

information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which an applicant may obtain an assignment or designation determination for combination products.

**DATES:** Submit either electronic or written comments on the collection of information by July 1, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, [Jonnalynn.capezzuto@fda.hhs.gov](mailto:Jonnalynn.capezzuto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—(OMB Control Number 0910-0523)—Extension**

This regulation relates to Agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Pub. L. 101-629), and amended

by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product. The second purpose of this regulation is to enhance the efficiency of Agency management and operations by providing procedures for classifying and determining which Agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which Agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products and combination products. The respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Part 3 .....	43	1	43	24	1,032

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

These burden estimates are based on the number of applications FDA received over the past two fiscal years.

Dated: April 26, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-10376 Filed 5-1-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Gastroenterology and Urology 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:* Gastroenterology and Urology 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 June 27, 2013, from 8 a.m. to 6 p.m.

*Location:* Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's phone number is 301-948-8900.

*Contact Person:* Shanika Craig, [Shanika.Craig@fda.hhs.gov](mailto:Shanika.Craig@fda.hhs.gov), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6639, 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 meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On June 27, 2013, during session I, the committee will discuss and make recommendations regarding the proposed classification of sorbent hemoperfusion systems, one of the remaining preamendments class III devices. The class III sorbent hemoperfusion system is a device intended for the treatment of poisoning, drug overdose, hepatic coma, and metabolic disturbances. It consists of an extracorporeal blood system and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated carbon or resins, which may be coated or immobilized to prevent fine particles from entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. Sorbent hemoperfusion systems may also include the machine or instrument used to drive and manage blood and fluid flow within the extracorporeal circuit, as well as any accompanying controllers, monitors, or sensors.

On April 4, 2013 (78 FR 20268), FDA issued a proposed order which, if made final, would reclassify sorbent hemoperfusion systems labeled for the treatment of poisoning and drug overdose class II subject to premarket notification [510(k)] and special controls, while sorbent hemoperfusion systems labeled for the treatment of

hepatic coma and metabolic disturbances would remain class III requiring premarket approval (PMA) applications. The committee's discussion will involve making recommendations regarding the regulatory classifications noted above. The committee will also discuss whether the proposed special controls are adequate to reasonably ensure the safety and effectiveness of sorbent hemoperfusion devices labeled for the treatment of poisoning and drug overdose. The regulatory history of sorbent hemoperfusion has been discussed as part of a previously published proposed rule (77 FR 9610).

During session II on June 27, 2013, the committee will discuss and make recommendations regarding the proposed classification of implanted blood access devices for hemodialysis from class III to class II. The class III implanted blood access devices for hemodialysis include various flexible or rigid tubes, such as catheters, cannulae or hollow needles. Chronic hemodialysis catheters are soft, blunt-tipped plastic catheters that have a subcutaneous "cuff" for tissue ingrowth. They are placed in a central vein to allow blood access. Chronic hemodialysis catheters serve as conduits for the removal of blood from the patient, delivery to a hemodialysis machine for filtering, and return of filtered blood to the patient. They have no moving parts, consisting, essentially, of flexible tubing terminating in rigid Luer lock connectors for attachment to a dialysis machine. Subcutaneous catheters are totally implanted below the skin surface with no external communication. Arteriovenous shunts and vessel tips are tubing with tapered tips that are inserted into the artery and vein. The tubing is attached to the roughened or etched outer surface of the tip. The tubing is external to the skin and can be accessed with needles. They are similar to subcutaneous catheters.

On June 20, 2012 (77 FR 36951), FDA issued a proposed rule which, if made final, would make the class III implanted blood access devices class II subject to premarket notification [510(k)] and special controls. The regulatory history of implanted blood access devices has been discussed as part of the proposed rule (77 FR 36951).

The committee's discussion will involve making recommendations regarding regulatory classification to either reaffirm class III or reclassify these devices into class II and comment on whether special controls are adequate to reasonably ensure the safety and effectiveness of this device.

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 meeting 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 June 11, 2013. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. for session I and session II will start immediately after lunch between approximately 1:30 p.m. and 2:30 p.m. 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 June 3, 2013. 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 June 4, 2013.

