Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06992 Filed 4–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3535]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Special Protocol Assessment; Guidance for Industry

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.

DATES: Submit written comments (including recommendations) on the collection of information May 4, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0470. 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.

Special Protocol Assessment

OMB Control Number 0910–0470—Revision

This information collection request supports Agency guidance entitled ''Special Protocol Assessment'' (Revision 1) (83 FR 16367, April 16, 2018), which describes procedures FDA uses to evaluate issues related to the adequacy (*e.g.,* design, conduct, analysis) of certain proposed studies. A copy of the guidance is available from our website at *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.* The guidance describes procedures for sponsors to request special protocol assessment and for FDA to act on such requests. The guidance provides information on how FDA interprets and applies provisions of the Food and Drug Administration Modernization Act of 1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products. The guidance describes the following two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol; and (2) the submission of a request for special protocol assessment.

I. Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in an FDA assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that FDA may review reference material related to carcinogenicity protocol design before receiving the carcinogenicity protocol.

II. Request for Special Protocol Assessment

The guidance asks that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to FDA in triplicate with Form FDA 1571 (*https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf*) attached. The guidance also suggests that the sponsor submit the cover letter to a request for special protocol assessment via Fax to the appropriate division in CDER or CBER. FDA regulations (21 CFR 312.23(d)) state that information provided to us as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA, and the reporting and recordkeeping burden has been approved by OMB under OMB control number 0910–0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via Fax to the appropriate division in CDER or CBER to enable FDA staff to prepare for the arrival of the protocol for assessment. FDA recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1) To ensure that each request is kept in the administrative file with the entire IND and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in FDA's tracking databases enables the appropriate Agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

- Questions to FDA concerning specific issues regarding the protocol.
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product that FDA

regulates under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) requesting special protocol assessment.

In the **Federal Register** of January 3, 2020 (85 FR 320) we published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the information collection topics solicited in the notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification for Carcinogenicity Protocols	106	1.78	189	8	1,510
Requests for Special Protocol Assessment Reports	113	1.03	116	15	1,740
Total			305		3,250

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

Burden Estimate: Table 1 provides an estimate of the annual reporting burden for notifications for a carcinogenicity protocol and requests for a special protocol assessment.

Notification for a Carcinogenicity Protocol: Based on the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols currently submitted to CDER and CBER, CDER estimates that it will receive approximately 188 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 105 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment: Based on the number of requests for special protocol assessment currently submitted to CDER and CBER, CDER estimates that it will receive approximately 108 requests for special protocol assessment per year from approximately 105 sponsors. CBER estimates that it will receive approximately eight requests from approximately eight sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the Agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol.

Based on our experience with these submissions, we estimate approximately 15 hours on average would be needed per response. The information collection reflects an adjustment in burden by 608 hours. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: March 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06983 Filed 4–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0907]

Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments; postponement.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the public meeting entitled ''Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027; Public Meeting; Request for Comments'' that appeared in the **Federal Register** on March 6, 2020, and was scheduled for April 7, 2020, is postponed to May 5, 2020, and will take place by webcast only.

DATES: The public meeting will take place remotely on May 5, 2020, beginning at 9 a.m. EST. Submit either electronic or written comments on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program by June 5, 2020.

FOR FURTHER INFORMATION CONTACT: Ellen Olson, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 1664, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4322, *ellen.olson@fda.hhs.gov* or *CDRH-OPEQ-StrategicInitiatives@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The public meeting entitled ''Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027; Public Meeting; Request for Comments'' announced in the **Federal Register** of March 6, 2020 (85 FR 13165), and scheduled for April 7, 2020, is postponed to May 5, 2020, and will take place virtually due to extenuating circumstances. There will no longer be an in-person meeting and instead the meeting will be held by webcast only. The webcast link and connection instructions will be available on the registration web page (*https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/2020-medical-device-meetings-and-workshops*) after April 23, 2020. Interested participants may continue to register and, if applicable, to specify whether they would like to present during a particular session or the public comment session.

Dated: March 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07016 Filed 4–2–20; 8:45 am]

BILLING CODE 4164–01–P