Categories in Food Facility Registrations and Updates to Food Categories'' and gave interested parties an opportunity to submit comments to us by September 14, 2012, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance. We reviewed and evaluated these comments and have modified the final guidance where appropriate. Changes to the guidance include amending a typographical error in the fishery/seafood product categories. We also added the word ''nutritional'' to the pet supplements category in the food for animal consumption food product categories to clarify that the category applies to ''pet nutritional supplements.'' The guidance announced in this notice finalizes the draft guidance dated August 2012.

As noted previously, section 415(a)(2) of the FD&C Act provides, in relevant part, that a food facility must submit to FDA a registration containing information about the general food category (as identified in § 170.3 or any other food category as determined appropriate by FDA, including ''by guidance'') of a food manufactured/processed, packed or held at such facility, if we determine ''through guidance'' that such information is necessary. Because of Congress's explicit statutory authorization in section 415(a)(2) of the FD&C Act to effectuate binding requirements based on actions by guidance, this document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document's nonbinding effect. *See* 21 CFR 10.115(d)(i).

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited, and our guidances also ordinarily include the following standard paragraph:

''This guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.''

We are not including this standard language in this guidance because it is not an accurate description of the effect of this guidance. This guidance contains findings that serve as the predicates for binding requirements on industry. As stated in ''Guidance for Industry on Necessity of the Use of Food Product Categories in Registration of Food Facilities'' (2003), which was issued under section 415 of the FD&C Act, as added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), we found that inclusion of the food categories in § 170.3 in food facility registrations is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency. Based in part on this finding, FDA's regulations for the registration of food facilities in 21 CFR part 1, subpart H currently require that a food facility submit a registration to FDA containing information on applicable food product categories as identified in § 170.3 for food manufactured/processed, packed, or held at such facility. As provided in section 102 of FSMA, this guidance contains FDA's finding that inclusion of other food categories in food facility registrations is also necessary to facilitate such rapid communications. In addition, this guidance sets forth the other food product categories to be included in food facility registrations determined to be appropriate by FDA for the purposes of food facility registration. Insofar as this guidance modifies food product categories for food facility registration under section 415 of the FD&C Act, it has binding effect. For these reasons, we are not including the standard guidance paragraph in this guidance.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 1.230 through 1.235 have been approved under OMB Control No. 0910–0502.

III. Comments

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

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: October 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–26239 Filed 10–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2012–N–0001]

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 12, 2012, from 8 a.m. to 5:30 p.m. and on December 13, 2012, from 8 a.m. to 3:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors

to the White Oak Campus must enter through Building 1.

Contact Person: 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, email: *DSaRM@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Food and Drug Administration Amendments Act of 2007 requires FDA to bring, at least annually, one or more drugs with Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) before CDER's Drug Safety and Risk Management Advisory Committee (DSaRM). The Agency plans to present information on the risk management of teratogens, some of which have REMS with ETASU.

On December 12, 2012, the committee will meet to discuss the various strategies used by the Agency to define and address teratogenic risk, including requiring REMS with ETASU. The discussion will include an evaluation of the different strategies and the decision framework for selecting risk management strategies for teratogens. The committee will discuss whether the risk management strategies, including REMS with ETASU, assure safe use, are not unduly burdensome to patient access to the drug, and to the extent practicable, minimize the burden to the health care delivery system.

On December 13, 2012, the committee will discuss two common risk management tools used to minimize the risk of teratogens—contraception and pregnancy testing. The committee will discuss considerations for standardizing recommendations for use of these two tools.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 28, 2012. Oral presentations from the public will be scheduled between approximately 1:40 p.m. to 2:10 p.m. on December 12, 2012, and between approximately 12:45 p.m. to 1:15 p.m. on December 13, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 19, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 20, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 16, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–26162 Filed 10–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: The Jackson Heart Study (JHS)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: *Title:* The Jackson Heart Study: Annual Follow-up with Third Party Respondents. *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925–0491). *Need and Use of Information Collection:* This project involves annual follow-up by telephone of participants in the JHS study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in African American men and women. Recruitment of 5,500 JHS participants began in September 2000 and was completed in March 2004. 5,302 participants completed a baseline Exam 1 that included demographics, psychosocial inventories, medical history, anthropometry, resting and ambulatory blood pressure, phlebotomy and 24-hour urine collection, ECG, echocardiography, and pulmonary function. JHS Exam 2 began September 26 2005, followed by a more comprehensive Exam 3 that began in February 2009. The two new exams include some repeated measures from Exam 1 and several new components, including distribution of self-monitoring blood pressure devices. The continuation of the study allows continued assessment of subclinical coronary disease, left ventricular