the existence of a particular REMS or the requirements under a particular REMS program, and how to improve the clarity of REMS materials.

- *Topic 3: Improved integration of activities required under a REMS.*

Discussion will focus on two closely related subtopics: (1) Strategies to improve the integration of REMS requirements into the health care delivery system through process improvement (*e.g.,* streamlining REMS processes that have an impact on stakeholder workflow or the care process, and reducing redundancies by leveraging existing training or certification requirements to meet REMS requirements); and (2) strategies to integrate REMS into electronic health care systems (*e.g.,* electronic health records, decision support systems, and pharmacy management systems).

- *Topic 4: Improved methods for measuring the burden of REMS on the health care delivery system and the impact on patient access.*

Discussion will focus on identifying the most effective methods for evaluating the burden of REMS on the health care delivery system and the impact on patient access, with a goal of not only characterizing and quantifying these effects, but also identifying opportunities for improvements to a REMS program and better understanding the effect of changes to a program. This may include discussion of how to address methodological challenges in the measurement of burden and access, and how to incorporate stakeholder input into REMS design and assessment.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the public meeting, and the background material will be posted on FDA's Web site after the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm,* and to the docket at *http://www.regulations.gov.*

Dated: July 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18149 Filed 7–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0146]

Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards.'' The draft guidance, when finalized, will contain FDA recommendations on third-party auditor/certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by the FDA Food Safety Modernization Act (FSMA).

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 this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments by October 7, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to Charlotte A. Christin, Office of Compliance, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charlotte A. Christin, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–3708.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry and FDA staff entitled ''Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards'' (draft guidance). This draft guidance is being made available consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on ''Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

Section 808 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 384d) was added by FSMA and directs FDA to establish a program for the recognition of accreditation bodies that accredit third-party auditors/certification bodies to conduct food safety audits and to issue food and/or facility certifications that FDA may use in certain circumstances to facilitate the entry of foods presented for import.

Section 808(b)(2) of the FD&C Act requires FDA to develop model accreditation standards that recognized accreditation bodies shall use to qualify third-party auditors/certification bodies for accreditation, and in so doing, to look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs. This draft guidance, when finalized, will constitute the model accreditation standards referred to in section 808(b)(2) of the FD&C Act. The draft guidance contains FDA recommendations on third-party auditor/certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by FSMA.

FDA was guided in developing this draft guidance, in part, by the National Technology Transfer and Advancement Act of 1995, which directs Federal Agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical.

In developing the draft guidance, FDA considered several voluntary consensus standards for their relevance to the qualifications of third-party auditors/certification bodies that would certify foreign food facilities and/or their foods for conformance with the requirements of the FD&C Act. FDA also sought to identify the standards most commonly used by stakeholders (*e.g.,* other governments, public and private accreditation bodies, the food industry, and the international standards community) in qualifying third-party auditors/certification bodies for conducting food safety audits. As a result, FDA was guided in developing the draft model accreditation standards guidance document by International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) ISO/IEC 17021: *Conformity Assessment—Requirements for bodies providing audit and certification management systems* (2011) (''ISO/IEC 17021:2011'') and included an appendix containing a crosswalk between ISO/IEC 17021:2011 and ISO/IEC 17065: *Conformity assessment—Requirements for bodies certifying products, processes and services* (''ISO/IEC 17065:2012'').

The draft guidance document is issued as a companion to the proposed rule ''Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' that was published in the **Federal Register** of July 29, 2013 (78 FR 45781). When this guidance is finalized, it will serve as a companion guidance document to the final rule.

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's July 29, 2013, proposed rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, which this draft guidance is intended to interpret. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (see 78 FR 45781 at 45825, reference 25, pages 216–239, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*) and has submitted the proposed collections to OMB for approval.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

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

Dated: July 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18142 Filed 7–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality: Change in Meeting Dates

ACTION: Notice of change in meeting dates.

SUMMARY: Health Resources and Services Administration is issuing this notice to change the meeting dates for the Notice is hereby given of a change in the meeting of the Secretary's Advisory Committee on Infant Mortality (SACIM). The meeting was originally scheduled for July 13–14, 2015 and was published in the **Federal Register** on June 26, 2015, 80 FR 123 (page 36826).

DATES: The meeting dates have changed to August 10, 2015, starting at 8:30 a.m. (EST) and ending at 5 p.m. (EST) and August 11, 2015, starting at 8:30 a.m. (EST) and ending at 3:30 p.m. (EST).

The meeting remains virtual via webinar and phone using the following links: URL: *https://hrsa.connectsolutions.com/sacim_seminar_200/.* Call-In Number: 1.888.942.8170. Passcode: 3494113.

For more details, please visit the ACIM Web site: *http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality/index.html.* The meeting is open to the public with attendance limited to availability of call-in lines.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Michael C. Lu, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, Room 18 W, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, Ph.D., M.P.H., SACIM Designated Federal Official, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–0543, email: *David.delaCruz@hrsa.hhs.gov.* Public comments must be submitted to Dr. de la Cruz by email no later than August 3, 2015.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–18179 Filed 7–23–15; 8:45 am]

BILLING CODE 4165–15–P