submission of the information by the public and stakeholders does not guarantee that an investigation against a retailer will be triggered, and FDA will work to ensure that no specific retailer or supplier is unfairly targeted.

To clarify that Form FDA 3779 is not an inspection report, FDA is amending the title of Form FDA 3779 to ''Potential Tobacco Product Violations Reporting.'' FDA is making this change to reflect that the form is voluntary, that the form is intended to be a means for the public to submit information to FDA regarding possible violations of the laws that it enforces, and that a Form FDA 3779 submission is not, by itself, enough to warrant further FDA action.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and Form FDA 3779	Number of respondents	Annual frequency per response	Total annual responses	Average burden per response	Total hours
Reporting potential violations of the FD&C Act, as amended by the Tobacco Control Act, by telephone, Internet or paper form, smartphone application or email	1,000	1	1,000	0.25	250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that submitting the information (by phone, Internet form, paper form by mail, smartphone application, or email) will take 15 minutes per response. Since a similar type of reporting went into effect for the cigarette flavor ban, FDA has received several reports via the Internet or email. Based on the rate of reporting for the cigarette flavor ban, reports received from FDA's toll-free telephone number and email address, and FDA experience, FDA estimates the number of annual respondents to this collection of information will be 1,000, who will each submit 1 report by phone, Internet form, paper form, smartphone application, or email. Each report is expected to take 15 minutes to complete and submit, therefore, total burden hours for this collection of information is estimated to be 250 hours (1,000 responses × 0.25 hours per response). Because of the variety of products regulated by FDA under the authority of the FD&C Act, as amended by the Tobacco Control Act, FDA expects the rate of calls and reports received to remain constant over the next 3 years.

Dated: March 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5634 Filed 3–7–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0197]

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Shortages Data Collection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Emergency Shortages Data Collection System.

DATES: Submit either electronic or written comments on the collection of information by May 7, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emergency Shortages Data Collection System—Section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0491)—Extension

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Subsequent to the events of September 11, 2001, and as part of broader

counterterrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of Federally declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans, and raw material constraints for medical devices that would be in high demand, and/or would be vulnerable to shortages in specific disaster/emergency situations or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, and support real-time decisionmaking by HHS during actual emergencies or emergency preparedness exercises.

FDA developed ''The Emergency Medical Device Shortages Program Survey'' in 2002 to support the acquisition of such data from medical device manufacturers. In 2004, CDRH changed the process for the data collection, and the electronic database in which the data were stored was formally renamed the ''Emergency Shortages Data Collection System'' (ESDCS). Recognizing that some of the data collected may be commercially confidential, access to the ESDCS is restricted to members of the CDRH Emergency Shortage Team (EST) and senior management with a need-to-know. At this time, the need-to-know senior management personnel are limited to two senior managers. Further, the data are used by this defined group only for decisionmaking and planning in the context of a Federally declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by non-disaster-related device shortage.

The data procurement process consists of an initial scripted telephone call to a regulatory officer at a registered manufacturer of one or more key medical devices tracked in the ESDCS. In this initial call, the EST member describes the intent and goals of the data collection effort and makes the specific data request. After the initial call, one or more additional followup calls and/or electronic mail correspondence may be required to verify/validate data sent from the manufacturer, confirm receipt, and/or request additional detail. Although the regulatory officer is the agent who the EST member initially contacts, regulatory officers may designate an alternate representative within their organization to correspond subsequently with the CDRH EST member who is collecting or verifying/validating the data.

Because of the dynamic nature of the medical device industry, particularly with respect to specific product lines, manufacturing capabilities, and raw material/subcomponent sourcing, it is necessary to update the data in the ESDCS at regular intervals. The EST makes such updates on a regular basis, but makes efforts to limit the frequency of outreach to a specific manufacturer to no more than every 4 months.

The ESDCS will only include those medical devices for which there will likely be high demand during a specific emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture or loss of one or more of these manufacturers would create a shortage.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
903(d)(2)	125	3	375	0.5	188

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based the burden estimates in table 1 of this document on past experience with direct contact with the medical device manufacturers and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year either to obtain primary data or to verify/validate data. Because the requested data represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Dated: March 2, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5633 Filed 3–7–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0403]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: On August 30, 2011, the Agency submitted a proposed collection of information entitled '' Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act'' 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.