TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 60—Patent Term Restoration	Number of respondents	Number of responses per respondent	Total responses (2016–2018)	Average burden per response	Total hours (2016–2018)	Average annual burden hours
60.24; revision of regulatory review period determinations	12	1.333	16	100	1,600	533.33
60.30; due diligence petitions	1	1	3	50	150	50
60.40; due diligence hearings	1	1	1	10	10	3.3
Total						586.63

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

Our estimated burden for the information collection reflects a small increase (+7 responses) associated with submissions received under § 60.24 in previous years.

Dated: August 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17999 Filed 8–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2396]

Psychopharmacologic Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Psychopharmacologic Drugs Advisory Committee scheduled for July 31, 2019, has been canceled. This meeting was announced in the **Federal Register** of June 14, 2019. This meeting has been canceled because of new information regarding the application. The Agency intends to continue evaluating the application and, as needed, will announce future meeting dates in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Jay Fajiculay, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting, which was announced in the **Federal Register** of June 14, 2019 (84 FR 27783).

Dated: August 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18026 Filed 8–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0902]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

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 (PRA).

DATES: Fax written comments on the collection of information by September 20, 2019.

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 0910–0393. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Prescription Drug Product Labeling; Medication Guide Requirements

OMB Control Number 0910–0393—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern. Medication Guides provide patients the most important information about drug products, including the drugs' approved uses, contraindications, adverse drug reactions, and cautions for specific populations. These regulations are intended to improve the public health by providing information necessary for patients to use certain medications safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA:

- § 208.20 (21 CFR 208.20)—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.
- §§ 314.70(b)(3)(ii) and 601.12(f) (21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f))—Application holders must submit changes to Medication Guides as supplements to their applications to FDA for approval.
- § 208.24(c) (21 CFR 208.24(c))—Each distributor or packer who receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides to each authorized dispenser to whom it ships a drug product.

• § 208.24(e) (21 CFR 208.24(e))—Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide a Medication Guide directly to each patient when dispensing the product to the patient or to the patient's agent, unless an exemption applies under § 208.26 (21 CFR 208.26).

• § 208.26(a)—Requests may be submitted for an exemption or a deferral from particular Medication Guide content or format requirements.

In the **Federal Register** of October 26, 2018 (83 FR 54110), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received encouraging the use of ''provider-neutral language'' in places where terms such as ''doctor'' or ''physician'' are used suggesting that these terms may cause some confusion for patients. We are appreciative of this recommendation; however, we decline to implement such changes.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and Format of a Medication Guide—§ 208.20	61	1	61	320	19,520
Supplements and Other Changes to an Approved Application—§§ 314.70(b)(3)(ii) and 601.12(f)	155	1	155	72	11,160
Exemptions and Deferrals—§ 208.26(a)	1	1	1	4	4
Total					30,684

[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]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Distributing Medication Guide to Authorized Dispenser—§ 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distributing and Dispensing a Medication Guide to Patient—§ 208.24(e)	88,736	5,705	506,238,880	0.05 (3 minutes)	25,311,944
Total					27,460,694

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

Our estimated annual reporting burden for the information collection reflects an overall increase of 4,664 total hours. We attribute this adjustment to an increase in the number of submissions we received over the last few years. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our annual third-party disclosure burden estimate.

Dated: August 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18000 Filed 8–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0221]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 21, 2019.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Family Planning Annual Report (FPAR).

Type of Collection: Renewal with change.

OMB No.: 0990–0221.

Abstract: The Office of Population Affairs within the Office of the Assistant Secretary for Health is requesting an extension on a currently approved Family Planning Annual Report (FPAR) data collection and reporting tool (OMB No. 0990–0221). This annual reporting requirement is for family planning services delivery projects authorized and funded by the Title X Family Planning Program [''Population Research and Voluntary Family Planning Programs'' (Public Law 91–572)], which was enacted in 1970 as Title X of the Public Health Service Act (Section 1001; 42 U.S.C. 300). The FPAR data collection and reporting tool will include a new module to collect