Facilities guidance) describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities can submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility can qualify as a small business to obtain a reduction in fees. The guidance documents were issued consistent with our good guidance practice regulations (21 CFR 10.115), which provide for public comment at any time, and are available on our website at *https://www.fda.gov/media/87570/download* and *https://www.fda.gov/media/136683/download,* respectively.

All requests for dispute resolution should be sent via email to the Division of User Fee Management at *FDAUserFees@fda.hhs.gov.* If an outsourcing facility does not have email access, it can mail a request to FDA via the carrier of its choice to FDA, Division of User Fee Management, 10903 New Hampshire Ave., Bldg. 32, Room 4245, Silver Spring, MD 20993.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section; guidance or associated FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using the SPL Format; 207.61; Section III. of the "eDRLS" [2]guidance.	100	1	100	4.5	450
Waiver Request from Electronic Submission of Registration Information; 207.65; Section VI. of the "eDRLS" [2]guidance.	1	1	1	1	1
Remission of Annual Establishment Fee from FDA Invoice; Section E.1. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	90	1	90	0.5 (30 minutes)	45
Request for Small Business Reduction (Form FDA 3908)	8	1	8	25	200
Reinspection Fees; Section C. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	12	1	12	0.5 (30 minutes)	6
Reconsideration Requests; Section V.B.1. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	1	1	1	1	1
Appeal of Reconsideration Denials; Section V.B.2. of the Fees for Human Drug Compounding Outsourcing Facilities guidance.	1	1	1	1	1
Total			213		704

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] "Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing" (May 2009; available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-drug-establishment-registration-and-drug-listing*).

We estimate 100 respondents annually will submit outsourcing facility registrations using the SPL format as specified in Agency guidance and assume each registration will require 4.5 hours to prepare and complete. We expect no more than one waiver request from the electronic submission requirement annually and assume each waiver request will require 1 hour to prepare and submit. We estimate each of the 90 registrants will remit annual establishment fees and assume this task requires 30 minutes per respondent. We estimate that 8 of those respondents will request a small business reduction in the amount of the annual establishment fee using Form FDA 3908.

We estimate 12 outsourcing facilities annually will remit reinspection fees and assume this will require 30 minutes. We also estimate that we will receive one request for reconsideration and one appeal of a denial of a request for reconsideration and assume 1 hour per respondent for this activity.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Retention of Small Business Designation Notification Letter	8	1	8	0.5 (30 minutes)	4

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

We estimate that annually 8 outsourcing facilities will maintain a copy of their small business designation letter and that maintaining each record will require 30 minutes. These estimates reflect a slight increase in the number of annual registrations, but a decrease in reinspection fee submissions.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17676 Filed 8–28–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–9349]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Reports of Removals and Corrections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with reports of removals and corrections for medical and radiation emitting products

regulated by FDA's Center for Devices and Radiological Health (CDRH).

DATES: Either electronic or written comments on the collection of information must be submitted by October 30, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 30, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–9349 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Reports of Removals and Corrections.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

OMB Control Number 0910–0359—Extension

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 by mail, email, or using FDA's Electronic Submission Software (eSubmitter). To assist respondents with submitting reports of corrections or removals, we developed Form FDA 5072, ''Device Correction/Removal Report for Industry,'' a fillable PDF. Reports created using eSubmitter are transmitted to CDRH through FDA's Electronic Submission Gateway (ESG). Instructions for the completing Form FDA 5072 are provided in pop-up text boxes that appear over each data field. We expect that use of the fillable form will expedite processing of the reports of corrections or removals submitted to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR; IC activity	Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]	Total operating & maintenance costs
Electronic process setup		463	1	463	3.08	1,426	$23,150
806; device product corrections or removals.	FDA Form 5072: ''Device Correction/Removal Report for Industry''.	925	1	925	10	9,250	
4.102; combination product corrections or removals (including sharing information with other constituent part applicants under 4.103).		20	1	20	10	200	
Total				1,408		10,876	23,150

[1] Figures rounded.

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.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR; IC activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]
806.20; device product corrections and removals	110	1	110	10	1,100
4.105; device-led combination products [1]	279	1	279	.5 (45 minutes)	140
Total			389		1,240

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

Our estimated burden for this information collection reflects an overall decrease of 833 hours, with a corresponding decrease of 162 total annual responses and an increase of 170 total annual records. We attribute this adjustment to a decrease in the number of device correction and removal reports received over the last few years, which has reduced our reporting burden estimate from 1,033 to 925 respondents under 21 CFR part 806. This decrease in reporting burden is partially offset by an increase in recordkeeping burden, driven by a revised estimate of records per recordkeeper for device-led combination products under 21 CFR 4.105 and a modest increase in the number of device correction and removal recordkeepers. The estimated Operating and Maintenance Costs associated with electronic process setup has decreased by $2,700 as a result of fewer respondents expected to purchase a digital verification certificate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17675 Filed 8–28–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0004]

Authorization of Emergency Use for Three Animal Drugs for the Prevention and Treatment of New World Screwworm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the issuance of three Emergency Use Authorizations (EUA or Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for new animal products. FDA has issued one EUA for an animal product as requested by Zoetis Inc. for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax;* NWS) larvae (myiasis) in dairy cattle, horses, swine, sheep, and deer. FDA has issued one EUA for an animal product as requested by Felix Pharmaceuticals Pvt. Ltd. for the treatment of infestations caused by NWS myiasis in dogs, puppies, cats, and kittens. FDA has issued one EUA for an animal product as requested by Alberta Vet Labs Ltd for the short-term prevention of infestations caused by NWS myiasis in horses. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the August 18,