

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]

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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

dysfunction, progression of carotid atherosclerosis and left ventricular hypertrophy, and responses to stress, racism, and discrimination as well as new components such as renal disease, body fat distribution and body composition, and metabolic consequences of obesity. The JHS Community Health Advisor Networks (CHANs) comprise another component of the study. The JHS data shows high prevalences of risk factors: 73% of recruited participants are hypertensive, 29% are diabetic, 56% are obese (BMI > 30kg/m²), and 30% have the metabolic syndrome. Exploration of the impact on and interaction of high risk

factor levels with other measures of clinical and subclinical disease will help identify unique approaches through epidemiology and prevention research to reduce the disproportionate burden of CVD in African-Americans. . The JHS CHANs play an important role to address CVD prevention by providing training to community members to spread health promotion and prevention messages within the Jackson community. The JHS Community Health Advisors (CHAs) are trained and certified to organize and conduct various outreach activities in five Jackson-area communities. Data on the JHS CHAs will be collected. *Frequency*

of Response: One-time. *Affected Public:* Individuals or households; Businesses or other for-profit; not-for-profit institutions. *Type of Respondents:* Middle aged and elderly adults; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 478; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* 2.47; and *Estimated Total Annual Burden Hours Requested:* 1253. The annualized cost to respondents is estimated at \$24,206. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

Type of respondents	Number of respondents	Frequency of responses	Average time per response	Annual hour burden
Families	200	1	1/6	33 1/3
Physicians	200	1	15/60	50
Communities:				
Bolton	16	10	90/60	240
Canton	14	10	90/60	210
Clinton	13	10	90/60	195
Jackson	15	10	90/60	225
Rankin	20	10	90/60	300
Total	478			1253 1/3

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Cheryl Nelson, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892-7934, or call non-toll-free number 301- 435-0451 or Email your request, including your address to: NelsonC@nhlbi.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 18, 2012.

Lynn Susulske,
NHLBI Project Clearance Liaison, National Institutes of Health.

Michael Lauer,
Director, DCVS, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics

AGENCY: National Institutes of Health, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) hereby announces the Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics for 2012. The

BPCA seeks to improve the level of information on the safe and effective use of pharmaceuticals used to treat children. It requires that the NIH identify the drugs of highest priority for study in pediatric populations and publish a list of drugs/needs in pediatric therapeutics. This notice fulfills the requirement to publish that list.

SUPPLEMENTARY INFORMATION: The pediatric medical community, the public health community, and government agencies have recognized multiple gaps in knowledge regarding the use of therapeutics in children, including the correct dose, appropriate indications, side effects, and safety concerns of pharmaceuticals in the short- and long-term. These gaps have frequently resulted in inadequate labeling for pediatric use and in widespread off-label use of prescription drugs in children. Off-label use of a drug substantially limits the ability to gain clinical information of the drug product, such as appropriate dosing of a drug, changes in drug metabolism and response during growth and development, and important short- and long-term effects. Contributing factors to extensive off-label product use include limited access to patient populations for study, lack of knowledge related to the ethical conduct of clinical trials in