delve further into how much authority respondents have. We will also ask all respondents how many prescriptions they write in 1 week.

(Comment 55) One comment suggested reexamining the questionnaire from the Office of Prescription Drug Promotion's online DTC promotion study (Docket No. FDA–2011–N–0230) in light of this survey to explore the possibility of comparing responses on similar questions.

(Response) We appreciate this suggestion and will examine the data from both studies to see if any descriptive comparisons can be made.

Please note that in response to all comments received, whether we have adapted the suggestions or not, we will specifically examine the items mentioned in cognitive testing. During this testing, nine respondents will participate in the survey while explaining why and how they have chosen their answers and which questions they find difficult to respond to or to understand.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	3,500	1	3,500	0.03	105
Pretest	25	1	25	0.33	8
Main Study	2,000	1	2,000	0.33	660
Total					773

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

V. References

The following references have been placed on display in the Division of Dockets Management (FDA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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Dated: October 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24973 Filed 10–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1025]

The Science of Small Clinical Trials; Notice of Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA), together with the National Institutes of Health (NIH) Office of Rare Diseases Research, National Center for Advancing Translational Sciences, is announcing a course entitled ''The Science of Small Clinical Trials.'' The course is intended to present an overall framework and provide training in the scientific aspects of designing and analyzing clinical trials based on small study populations. The course will bring together subject experts and stakeholders to identify when such trials should be conducted, along with strategies and trial designs that are conducive to overcoming the challenges they present.

The goal of this course is to engage and educate FDA reviewers, NIH scientists, clinicians, academics and industry representatives with experience in human subject research, seeking to build upon their existing knowledge and to obtain a broader

context of what is known about small clinical trials across medical products (e.g. drugs, biologics, and devices).

Date and Time: The course will be held on November 27, 2012, from 8 a.m. to 5 p.m., and November 28, 2012, from 8 a.m. to 3 p.m.

Location: The course will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Section A, Silver Spring, MD 20993–0002. Entrance for course 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.* A live Web cast will be made available for FDA participants only. For participants who cannot attend the live course, a recorded Web cast will be made available after the course.

Contact: For information regarding this notice: Francesca Joseph, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5264, Silver Spring, MD 20993–0002, 301–796–6805, FAX: 301–847–8621, email: *Francesca.Joseph@fda.hhs.gov.*

For information regarding the course and registration: Megan McNamee, ICF International, 530 Gaither Rd., suite 500, Rockville, MD 20850, 301–407–6627, email: *Megan.Mcnamee@icfi.com.*

Registration: Interested participants may register for this course at the following Web site: *https://events-support.com/events/FDA–NIH_Science_Small_Clinical_Trials.*

If you need sign language interpretation during this course, please contact Francesca Joseph at *Francesca.Joseph@fda.hhs.gov* by October 26, 2012.

The FDA–NIH Science of Small Clinical Trials Course is presented by FDA's Office of Orphan Product Development, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health; the NIH Office of Rare Disease Research, National Center for Advancing Translational Sciences; and will also include participation from outside experts in the field. This educational event will consist of live presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. It will also include case studies of regulatory trials and interactive panel discussions. The course will be recorded for subsequent posting on FDA's Web site.

(FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: October 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24977 Filed 10–10–12; 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.

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 November 1, 2012, from 8 a.m. to 6 p.m.

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

Contact Person: LCDR Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993–0002, 301–796–3805, *Avena.Russell@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 November 1, 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 multi-lumen device with two balloons mounted near the distal tip. The proximal end has a multi-port manifold which 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 (SAH), 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:

- The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature (K023914).
- 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 Catheter 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 panel will be asked to discuss the safety and effectiveness data from the ''Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke (SENTIS)'' clinical trial