TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Including a domestic address or phone number and a statement of its purpose on OTC drug labeling (21 U.S.C. 502(x))	300	3	900	4	3,600

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

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03457 Filed 2–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0567]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

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: Pediatric 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 April 12, 2016, from 8 a.m. to 5:30 p.m.

ADDRESSES: FDA is establishing a public docket [Docket No. FDA–2016–N–0567] to receive input on pediatric-focused safety reviews and appropriate pediatric development plans for prescription opioid drugs. Comments about the upcoming September advisory committee meeting should not be submitted to the docket number listed at the top of this **Federal Register** notice [Docket No. FDA–2016–N–0567], which is to provide an opportunity for the public to provide input concerning the products before the Committee on April 12, 2016.

Location: Double Tree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910, 301–589–5200. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-washington-dc-silver-spring-DCASSDT/index.html.*

Contact Person: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 240–402–3838, email: *marieann.brill@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 April 12, 2016, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155). See the list of the products in this document to be discussed.

In addition, FDA will be providing information on a proposed public advisory committee meeting for September 15 and 16, 2016, on appropriate pediatric development plans for prescription opioid drugs. Prior to the safety reviews and the open public hearing (see later in this section for further information), FDA will present, from approximately 8:30 to 9:30 a.m., a framework of current plans for a 2-day joint meeting of the PAC, the Anesthetic and Analgesic Drug Products Advisory Committee, and the Drug Safety and Risk Management Advisory Committees.

Elsewhere in this issue of the **Federal Register**, FDA is publishing an announcement of this advisory committee meeting to be held on September 15 and 16, 2016, on the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Following the presentation on the proposed framework for the September meeting, there will be an hour of open public hearing from 9:30 a.m. to 10:30 a.m. to provide an opportunity for the public to provide input concerning the topics before the PAC, including the use of opioids for control of severe pain in the pediatric population. To assist with the planning of this advisory committee meeting, FDA is establishing a public docket [Docket No. FDA–2016–N–0584] to receive input on appropriate pediatric development plans for prescription opioid drugs. The docket will remain open following the September advisory committee meeting. Comments about the upcoming September advisory committee meeting should *not* be submitted to the docket number listed at the top of this **Federal Register** notice [Docket No. FDA–2016–N–0567]. Please also see the **ADDRESSES** section of this notice for further docket information.

The pediatric-focused safety reviews for the Centers will then occur. The PAC will meet to discuss the following products (listed by FDA Center):

- Center for Biologics Evaluation and Research (CBER):
  - FLULAVAL QUADRIVALENT (influenza virus vaccine)
  - FLULAVAL TRIVALENT (influenza virus vaccine)
  - FLUZONE QUADRIVALENT (influenza virus vaccine)
- Center for Drug Evaluation and Research (CDER):
  - ACIPHEX SPRINKLES (rabeprazole sodium)
  - SKYLA (levonorgestrel-releasing intrauterine system)
  - MYCAMINE (micafungin sodium)
  - NOXAFIL (posaconazole)
  - PRECEDEX (dexmedetomidine hydrocholoride)
  - SABRIL (vigabatrim)
  - SEROQUEL (quetiapine fumarate) and SEROQUEL XR (quetiapine fumarate extended-release)

- SKYLA (levonorgestrel-releasing intrauterine system)
- SYMBAX (fluoxetine hydrocholoride and olanzapine)
- VYVANSE CAPSULES (lisdexamfetamine dimesylate)
- XELODA (capecitabine)

- Center for Devices and Radiological Health (CDRH):
  - IMPELLA RP SYSTEM (humanitarian use device (HUD))
  - LIPSORBER LA-15 SYSTEM (HUD)
  - MEDTRONIC ACTIVA DYSTONIA THERAPY (HUD)

In addition to the agenda items, the PAC will remain in public session over the lunch hour on April 12, 2016, to hear a presentation and provide feedback on an FDA proposal for a risk-based approach to the pediatric-focused safety reviews mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. The working lunch currently is scheduled between approximately 12:30 p.m. and 1:15 p.m.

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 April 5, 2016. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.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 March 28, 2016. 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 March 29, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Marieann Brill 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: February 16, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–03469 Filed 2–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0096]

Determining the Extent of Safety Data Collection Needed in Late-Stage Premarket and Postapproval Clinical Investigations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Determining the Extent of Safety Data Collection Needed in Late-Stage Premarket and Postapproval Clinical Investigations.'' The guidance is intended to help sponsors determine the amounts and types of safety data to collect in late-stage premarket and postapproval clinical investigations based on what is already known about a drug's safety profile. Sponsors collect extensive safety data in clinical investigations of drug and biological products conducted to support marketing approval (premarket) and after approval (postapproval). FDA believes that selective safety data collection may be possible for some late-stage premarket and postapproval clinical investigations because certain aspects of a drug's safety profile will be sufficiently well-established and comprehensive data collection is not needed. This guidance finalizes the draft guidance issued in February 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–0096 for ''Determining the Extent of Safety Data Collection Needed