

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.

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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, PRASStaff@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.

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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