Compounding Office Stock Drugs for Use in Nonfood-Producing Animals'' *and* any other animal drug from a bulk drug substance, provided there is no marketed approved/indexed human or animals drugs with the same active moiety and route of administration). We invite comment on this or other options.

2. FDA seeks information on the relative percentages of drugs being compounded from bulk drug substances that meet the definition of a copy under this guidance (same active moiety and route of administration as FDA-approved/indexed drug) compared with those that do not meet the definition of a copy.

3. FDA seeks general comment on whether any parts of GFI #256 negatively affect the market incentives to produce these same drugs under CGMP as described in this guidance.

4. FDA seeks information on how many/which of the drugs on ''The List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals'' are presently being produced according to CGMP. We are specifically interested in understanding whether federally-registered facilities are able to meet veterinarians' needs with respect to these drugs.

5. FDA seeks information from conventional animal drug manufacturers (federally-registered facilities under FD&C Act section 510) as to whether they are likely to compound under this guidance and which, if any, barriers exist (*e.g.,* pharmacist supervision).

6. FDA seeks comment from conventional animal drug manufacturers who make approved products whether any aspects of this guidance should be specifically tailored to better accommodate manufacturers who wish to compound copies of their own approved products (*i.e.,* to meet the medical needs of individual animal patients who are not suitable candidates for the approved version). We recognize these registered facilities have particular expertise in these BDS, as well as access to various stages of in-process materials for the approved product, and request comment on how this should be addressed in GFI #256B.

7. FDA seeks comment/information as to the impact of recent United States Pharmacopeia (USP) changes to chapters <795> and <797> for State-licensed compounding pharmacies and whether animal patients would benefit from state-licensed pharmacies (*e.g.,* non-compounding, retail/dispensing-only pharmacies) being able to obtain compounded animal drugs made under CGMP in federally-registered facilities under GFI #256B, which they would dispense. FDA has preliminarily considered this change, but FDA has concerns about our ability to control the inappropriate distribution of copies if the compounding of animal drugs from BDS is conducted in a separate facility and/or by parties who are unrelated to the pharmacist/facility who obtains and maintains the medical rationale, particularly given there are tens of thousands of non-compounding retail/dispensing pharmacies that could distribute these drugs. We seek comment on any challenges posed by this option, such as:

- Difficulties in taking action against a federally-registered facility if adequate medical rationale is not collected by 3rd party pharmacies that distribute the federally-registered facility's drugs;
- Ability to assess medical rationale (including asking standard inspectional questions about a firm's process for collecting rationale) if a single compounder's drugs are distributed by (and medical rationale collected by) numerous, potentially unrelated pharmacies; and
- Ability to assess a federally-registered facility's decision to use BDS as opposed to approved products as the source of active ingredients when some of the justifications for using BDS are inherently patient or species specific (*e.g.,* patient or species allergic to specific ingredient) and the federally-registered facility may not know the identity or needs of the animal patient to whom a state licensed pharmacy may subsequently dispense a drug;
- Practical and legal limitations on FDA's ability to conduct a full inspection and review all records recommended by this guidance (including reviewing original records of medical rationale for patient-specific prescriptions) if they are created and maintained by a pharmacy that did not manufacture, produce, or otherwise compound the drug (*i.e.,* a non-compounding retail pharmacy that only fills patient-specific prescriptions from drugs it obtained from a federally-registered facility);
- Changes that might mitigate the practical and legal constraints related to inspecting countless retail/dispensing-only pharmacies, including:
  - recommending the federally-registered facility maintain copies of all medical rationale (even the medical rationale obtained elsewhere);
  - limiting the recommendation to a federally-registered facility that distributes to pharmacies under common ownership and control; and/or
  - limiting the recommendation only to drugs that do not meet the definition of a copy.

8. FDA seeks information from federally-licensed facilities, particularly outsourcing facilities, as to their current practices and future ability/willingness to dispense patient-specific prescriptions. We note that the guidance treats prescriptions for groups of animals as patient-specific in certain circumstances.

