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.*

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