TABLE 7—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS

PHS guideline section	Description of collection of information activity	21 CFR section (unless otherwise stated)
2.2.1	Document off-site collaborations	312.52.
2.5	Sponsor ensures counseling patient + family + contacts	312.62(c).
3.1.1 and 3.1.6	Document well-characterized health history and lineage of source animals	312.23(a)(7)(a) and 211.84.
3.1.8	Registration with and import permit from the Centers for Disease Control and Prevention.	42 CFR 71.53.
3.2.2	Document collaboration with accredited microbiology labs	312.52.
3.2.3	Procedures to ensure the humane care of animals	9 CFR parts 1, 2, and 3 and PHS Policy.[1]
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council's (NRC) Guide.	AAALAC International Rules of Accreditation[2] and NRC Guide.[3]
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care.	211.100 and 211.122.
3.2.6	Animal facility SOPs	PHS Policy.[1]
3.3.3	Validate assay methods	211.160(a).
3.6.1	Procurement and processing of xenografts using documented aseptic conditions.	211.100 and 211.122.
3.6.2	Develop, implement, and enforce SOP's for procurement and screening processes.	211.84(d) and 211.122(c).
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient.	312.32(c).
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected.	312.23(a)(6).
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (justify >2 yrs.); investigator case histories (2 yrs. after investigation is discontinued).	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c).
4.1.2	Sponsor to justify amount and type of reserve samples	211.122.
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal).	312.57(a).
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection.	312.32.
4.2.2.1	Document collaborations (transfer of obligation)	312.52.
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly).	312.50.
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories.	312.57 and 312.62(b).

[1] The ''Public Health Service Policy on Humane Care and Use of Laboratory Animals'' (*https://olaw.nih.gov/policies-laws/phs-policy.htm*).
[2] AALAC International Rules of Accreditation (*https://www.aaalac.org/accreditation-program/rules-of-accreditation/*).
[3] The NRC's ''Guide for the Care and Use of Laboratory Animals.''

Based on a review of the information collection since our last request for OMB approval, we have adjusted our burden estimate which has resulted in a burden increase of 3.09 hours (new total of 62.12 hours) from our previous estimate of 59.03 hours. Change in the increase in burden was the result of the change of the number of recordkeepers due to the change in the number submission of IND's sponsors and a change in the number of animal source facilities.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14227 Filed 7–28–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0082]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Compounding Animal Drugs From Bulk Drug Substances

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 August 28, 2025.

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 0910–0904. 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.

Compounding Animal Drugs From Bulk Substances

OMB Control Number 0910–0904—Extension

This information collection helps support recommendations discussed in FDA guidance. Animal drugs compounded from bulk drug substances by pharmacists and veterinarians do not meet certain important requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). To be legally marketed in accordance with animal drug approval requirements of the FD&C Act, an approval, conditional approval, or listing on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species [1] is required, and compounded drugs do not go through any of these pre-market review processes. (Information collection associated with new animal drug applications is approved under OMB control no. 0910–0032; information collection pertaining to index of legally marketed unapproved new animal drugs for minor species is approved under OMB control no. 0910–0605.) Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (CGMP) requirements and have adequate directions for use, requirements not met by compounded drugs.[2] Thus, drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). However, FDA has generally refrained from taking enforcement action against animal drugs compounded from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist.

To assist respondents in understanding FDA's current thinking about animal drug compounding from bulk substances, our Center for Veterinary Medicine developed GFI #256 entitled ''*Compounding Animal Drugs from Bulk Drug Substances*'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances*). The guidance describes circumstances under which FDA generally does not intend to take enforcement action against pharmacists and veterinarians who compound animal drugs from bulk drug substances.

In the **Federal Register** of May 1, 2025 (90 FR 18665), we published a 60-day notice soliciting comment on the proposed collection of information. Three comments were submitted to the docket by various trade associations, however the first two were not responsive to the information collection topics solicited under 5 CFR 1320.8(d). Rather, the comments appeared to be proffered in accordance with our Good Guidance Practice regulations in 21 CFR 10.115 and we therefore refer the commenters to 21 CFR 10.115(f) regarding how the public may participate in the development of FDA guidance documents. The third comment suggested improvements to increase the utility of Form FDA 1932a, *Veterinary Adverse Drug Reaction, Lack of Effectiveness, Or Product Defect Report,* approved for use in OMB control no. 0910–0291, currently pending OMB review. We appreciate this comment and continue to make technological enhancements to our collection instruments as our limited resources allow. At the same, none of the comments offered an alternative estimate, and we therefore retain the estimate of burden for the information collection as communicated in our 60-day notice, which is as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Documenting rationales by licensed veterinarian/pharmacist compounders in state-licensed pharmacies or Federal facilities.	7,500	1,134	8,505,000	0.017 (1 minute)	144,585

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

We base our estimate on our experience with the regulation of compounded animal drugs. 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: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5234]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notification Procedures for Statements of Dietary Supplements

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 August 28, 2025.

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

[1] Sections 512, 571, and 572 of the FD&C Act (21 U.S.C. 360b, 360ccc, 360ccc–1).

[2] Section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), 21 CFR parts 210 and 211, and section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)).