9. FDA seeks information about the impact any changes or proposals above in this guidance have on zoos, as well as any unique factors that distinguish zoos from other consumers of, or markets for, animal drugs.

10. FDA is concerned that ''groups of animals,'' as described in GFI #256, is being misused as a means of dispensing office stock. We have made minor changes and clarifications in draft GFI #256B to address this issue (*e.g.,* clarifying what constitutes a group and how groups should be described), but we seek comment on whether it is appropriate to further revise our recommendations on prescribing to groups of animals, such as treating prescriptions for groups of animals as patient-specific only when every animal in the group is treated simultaneously for the same indication (*e.g.,* contagious disease threatening entire group due to its presence in a specific, identified location, or entire group exposed to toxin) or where it is impractical to not treat all animals simultaneously. FDA requests comment on both specific situations (''contagious disease,'' ''toxic exposure,'' etc.) and general recommendations (''when necessary to treat simultaneously'') where prescriptions should be written for groups of animals.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–17580 Filed 8–27–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–2365]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated With Animal Drug and Animal Generic Drug User Fees

**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 by September 28, 2026.

**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 0910–0540. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, *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.

## Animal Drug and Animal Generic Drug User Fee Programs

*OMB Control Number 0910–0540—Extension*

This information collection helps support implementation of the Animal Drug User Fee Act of 2003 (ADUFA) (Pub. L. 108–130) and Animal Generic Drug User Fee Act of 2008 (AGDUFA) (Pub. L. 110–316), established in sections 740 and 741 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j–12 and 21 U.S.C. 379j–21), respectively. Under ADUFA, FDA assesses and collects user fees for certain new animal drug applications and supplements, products, establishments, and sponsors of new animal drug applications and/or investigational new animal drug files. The ADUFA program is currently reauthorized through September 30, 2028, and FDA efforts to engage interested stakeholders in the 2028 reauthorization is ongoing. More information regarding the ADUFA program can be found at *https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa,* including current user fee rates applicable to animal drug submissions. Under AGDUFA, FDA assesses and collects user fees for certain abbreviated (generic) new animal drug applications, supplements, and generic investigational new animal drug file submissions, products, and sponsors of generic new animal drug applications and/or generic investigational new animal drug files. The AGDUFA program is currently reauthorized through September 30, 2028, and FDA efforts to engage interested stakeholders in the 2028 reauthorization is ongoing. More information regarding the AGDUFA program can be found at *https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa,* including current user fee rates applicable to generic animal drug submissions.

These user fee program resources support FDA's responsibilities to ensure that new animal drugs are safe and effective for the animals, as well as ensuring the safety of food from treated animals.

Sponsors of new animal drug applications complete a user fee cover sheet and submit it through FDA's Center for Veterinary Medicine's (CVM, the Center) eSubmitter. The Animal Drug User Fee cover sheet (Form FDA 3546) is designed to collect the minimum necessary information to determine whether a fee is required for the review of an application or supplement or whether an application fee waiver was granted, to determine the amount of the fee required, and to ensure that each animal drug user fee payment is appropriately linked to the animal drug application for which payment is made. The form, when completed electronically, results in the generation of a unique payment identification number used by FDA to track the payment. The information collected is used by CVM to initiate the administrative screening of new animal drug applications and supplements.

Similarly, sponsors of abbreviated new animal drug applications and certain generic investigational new animal drug file submissions also complete a user fee cover sheet and submit it through CVM's eSubmitter. The AGDUFA cover sheet (Form FDA 3728) is also designed to collect the minimum necessary information to determine whether a fee is required for review of an application or submission to an investigational file, to determine the amount of the fee required, and to ensure that each animal generic drug user fee payment is appropriately linked to the abbreviated new animal drug application or generic investigational new animal drug file submission for which payment is made. The form, when completed electronically, results in the generation of a unique payment identification number used by FDA to track the payment. The information collected is used by CVM to initiate the administrative screening of abbreviated new animal drug applications and certain generic investigational new animal drug file submissions.

