Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2015–18203 Filed 7–23–15; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–1152]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: CGMP in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients: CGMP in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** On May 26, 2015, the Agency submitted a proposed collection of information entitled, ''Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients: CGMP in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0608. The approval expires on July 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 20, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–18140 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–2013–N–0502]**

### Risk Evaluation and Mitigation Strategies: Understanding and Evaluating Their Impact on the Health Care Delivery System and Patient Access; Public Meeting, Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA or Agency) is announcing a public meeting entitled ''Risk Evaluation and Mitigation Strategies (REMS): Understanding and Evaluating Their Impact on the Health Care Delivery System and Patient Access''. The purpose of the public meeting is to engage in constructive dialogue and information sharing among regulators, the scientific community, the pharmaceutical industry, public health agencies, patients, patient advocates, health care system administrators, prescribers, dispensers, hospitals, infusion centers, health informatics experts, third-party payers, distributors, and the general public concerning the impact of REMS on the health care delivery system, including the impact on patients and health care providers. The discussion will focus on strategies for characterizing and evaluating the impact of REMS on the health care delivery system and on patient access to drugs subject to REMS.

The primary focus of this meeting will be on REMS with Elements To Assure Safe Use (ETASU); however, the meeting will also include discussion of issues that may apply to all REMS. The input from this meeting and the public docket comments will be used to inform ongoing Agency initiatives related to optimizing REMS design, implementation, and assessment.

*Dates and Times:* The meeting will be held on October 5, 2015, from 8 a.m. to 5 p.m. and October 6, 2015, from 8 a.m. to 1 p.m.

*Location:* The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please visit *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Please arrive early to ensure time for parking and security screening.

*Contact Persons for meeting background and content:* Megan Moncur, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *REMSMeetingOct2015@fda.hhs.gov* .

*For registration, oral presentations, special accommodations, and other meeting logistics:* Cherice Holloway, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Phone 301–796–4909, FAX: 301–796–9832, *cherice.holloway@fda.hhs.gov.*

*Registration and Requests for Oral Presentations:* Registration is free and available on a first-come, first-served basis. You must register by September 21, 2015. Seating is limited, so register early. FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the meeting will be available. To register for this

meeting, please visit FDA's Drugs News & Events—Meetings, Conferences, & Workshops calendar at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* and select this meeting from the events list. If you need special accommodations because of a disability, please contact Cherice Holloway (see *Contact Persons*) at least 7 days before the meeting. Those without Internet access should contact Cherice Holloway to register.

This meeting includes public comment sessions in which FDA is seeking input on improved approaches for understanding, evaluating, and minimizing burden on the health care delivery system to the extent practicable and for helping to assure patient access to drugs that are subject to REMS. If you would like to present during a session, please identify the topic(s) you will address during registration (see section II).

FDA will do its best to accommodate requests to speak. FDA urges individuals and organizations with common interests to coordinate and/or request time for a joint presentation. Following the close of registration, FDA will allot time for each presentation and notify presenters by September 28, 2015. Do not present or distribute commercial or promotional material during the meeting. Registered presenters should check in at the registration desk before the meeting.

*Live Webcast of the Meeting:* To view the Connect Pro Webcast of this meeting, you must register online by 4 p.m., September 21, 2015. Webcast connections are limited, so register early. Organizations should register all viewers but access the Webcast using one connection per location.

Webcast viewers will be sent system requirements after registration and will be sent connection information after September 28, 2015. Visit *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm* for the Connect Pro Connection Test. To get a quick overview of Connect Pro, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this notice but is not responsible for any subsequent address changes after this document publishes in the **Federal Register**.)

*Comments:* FDA is holding this public meeting to obtain information on improved strategies for evaluating and minimizing the burden of REMS on the health care delivery system to the extent practicable and their impact on patient access to the drugs covered by such programs. FDA is opening a public docket for comments to be submitted to the Agency on the issues and questions presented during the meeting. Regardless of attendance at the public meeting, interested persons may submit electronic or paper comments to FDA's Division of Dockets Management by November 2, 2015.

Submit electronic comments 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. Send only one set of comments. Identify all comments with the docket number found in brackets in the heading of this document. When addressing specific topics (see section II), please identify the topic. 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*.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. The transcript may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD–ROM after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

**SUPPLEMENTARY INFORMATION:**

## I. Background

This meeting builds on prior stakeholder feedback on the design, implementation, and assessment of REMS, including feedback obtained through public meetings, stakeholder outreach, and comments to the public docket, including the recommendations and suggestions recently summarized in the Agency's report entitled ''Standardizing and Evaluating Risk Evaluation and Mitigation Strategies'' (the Standardizing and Evaluating REMS Report).[1] The report also describes the Agency's findings concerning strategies to standardize REMS, where appropriate, with the goal of reducing the burden of implementing REMS on health care providers, patients, and others in various health care settings.

The Agency seeks to build on this foundation by updating stakeholders and obtaining their feedback on some of our current and proposed initiatives aimed at anticipating and minimizing REMS' burden on the health care delivery system, helping to assure access to drugs that are subject to REMS with ETASU, and obtaining stakeholder recommendations on additional approaches to accomplish these goals. The Agency recognizes that REMS can impose burden on the health care delivery system. The statute requires ETASU to be commensurate with the specific serious risks listed in a drug's labeling, and, considering such risks, not be unduly burdensome on patient access to the drug, and, to the extent practicable, to minimize burden on the health care delivery system. We are also seeking input on the methods for evaluating REMS' burden on the health care delivery system and their impact on patient access to drugs.

The primary focus of this meeting will be on REMS with ETASU see section 505(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); however, the meeting will also include discussion of issues that may apply to all REMS.

## II. Who Is the Target Audience and Who Should Attend This Public Meeting?

This meeting is open to all interested parties. The target audience is comprised of regulators, the scientific community, the pharmaceutical industry, public health Agencies, patients, patient advocates, health care system administrators, prescribers, dispensers, hospitals, infusion centers, health informatics experts, third-party payers, distributors, and the general public who are interested in providing input on approaches for both anticipating and minimizing health care delivery system burden and for helping to assure patient access to drugs that are subject to REMS, as well as those interested in improving the approaches used to evaluate the burden of REMS on the health care delivery system and their impact on patient access.

## III. What Are the Topics We Intend to Discuss at the Public Meeting?

The meeting will include panel discussions and individual presentations. The main questions that will be considered are as follows: (1) How to anticipate and minimize the burden of REMS on the health care delivery system and patient access; and (2) how to improve the quality and effectiveness of methods used to evaluate REMS' burden on the health care delivery system and impact on patient access.

[1] In the **Federal Register** of September 23, 2014 (79 FR 56816), FDA published a notice announcing the availability of this draft report. The report is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm415751.pdf.*

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.