TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
600.12 [2]	131	51.54	6,752	32	216,064
600.12 (b)(2)	304	6.19	1,881	24	45,144
600.80(c)(1) and 600.80(i)	108	1,332.25	143,883	1	143,883
Total					405,091

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

Dated: July 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17675 Filed 7–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0215]

Draft Guidance for Industry and FDA Staff on In Vitro Companion Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''In Vitro Companion Diagnostic Devices.'' This guidance is intended to assist sponsors planning to develop a therapeutic product that depends on the use of an in vitro companion diagnostic device for its safe and effective use or an in vitro diagnostic device that is intended for use with a corresponding therapeutic product and included in the instructions for use in the labeling of those products. This guidance defines in vitro companion diagnostic devices; explains the need for FDA oversight of companion diagnostic devices; clarifies that, in most circumstances, if use of a companion diagnostic device is essential for the safe and effective use of a therapeutic product, the diagnostic device and therapeutic product should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling; provides guidance for industry and FDA staff on possible premarket regulatory pathways and FDA's regulatory enforcement policy; and describes certain statutory and regulatory approval requirements relevant to therapeutic product labeling that stipulate concomitant use of a companion diagnostic device to ensure safety and effectiveness of the therapeutic product. This draft guidance is not final, nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 12, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''In Vitro Companion Diagnostic Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send a fax request to 301–827–8149 to receive a hard copy. Alternatively, you may submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development (HFM–40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to the office that you are ordering from to assist in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiologic Health, Food and Drug Administration, Bldg. 66, rm. 5676, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4664; or Christopher Leptak, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, rm. 5102, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0017; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''In Vitro Companion Diagnostic Devices.'' This guidance is intended to provide assistance both to sponsors developing therapeutic products, which for purposes of this guidance includes therapeutic, preventive, or prophylactic drugs and biological products that depend on the use of and are labeled for use with an in vitro diagnostic device, and to sponsors of the companion diagnostics. This guidance defines ''companion diagnostic device'' and clarifies that in most circumstances, if use of a companion diagnostic device is essential for the safe and effective use of a therapeutic product, the diagnostic device and therapeutic product should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling.

Diagnostic tests have been employed for many years to enhance the use of therapeutic products. Recently, therapeutic products that depend on the use of a diagnostic test to meet their labeled safety and effectiveness claims have become more common. For example, a test could identify or limit appropriate populations for treatment or identify populations who should not receive a particular treatment because of

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.* 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* 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.

[FR Doc. 2011–17671 Filed 7–12–11; 8:45 am]

BILLING CODE 4160–01–P

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