Dated: June 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0197]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emergency Shortages Data Collection System

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 July 27, 2015.

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 0910–0491. Also include the FDA docket number found in brackets in the heading of this document.

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

Emergency Shortages Data Collection System—(OMB Control Number 0910–0491)—Extension

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic 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 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 18, 2015 (80 FR 14138), 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 [1]

Activity/FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Emergency Shortages Data Collection System (903(d)(2))	125	3	375	0.5 (30 minutes)	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: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children Request for Nominations

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of request for nominations.

SUMMARY: The Health Resources and Services Administration (HRSA) is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Heritable Disorders in Newborns and Children (Committee). The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of Health and Human Services. HRSA is seeking nominations of qualified candidates to fill three positions on the Committee.

Authority: Section 1111 of the Public Health Service (PHS) Act, Title XI, § 1111(g)(1) (42 U.S.C. 300b–10(g)(1)), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014. The Committee is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), and 41 CFR part 102–3 and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees.

DATES: Written nominations for membership on the Committee must be received on or before July 27, 2015.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Ms. Lisa M. Vasquez, Genetic Services Branch, Maternal and Child Health Bureau, Health Resources and Services Administration, *lvasquez@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Lisa Vasquez, Genetic Services Branch, Maternal and Child Health Bureau, HRSA, at *lvasquez@hrsa.gov* or (301) 443–4948. A copy of the Committee Charter and list of the current membership can be obtained by accessing the Advisory Committee Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

SUPPLEMENTARY INFORMATION: The Committee is chartered under section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2015 (Act). The Committee was established in 2003 to advise the Secretary of the U.S. Department of Health and Human Services regarding newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. In addition, the Committee provides advice and recommendations to the Secretary concerning the grants and projects authorized under section 1109 of the PHS Act and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns, and children having or at risk for heritable disorders.

The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees. The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the RUSP and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Nominations: HRSA is requesting nominations to fill three (3) positions for voting members to serve on the Committee. Nominations of potential candidates for consideration are being sought for individuals who are medical, technical, public health, or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for heritable disorders; who have expertise in ethics (*i.e.,* bioethics) and infectious diseases and who have worked and published material in the area of newborn screening; members of the public having special expertise about or concern with heritable disorders; or members from such federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary. Interested applicants may self-nominate or be nominated by another individual and/or organization.

Individuals selected for appointment to the Committee will be invited to serve for up to 4 years. Members who are not federal officers or permanent federal employees are appointed as special government employees and receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service. Members who are officers or employees of the United States Government shall not receive additional compensation for service on the Committee, but receive per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee. Nominees will be invited to serve during calendar year 2016.

The following information must be included in the package of materials submitted for each individual being