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 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.

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 (hours)	Total hours
Emergency Shortages Data Collection System (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 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06118 Filed 3–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Cardiovascular and Renal Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cardiovascular and Renal Drugs Advisory Committee. This meeting was

announced in the **Federal Register** of February 27, 2015 (80 FR 10700). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *CRDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 2015, FDA announced that a meeting of the Cardiovascular and Renal Drugs Advisory Committee would be held on April 15, 2015. On page 10700, in the first column, the *Agenda* portion of the document is changed to read as follows:

The committee will discuss the new drug application (NDA) 204958, cangrelor injection, submitted by The Medicines Company, for the proposed indication of reduction of thrombotic cardiovascular events in patients with coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI)—(PCI refers to the opening of narrowed blood vessels supplying the heart muscle by a balloon inserted through an artery puncture with or without a stent) who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable (P2Y12 is a protein involved in blood clotting. Inhibiting this protein is a key mechanism of action of cangrelor).

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06130 Filed 3–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–14AI0]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Hospital Ambulatory Medical Care Survey (NHAMCS) Supplement of Primary Care Policies for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes (NSPCP)—New—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cardiovascular disease is a leading cause of death and disability for men and women in the United States, among the most costly health problems facing our nation today, and among the most preventable. Risk factors for cardiovascular disease include high blood pressure and high cholesterol. Because over 50% of diabetics have high blood pressure, high cholesterol, or both conditions, the optimal systems to treat people with hypertension, high cholesterol, or diabetes are interrelated.

In 2005, CDC's Division for Heart Disease and Stroke Prevention (DHDSP) began developing evaluation indicators that reflect evidence-based outcomes from policy, systems, and environmental changes related to heart disease and stroke prevention. However, many of the indicators for short-term policy and systems changes do not have readily available data sources. This is particularly true for outcomes related to health care systems changes.

NCHS proposes to conduct a new information collection, the NSPCP. The survey will target primary care physicians specializing in internal medicine or family practice. Respondents will be drawn from a nationally representative sample of physicians. Physicians working in hospitals, federal facilities, nursing homes, rehabilitation centers and correctional facilities will not be eligible for the survey. Eligibility will be determined by phone.

The survey instrument will undergo cognitive testing before administration.

The telephone screener will be administered to the individual who answers the phone at the selected practice. We anticipate that this will likely be an office assistant or medical secretary. The primary purpose of the screener is to ensure correct contact information for the physician, so we anticipate that an office assistant or medical secretary will be able to answer the screener questions in a short amount of time. We have estimated 10 minutes per response.

Administrators of the mail-based survey will collect information about physician practices' use of evidence-based systems, including multidisciplinary team approaches for chronic disease treatment, electronic health records (EHR) with features appropriate for treating patients with chronic disease (*e.g.,* clinical decision supports, patient registries), and patient follow-up mechanisms. Approximately 946 physicians will participate in the