industry, each containing one or more comments on the proposed collection of information.

(Comment 1) Several comments expressed appreciation for FDA's efforts in developing a comprehensive understanding of the outsourcing facility sector, its challenges, and opportunities for advancement. Other comments expressed appreciation for FDA's efforts to ensure that the survey questions capture the most important information from compounding outsourcing facilities and that the survey not place an undue burden on respondents.

(Response 1) We agree that the information being collected has utility for understanding of the outsourcing facility sector, its challenges, and opportunities for advancement and that we are making an effort to not place an undue burden on respondents.

(Comment 2) One comment suggested that certain questions focus on financial considerations and economic consequences and argued that they are not necessary for FDA's oversight of outsourcing facilities and are unrelated to FDA's public health mission and the quality and safety of compounded drugs.

(Response 2) We have considered the comments and disagree. As stated previously, the Center of Excellence is conducting this research to better understand outsourcing facilities' challenges and opportunities in different areas to help guide decisions regarding future training and other engagement. We think that an important component to understanding the challenges and opportunities that outsourcing facilities face includes gaining insight into the financial considerations that impact outsourcing facilities' operations and business models.

(Comment 3) Several comments proposed changes to existing questions or the inclusion of new questions.

(Response 3) We have considered the comments requesting that the Agency update the questionnaire and disagree that certain questions should be modified or added. We believe that the information sought from the proposed questions will be captured within the existing questions or elsewhere in our research.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Survey Invitation	250	1	250	0.0833 (5 mins)	21
Survey Questionnaire	250	1	250	0.50 (30 mins)	125
Total			500		146

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

The universe of registered outsourcing facilities and related human prescription drug compounding businesses known to the Center of Excellence will be sent a survey invitation. We reduced our estimate of the number of respondents from 300 to 250. We estimate that approximately 250 respondents will receive an invitation to participate in the survey and will spend 5 minutes reading the invitation and considering whether to take the survey, for a total of 20.825 burden hours per year, rounded to 21 hours. Based on our historical experience, we anticipate that all those invited to participate in the survey will complete the survey. We estimate that respondents will spend 15 to 30 minutes to complete the revised survey. Using the upper-bound estimate, we report a reduction in burden hours to 30 minutes (0.50 hour) per survey response from our previous estimate of 1 hour per response. We estimate that approximately 250 respondents will spend 30 minutes completing the survey, for a total of 146 burden hours per year.

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. Our estimated burden for the information collection reflects an overall decrease of 454 hours and a corresponding decrease of 100 responses. We have also reduced our estimated burden per survey response from 1 hour to 30 minutes.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07557 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0082]

Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs From Bulk Drug Substances

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 the recordkeeping provisions set forth in Guidance for Industry, GFI #256—Compounding Animal Drugs from Bulk Substances.

DATES: Either electronic or written comments on the collection of information must be submitted by June 30, 2025.

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 June 30, 2025. 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–2025–N–0082 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs from Bulk Drug Substances.'' 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: 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: 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.

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

[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)).

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.

FDA estimates the burden of this collection of information 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 (1 minute)	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	144,585

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

We base our estimates 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: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07578 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0414]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

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 the information collection associated with Agency guidance on reagents for detection of specific novel influenza A viruses.

DATES: Either electronic or written comments on the collection of information must be submitted by June 30, 2025.

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 June 30, 2025. 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–2025–N–0414 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses.'' 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