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.