address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on December 17, 2012. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: November 9, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–27841 Filed 11–15–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by December 17, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance for Industry on Safety Labeling Changes; Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910-New)

This draft guidance provides information on the implementation of section 901 of the Food and Drug Administration Amendments Act of 2007, which authorizes FDA to require certain drug and biological product application holders to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or the Public Health Service Act. FDA plans to request safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B) of the FD&C Act (21 U.S.C. 355(o)(4)(B)), the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and submitting a statement detailing the reasons why the application holder does not believe a change is warranted (a rebuttal statement).

The submission of rebuttal statements may result in the collection of information that is not already approved by OMB. Based on FDA's experience thus far with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, FDA estimates that approximately six application holders will elect to submit approximately one rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, in the draft guidance, the Agency states that new labeling prepared in response to a safety labeling change notification should be available on the application holder's Web site within 10 calendar days of approval, which may result in the collection of information that is not already approved by OMB. FDA estimates that approximately 197 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

In the **Federal Register** of April 13, 2011 (76 FR 20686), FDA published a 60-day notice requesting public comment on the draft version of this guidance. None of the comments we received pertained to the information collection provisions.

FDA estimates the burden of the collections of information that have not already been approved by OMB is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rebuttal statement	6	1	6	6	36

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

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.

[FR Doc. 2012–27881 Filed 11–15–12; 8:45 am]

BILLING CODE 4160–01–P

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.