Both sections 740 and 741 of the FD&C Act provide for waivers, reductions, and exemptions of fees. To assist respondents with submitting requests for waivers or reductions of ADUFA user fees, we developed guidance for industry (GFI) #170 entitled ''Animal Drug User Fees and Fee Waivers and Reductions'' (April 2023), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-170-animal-drug-user-fees-and-fee-waivers-and-reductions.* This document discusses the types of fees FDA is authorized to collect under section 740 of the FD&C Act, and how to request waivers or reductions from these fees. Further, this guidance also describes what information FDA recommends be submitted in support of a request for a fee waiver or reduction, a request for reconsideration of denial of a fee waiver or reduction request, or an appeal of the denial decision in accordance with 21 CFR 10.75; how to submit such a request or appeal; and FDA's process for reviewing such requests or appeals.

Similarly, we developed guidance for industry (GFI) #199 entitled ''Animal Generic Drug User Fees and Fee Waivers and Reductions'' (May 2009), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-199-animal-generic-drug-user-fees-and-fee-waivers-and-reductions.* This document discusses the types of fees FDA is authorized to collect under section 741(a)(1) of the FD&C Act, and how to request waivers or reductions from these fees. Further, this guidance also describes what information FDA recommends be submitted in support of a request for a fee waiver or reduction, a request for reconsideration of denial of a fee waiver or reduction request, or an appeal of the denial decision in accordance with 21 CFR 10.75; how to submit such a 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 March 23, 2026 (91 FR 13854), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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 | FDA 3546 | 7 | 2 | 14 | 0.5 (30 minutes) | 7 |
| 741(a)(1); Animal Generic Drug User Fee cover sheet | FDA 3728 | 22 | 2.4 | 53 | 0.5 (30 minutes) | 26.5 |
| **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 | 4 | 2 | 8 | 0.5 (30 minutes) | 4 |
| 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 | 78 | 1 | 78 | 2 | 156 |
| 740(d)(1)(E); small business | N/A | 4 | 1 | 4 | 2 | 8 |
| 741(d)(1); minor use or minor species | N/A | 3 | 1 | 3 | 2 | 6 |
| 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 | | | | | | 349.5 |

[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 2022 to 2024. 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.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2026–17601 Filed 8–27–26; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–3240]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importation of Prescription Drugs

**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 by September 28, 2026.

**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 0910–0888. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–1244, *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.

### Importation of Prescription Drugs—21 CFR Part 251

*OMB Control Number 0910–0888—Extension*

This information collection supports implementation of section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384), and applicable regulations in part 251 (21 CFR part 251). The purpose of section 804 of the FD&C Act is to reduce the cost of covered products to American consumers without imposing additional risk to public health and safety. The regulations in part 251 set forth procedures Section 804 Importation Program sponsors (SIP Sponsors) must follow when submitting plans to implement time-limited programs to begin importation of drugs from Canada. The regulations also establish criteria for FDA review and authorization of a SIP proposal or supplemental proposal. Additionally, the regulations set forth requirements for eligible prescription drugs and requirements for entities that engage in importation of eligible prescription drugs. Finally, the regulations provide for exempt eligible prescription drugs that meet certain requirements from section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)).

*Description of Respondents:* Respondents to the collection of information are SIP Sponsors (States or Indian Tribes, or in certain future circumstances, pharmacists or wholesale distributors, and any cosponsor(s)), importers (pharmacists or wholesaler distributors), and manufacturers of eligible prescription drugs.

In the **Federal Register** of April 16, 2026 (91 FR 20462) FDA published a 60-day notice soliciting comment on the proposed collection of information. We received one comment containing several topics. These issues included cost savings, patient risks, continuity of care, and product labeling. Because these topics are outside the scope of the 60-day notice, we decline to address