collection, FDA is conservatively estimating the total number of annual respondents to this collection of information to be 100.

When the FTC requested an extension of their approved warning plan information collection in 2007, based on over 20 years implementing the warning plan requirements and taking into account increased computerization and improvements in electronic communication, the FTC estimated submitting an initial plan would take 60 hours. Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs
Submission of rotational plans for health warning statements	100	1	100	60	6,000	$1,200

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

FDA estimates a total of 100 respondents will respond to this collection of information and take 60 hours to complete a rotational warning plan for a total of 6,000 burden hours. In addition, capital costs are based on 100 respondents mailing in their submission at a postage rate of $12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to FDA to be $1,200.

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03478 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–2007–D–0429 (formerly Docket No. 2007D–0496)]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection 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 March 21, 2016.

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 title. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; OMB Control Number 0910–0641—Extension

Section 502(x) of the FD&C Act (21 U.S.C. 352(x)), which was added by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462), requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a manufacturer, packer, and distributor may receive a report of a serious adverse event associated with the product. The guidance document contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 502(x) of the FD&C Act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 502(x) of the FD&C Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (issued in section 502(b)(1) of the FD&C Act) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

In the **Federal Register** of July 17, 2015 (80 FR 42502), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. However, these comments did not address the information collection.

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

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)