

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. 2013-16643 Filed 7-10-13; 8:45 am]  
**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0115]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 12, 2013.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0601. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, *Ila.Mizrachi@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Manufactured Food Regulatory Program Standards—(OMB Control Number 0910-0601)—Extension**

In the *Federal Register* of July 20, 2006 (71 FR 41221), FDA announced the availability of a draft document entitled "Manufactured Food Regulatory Program Standards (MFRPS)." These draft program standards are the

framework that States should use to design and manage its manufactured food program. The implementation of the standards will be negotiated as an option for payment under the State food contract. States that are awarded this option will receive up to \$25,000 over a period of 5 years to fully implement the program standards. Additionally, 26 States may receive up to \$300,000 each year for a period of 5 years to be in compliance with the 10 standards.

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if they meet the elements of each standard. The State program should use the worksheets and forms contained herein; however, it can use alternate forms that are equivalent. The State program maintains the documents and verifying records required for each standard. The information contained in the documents must be current and fit-for-use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met; (2) improvements needed to meet the program element or documentation requirement of the standard; and (3) projected completion dates for each task.

In the *Federal Register* of February 19, 2013 (78 FR 11651), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Departments of Agriculture or Health .....	44	1	44	303	13,332

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden has been calculated to 303 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward

implementation of each of the 10 standards contained in MFRPS. The hours per respondent will remain the same as implementation to account for continuing improvement and self-sufficiency in the program.

Dated: July 5, 2013.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2013-16620 Filed 7-10-13; 8:45 am]  
**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Cancellation****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee scheduled for July 24 and 25, 2013, is cancelled. This meeting was announced in the *Federal Register* of April 25, 2013 (78 FR 24426).

**FOR FURTHER INFORMATION CONTACT:** Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993, 301-796-7047, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: July 5, 2013.

**Leslie Kux,***Assistant Commissioner for Policy.*

[FR Doc. 2013-16621 Filed 7-10-13; 8:45 am]

**BILLING CODE 4160-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2013-N-0757]

**Establishment of a Public Docket for Comment on the Report Prepared Under the Food and Drug Administration Safety and Innovation Act Section 1138****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a public docket for comments pertaining to the report

mandated under the Food and Drug Administration Safety and Innovation Act (FDASIA) Section 1138, enacted July 9, 2012, and posted on the FDA Web site on July 9, 2013. This docket is intended to solicit input on this report from all relevant stakeholders.

**DATES:** Submit electronic or written comments by September 9, 2013.

**ADDRESSES:** 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. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Jonca Bull, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4274, Silver Spring, MD 20993-0002, 301-796-8000, email: [jonca.bull@fda.hhs.gov](mailto:jonca.bull@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

On July 9, 2012, President Obama signed FDASIA (Pub. L. 112-144) into law. Section 1138 of FDASIA requires that FDA review and modify, as necessary, the FDA communication plan to inform and educate health care providers and patients on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

Section 1138 of FDASIA requires that FDA shall publicly post the communication plan on the Internet Web site of the Office of Minority Health of FDA, and provide links to any other appropriate Internet Web site, and seek public comment on the communication plan.

FDA is opening a docket for 60 days to solicit input from all relevant stakeholders regarding the communication plan and Internet links. This docket is intended to ensure that stakeholders have an opportunity to provide comments for further improvements to the plan.

**II. Comments**

Interested persons may submit either electronic comments regarding this document 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 will be posted to the docket at <http://www.regulations.gov> and may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2013.

**Leslie Kux,***Assistant Commissioner for Policy.*

[FR Doc. 2013-16617 Filed 7-10-13; 8:45 am]

**BILLING CODE 4160-01-P****DEPARTMENT OF JUSTICE****Notice of Lodging of Proposed Amendment to Consent Decree Under the Clean Water Act**

On July 5, 2013, the Department of Justice lodged a proposed amendment to a consent decree with the United States District Court for the Eastern District of Missouri in the lawsuit entitled in *United States, et al. v. Metropolitan St. Louis Sewer District*, Civil Action No. 4:07-CV-01120.

Under the original 2012 consent decree, the Metropolitan St. Louis Sewer District ("MSD") agreed to undertake numerous measures to come into compliance with the Clean Water Act, including constructing and implementing specific combined sewer overflow control measures. MSD still is in the process of complying with the 2012 decree. However, the proposed amendment would replace two CSO control measures (a treatment facility and a local storage facility) as required by the 2012 decree with one single CSO storage facility.

The publication of this notice opens a period of public comment on the proposed amendment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, et al. v. Metropolitan St. Louis Sewer District*, D.J. Ref. No. 90-5-1-1-08111. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail: