request or appeal; and FDA's process for reviewing such requests or appeals.

We use the information submitted by respondents to determine whether requests for waiver or reduction of user fees, reconsideration requests, or appeals may be granted.

In the **Federal Register** of April 27, 2023 (88 FR 25658), we published a 60-day notice soliciting public comment on the proposed information collection. One general comment was received encouraging FDA in its mission to promote and protect animal health.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act section; activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User fee cover sheets, by type:						
740(a)(1); Animal Drug User Fee cover sheet.	3546	15	1	15	1	15
741(a)(1); Animal Generic Drug User Fee cover sheet.	3728	22	2	44	0.08 (5 minutes)	3.5
Waiver and other requests, by type:						
740(d)(1)(A); Significant barrier to innovation.	N/A	65	1	65	2	130
740(d)(1)(B); Fees exceed cost.	N/A	8	3.75	30	0.5 (30 minutes)	15
740(d)(1)(C); Free choice feeds.	N/A	4	1	4	2	8
740(d)(1)(D); Minor use or minor species.	N/A	73	1	73	2	146
740(d)(1)(E); Small business.	N/A	1	1	1	2	2
741(d)(1); Minor use or minor species.	N/A	2	1	2	2	4
Request for reconsideration of a decision.	N/A	1	1	1	2	2
21 CFR 10.75; Appeal of a decision.	N/A	1	1	1	2	2
Total						327.5

[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 an overall increase. We attribute this adjustment to an increase in the number of submissions we have received since our last evaluation. The total number of annual responses is based on the average number of submissions received by FDA in fiscal years 2019 to 2021. The estimated time we attribute to the hours per response is based on our experience with the various submissions and reflects the average burden we attribute to all respondents.

Dated: August 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17260 Filed 8–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1006]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 by September 11, 2023.

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 0910–0359. 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.

Medical Devices; Reports of Corrections and Removals—21 CFR Part 806

OMB Control Number 0910–0359—Revision

This information collection supports implementation of provisions of section 519(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(g)) requiring device manufacturers and importers to report promptly to FDA certain actions concerning device corrections and removals and to maintain associated records. Applicable regulations are found in 21 CFR part 806 and set forth definitions, prescribe format and required content elements for reporting, and identify actions that are exempt from the reporting requirements. The information collected is used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. The information also helps ensure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate.

Reports of corrections and removals may be submitted to FDA via mail, email, or using FDA's Electronic Submission Gateway (ESG). To assist respondents with submitting reports of corrections or removals, we developed a fillable PDF electronic submission template entitled, ''Device Correction/Removal Report for Industry,'' that transmits required data to FDA's Recall Enterprise System. Instructions for the fillable template are provided in pop-up text boxes that appear over each data field. We expect that use of the fillable template will expedite processing of the reports of corrections or removals submitted to FDA.

In the **Federal Register** of April 11, 2023 (88 FR 21677), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part; collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Electronic process setup	517	1	517	3.08	1,592	$25,850
806; Submission of corrections and removals	1,033	1	1,033	10	10,330	
4.102(c)(1)(iii); Submitting correction or removal reports (including any sharing of information with other constituent part applicants as required under 4.103)	20	1	20	10	200	
Total					12,122	25,850

For respondents who submit corrections and removals using the ESG, the operating and maintenance costs associated with this information collection are approximately $50 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be reduced if the respondent has already purchased a verification certificate for other electronic submissions to FDA. This burden may also be reduced if respondents utilize the new PDF template and submit it to the Agency using email, mitigating the need for a digital verification certificate.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR part; collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
806; Records of corrections and removals	93	1	93	10	930
4.105(b); recordkeeping by device-led combination products.	279	1	279	0.5 (30 minutes)	140
Total					1,070

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Figures have been rounded.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate, however we have revised the collection to include the new electronic reporting instrument ''Device Correction/Removal Report for Industry.'' We estimate that 50 percent of submitters will use the ESG to submit the required information. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG. For the purposes of estimating the burden, we assume that all respondents who submit corrections and removals using the electronic process will establish a new WebTrader account and purchase a digital verification certificate.

Dated: August 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17264 Filed 8–10–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1922]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.