(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 decision-making by the Department of Health and Human Services 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 decision-making 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 follow-up 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.

In the **Federal Register** of March 8, 2012 (77 FR 14020), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act Section	Number of respondents	Number of responses per response	Total annual responses	Average burden per response (hours)	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: May 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13524 Filed 6–4–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration (OMB No. 0915–0212)—[Revision]

In response to Executive Order 12862, the Health Resources and Services Administration (HRSA) is proposing to conduct voluntary customer surveys of its partners to assess strengths and

weaknesses in program services and processes. HRSA partners are typically State or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting a generic approval from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance provided by a contractor, or in-class evaluation forms completed by providers who receive training from HRSA grantees, to measure satisfaction with the training experience. Results of these surveys will be used to plan and redirect resources and efforts as needed to improve services and processes. Focus groups may also be used to gain partner input into the design of mail and telephone surveys. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred data collection methods.

A generic approval will permit HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If generic approval is granted, information on each individual partner survey will not be published in the **Federal Register**.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
In-Class Evaluations	40,000	1	40,000	.05	2,000
Mail/Telephone Surveys	12,000	1	12,000	.25	3,000
Focus Groups	250	1	250	1.5	375
Total	52,250				5,375

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: May 30, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–13534 Filed 6–4–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program FY 2012 Competitive Funding Opportunity Announcement (OMB No. 0915–xxxx)—[New]

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (the Act). Section 2951 of the Act amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant, and Early Childhood Home Visiting Program (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills docid=f:h3590enr.txt.pdf,* pages 216–225). The Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the federal, state, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs.

Under this program $91 million was made available to eligible States and territories by formula in FY 2010, and in FY 2011, $125 million was made available by formula. Additionally, a competitive funding opportunity announcement (FOA) was issued in June 2011 to allow interested States to apply for one of two possible grant types: Development Grants and Expansion Grants. Development Grants are intended to support States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts. Expansion Grants are intended to recognize States and jurisdictions that have already made significant progress towards a high-quality home visiting program or towards embedding their home visiting program into a comprehensive, high-quality early childhood system. Of State applicants to the competitive grant program, 13 States were awarded Development Grants, and nine States were awarded Expansion Grants. Currently, the 54 States and jurisdictions participating in the formula-funded program have begun implementing their State Home Visiting Plans.

Because the FY 2011 formula grants were for 2 years, no additional FOA will be issued this year for such grants, but the State grantees will be completing non-competing progress reports in order to secure the release of their FY 2012 allocations. The 22 States that received competitive grant funding have also begun to carry out these proposed programs, integrating them with their formula-based programming. These competitive grants are for 2 years (Development Grants) and 4 years (Expansion Grants) respectively, and those grantees will also be completing non-competitive progress reports for FY 2012.

An additional $83.9 million is available in FY 2012 for the 2-year Development and Expansion Grants. Ten Expansion Grants, totaling $71.9 million, have been awarded by rank order from among high-ranking applicants under the FY 2011 announcement. An FY 2012 competitive FOA will announce approximately $12 million for new Development Grants. The intent of these Development Grants, as announced in FY 2011, is to support States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity to sustain