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 James Clark, Committee Management Staff, at [james.clark@fda.hhs.gov](mailto:james.clark@fda.hhs.gov), or 301-796-5293 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: April 26, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-10394 Filed 5-1-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0294]

#### Submission of New Drug Application/Abbreviated New Drug Application Field Alert Reports: Notice of Form FDA 3331—Automated Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a pilot program to test an XML (extensible markup language)-enabled Adobe PDF form, Form FDA 3331—Automated to submit new drug application (NDA) and abbreviated new drug application (ANDA) Field Alert Reports (FARs) as required by FDA regulations. This pilot program is intended to provide FDA with information to allow the Agency to modernize the FAR submission and review pathway and will permit integration with electronic archive filing systems.

**DATES:** The XML-enabled Adobe PDF form, Form FDA 3331—Automated, will be available for piloting between May 1, 2013, and January 1, 2014.

**ADDRESSES:** Electronic or written general comments regarding the pilot may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The automated form, detailed instructions for use, and frequently asked questions are available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm347604.htm>.

Questions or feedback about the pilot program should be sent to district Drug Field Alert Monitors (contact information for each of these individuals is available on FDA's Web site at <http://www.fda.gov/ICECI/Inspections/IOM/ucm124063.htm>). FDA's Center for Drug Evaluation and

Research (CDER) has also established an email account, [CDER-FAR-XML@fda.hhs.gov](mailto:CDER-FAR-XML@fda.hhs.gov), to receive feedback on participants' experiences using the XML-enabled Form FDA 3331—Automated.

#### FOR FURTHER INFORMATION CONTACT:

Mark Browning, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-5342.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This pilot program seeks to modernize the FAR submission and review pathway using an XML-enabled PDF form to enable integration with electronic archive filing systems and simplify data integration across the enterprise. Under existing procedures, firms typically submit FARs via fax or scanned copy to their respective FDA district offices, and the district offices then provide them to CDER for additional review and analysis. Under this pilot program, participants will be able to send the FAR report simultaneously to the selected FDA district office and to CDER's Office of Compliance, allowing for improved coordination within the Agency as well as more efficient reporting by industry. The pilot program will also offer industry participants the opportunity to provide the Agency with feedback regarding the use of the automated form. FDA will take industry feedback into account when improving the FAR reporting process overall.

The pilot is open to all NDA and ANDA holders. Participation in the pilot program is voluntary and no additional software or licenses are needed to use the proposed Form FDA 3331—Automated. For the period of the pilot program, firms that elect to participate must continue to submit a signed Form FDA 3331 (whether the traditional or the automated version) via email, along with the pilot automated form. This parallel process during the pilot program will ensure delivery of all field alert reports and allow FDA to evaluate the utility of an automated form.

The pilot program will run for 8 months following the date of the **Federal Register** Notice and may be extended as needed to accrue sufficient reports and experience for a meaningful evaluation. After the pilot concludes, CDER and the Office of Regulatory Affairs will evaluate the forms submitted along with any direct industry feedback about using the automated form. If the pilot is successful, FDA would likely seek to

adopt a more permanent, required electronic reporting system, which would be implemented in accordance with existing regulation- and guidance-making processes, as needed.

The automated form, detailed instructions for use, and frequently asked questions are available on FDA's Web site at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm347604.htm>.

##### II. Comments and Other Feedback

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written general comments to the Division of Dockets Management (see **ADDRESSES**). 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>.

Participants should contact their district Drug Field Alert Monitors for questions or feedback about the pilot program. Contact information for each district Drug Field Alert Monitor is available on FDA's Web site at <http://www.fda.gov/ICECI/Inspections/IOM/ucm124063.htm>. CDER has also established an email account, [CDER-FAR-XML@fda.hhs.gov](mailto:CDER-FAR-XML@fda.hhs.gov), to receive feedback on participants' experiences using the XML-enabled Form FDA 3331—Automated.

##### III. The Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information that 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 collection of information in Form FDA 3331 has been approved under OMB control number 0910-0001.

Dated: April 26, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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