

the increased risk of a serious side effect. Another reason for this increasing interest is the emergence of new technologies that are improving our ability to individualize, or personalize, medical therapy by identifying patients who are more likely to respond positively or negatively to treatment, or who are at lower risk for a particular side effect.

When an appropriate scientific rationale supports such an approach, FDA encourages the development and use of therapeutic products that depend on the use of approved or cleared companion diagnostic devices, and the Agency has already approved/cleared several companion diagnostics for use with corresponding therapeutic products. FDA believes that use of a companion diagnostic with a therapeutic product raises important concerns about the safety and effectiveness of both the test and the therapeutic product. An erroneous test result could lead to withholding an appropriate therapy or to administering an inappropriate therapy. Healthcare professionals must be able to rely on information from companion diagnostic devices to help make critical treatment decisions. FDA oversight of companion diagnostics will protect patients from treatment risks that could arise from in vitro companion diagnostic devices that have inadequate performance characteristics. To facilitate the development and clearance or approval of therapeutic products that are intended for use with companion diagnostic devices, as well as the development of the companion diagnostics themselves, FDA is clarifying relevant policies related to these devices and products.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on companion diagnostic devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at [http://www.fda.gov/MedicalDevices/DeviceRegulationsGuidance/GuidanceDocuments/\\_default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationsGuidance/GuidanceDocuments/_default.htm).

Guidance documents are also available at <http://www.regulations.gov>. To receive "In Vitro Companion Diagnostic Devices", you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1737 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 21 CFR Part 807 Subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR Part 314 have been approved under OMB control number 0910-0001; the collections of information in 21 CFR Part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR Part 601 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR Part 814, subparts B and E, have been approved under OMB Control No. 0910-0231; the collections of information in 21 CFR Part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR Part 801 and 21 CFR 809.10 have been approved under OMB Control No. 0910-0485; and the collections of information in 21 CFR 201.56 and 21 CR 201.57 have been approved under OMB control number 0910-572.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: July 8, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

### Obstetrics and Gynecology Devices Panel of the Medical Devices 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:* Obstetrics and Gynecology Devices Panel of the Medical Devices 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 September 8 and 9, 2011, from 8 a.m. to 6 p.m.

*Location:* Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879.

*Contact Person:* Shanika Craig, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, 301-796-6639, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On September 8 and 9, 2011, the committee will discuss and make recommendations regarding the safety and effectiveness of transvaginal surgical mesh used for repair of pelvic organ prolapse. FDA is convening this meeting to seek expert opinion on the risks and benefits of these devices in light of adverse events, e.g., vaginal erosion leading to pelvic pain and dyspareunia, and available information on clinical benefit. The committee will be asked to provide scientific and clinical input on the Agency's proposed premarket and postmarket regulatory strategies for these devices, including

reclassification into Class III (premarket approval), labeling improvements and postmarket surveillance studies. The committee will also consider surgical mesh used to treat stress urinary incontinence.

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 August 30, 2011. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. on September 8 and 9, 2011. 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 August 22, 2011. 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 August 23, 2011.

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 AnnMarie Williams, Committee Management Staff, 301-796-5966 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/>

*About Advisory Committees/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: June 30, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-17695 Filed 7-13-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Formative Research Methodology Studies for the National Children's Study

*Summary:* Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for reinstatement of approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23608-23609, and allowed 60 days for public comment. Two written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. The written comments were identical and questioned the cost and utility of the study. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection: Title:* Formative Research Studies for the National Children's Study (NCS) *Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106-310) states:

(a) *Purpose.*—It is the purpose of this section to authorize the National Institute of Child Health and Human Development\* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) *In General.*—The Director of the National Institute of Child Health and Human Development\* shall establish a consortium of representatives from

appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) Investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) *Requirement.*—The study under subsection (b) shall—

(1) Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the results of formative research and pilot tests will be used to maximize the efficiency of NCS procedures, materials, and methods for outreach, engagement of stakeholders, recruitment and retention of Study subjects, and to ensure scientifically robust data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain OMB's generic approval to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider information collection surrounding outreach, engagement, recruitment, consent and questionnaire design, and retention activities.

The results from formative research and pilot tests proposed will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study recruitment, retention, study visit measures and study logistics. *Type of Review:* Reinstatement of OMB #0925-0590, Expiration June 30, 2011. *Frequency of Response:* Annual [As needed on an ongoing and concurrent basis]. *Affected Public:* Members of the public, researchers, practitioners, and other health professionals. *Type of Respondents:* Women of child-bearing age, fathers, community leaders, members, and organizations, health care facilities and professionals, public health, environmental, social and cognitive science professional organizations and practitioners, hospital