

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Type of submission	Number of respondents	Annual frequency per disclosure	Total annual disclosures	Hours per disclosure	Total hours
Post approved labeling on application holder's Web site	197	1	197	4	788

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

This draft guidance also refers to previously approved collections of information. Specifically, the draft guidance describes: Labeling supplements for new drug applications, abbreviated new drug applications, and biologics license applications submitted under 21 CFR 314.70, 314.71, 314.97, and 601.12, and the content and format of prescription drug labeling submitted under 21 CFR 201.56 and 201.57. These collections of information are subject to review by OMB under the PRA and are approved under OMB control numbers 0910-0001, 0910-0338, and 0910-0572. Section V of the draft guidance refers to the guidance entitled “Formal Dispute Resolution: Appeals Above the Division Level,” which describes collections of information approved under OMB control number 0910-0430.

Dated: November 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Neurological 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. This meeting is being rescheduled due to the postponement of the November 1, 2012, meeting due to unanticipated weather conditions caused by hurricane Sandy.

Name of Committee: Neurological 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 December 10, 2012, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Grand Ballroom, Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993-0002, 301-796-5290,

Natasha.Facey@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 meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On December 10, 2012, the committee will discuss current knowledge about the safety and effectiveness of the CoAxia NeuroFlo Catheter device for the intended use of diverting cardiac output to the cerebral vasculature via partial occlusion of the descending aorta, including in patients with acute ischemic stroke within 14 hours of symptom onset.

The CoAxia NeuroFlo Catheter is a 7F multilumen device with two balloons mounted near the distal tip. The proximal end has a multiport manifold that provides access for the guidewire, monitoring of blood pressure, and independent inflation of the individual balloons. The device is placed in the descending aorta. On March 30, 2005, a humanitarian device exemption application for the CoAxia NeuroFlo Catheter was approved for the following indication for use: The CoAxia NeuroFlo Catheter is intended for the treatment of cerebral ischemia resulting from symptomatic vasospasm following aneurismal subarachnoid hemorrhage,

secured by either surgical or endovascular intervention for patients who have failed maximal medical management.

Of note, the CoAxia NeuroFlo Catheter is identical in design to the CoAxia FloControl, which is currently cleared for the following general indications for use:

1. The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature (K023914).

2. The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature, which includes the descending aorta (K090970).

CoAxia has submitted a de novo application for the NeuroFlo for the following indication: The CoAxia NeuroFlo Catheter is intended for use in diversion of cardiac output via partial occlusion of the descending aorta, including patients with acute ischemic stroke within 14 hours of symptom onset. The CoAxia NeuroFlo Catheter is also intended for use in selectively stopping or controlling blood flow in the peripheral vasculature, which includes the descending aorta.

FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of this device based on the available premarket and postmarket data. In particular, the committee will be asked to discuss the safety and effectiveness data from the “Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke” (SENTIS) clinical trial as they relate to the proposed indications for use.

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 December 4, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 November 26, 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 28, 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 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/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: November 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1037]

Establishing a List of Qualifying Pathogens That Have the Potential To Pose a Serious Threat to Public Health; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain input on establishing a list of qualifying pathogens (i.e., those that have the potential to pose a serious threat to public health), as required under the Food and Drug Administration Safety and Innovation Act (FDASIA). This public hearing is being held to obtain comments from the public to determine the methodology that should be used in developing the list of qualifying pathogens, and to elicit suggestions for adding specific pathogens to the list.

DATES: *Date and Time:* The public hearing will be held on December 18, 2012, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the hearing may be extended or may end early.

Location: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Person: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7563, FAX: 301-847-8753, email: CDER-GAINPublicMtg@fda.hhs.gov.

Registration: The public hearing is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

If you need special accommodations due to a disability, please contact Lee Lemley (see *Contact Person*) at least 7 days in advance.

Requests for Oral Presentations: If you wish to make an oral presentation

during the public hearing, you must register by submitting either an electronic or written request by close of business on December 3, 2012. You must provide your name, title, business affiliation (if applicable), address, email address, and phone and type of organization you represent (e.g., industry, consumer organization), and a brief summary of the presentation (including the discussion topic(s) that will be addressed) to Lee Lemley (see *Contact Person*). You should identify which question(s) set forth in section II of this document you wish to address so that FDA can consider that in organizing the presentations.

FDA will notify registered presenters of their scheduled times, and will make available an agenda at <http://www.fda.gov/Drugs/NewsEvents/ucm319619.htm>. Once FDA notifies registered presenters of their scheduled times, presenters should submit an electronic copy of their presentation to Lee Lemley (see *Contact Person*) no later than December 12, 2012. Persons registered to make an oral presentation should check in before the hearing, and are encouraged to arrive early to ensure the designated order of presentation.

A live Webcast of this public hearing will be viewable at the following Web site: <https://collaboration.fda.gov/gain121812/>. A video record of the public hearing will be available at the same Web site for 1 year.

Comments: Regardless of attendance at the public hearing, interested persons may submit either written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to <http://www.regulations.gov>. Submit electronic or written comments by December 3, 2012. You should annotate and organize your comments so that they identify the specific questions to which they refer. 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>.

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open until January 25, 2013.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management