qualitative insights but will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collection designed to produce reliably actionable results, such as monitoring trends over time or documenting program performance.

Respondents to this collection of information represent a broad range of customers and stakeholders who have specific characteristics related to certain products or services regulated by FDA. These stakeholders include members of the general public, healthcare professionals, industry, and others who have experience with a product under FDA's jurisdiction.

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
Focus groups	3,000	1	3,000	1.75	5,250
Customer comment cards/forms	1,500	1	1,500	0.25 (15 minutes)	375
Small discussion groups	800	1	800	1.75	1,400
Customer satisfaction surveys	20,000	1	20,000	0.33 (20 minutes)	6,600
Usability studies	1,100	1	1,100	1	1,100
Total					14,725

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17605 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–2018–D–4533]

Compounding Animal Drugs From Bulk Drug Substances: Compounding Under CGMP in Federally-Registered Facilities; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry (GFI) #256B entitled ''Compounding Animal Drugs from Bulk Drug Substances: Compounding under CGMP in Federally-Registered Facilities.'' This draft guidance, when finalized, will describe FDA's current thinking regarding the circumstances under which we generally do not intend to take action against the compounding of animal drug products from bulk drug substances (BDS) when done in accordance with Current Good Manufacturing Practice (CGMP) at drug production facilities that are registered with FDA.

DATES: Submit either electronic or written comments on the draft guidance by November 27, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2018–D–4533 for ''Compounding Animal Drugs from Bulk Drug Substances: Compounding under CGMP in Federally-Registered Facilities.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Cindy L. Burnsteel, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–0817, *Cindy.Burnsteel@fda.hhs.gov.*

With regard to the collection of information: 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:

I. Background

FDA is announcing the availability of a draft guidance for industry #256B entitled ''Compounding Animal Drugs from Bulk Drug Substances: Compounding under CGMP in Federally-Registered Facilities.''

FDA has generally exercised enforcement discretion with regard to animal drug compounding from BDS under certain circumstances when no other medically appropriate treatment options exist. In the **Federal Register** of April 14, 2022 (87 FR 22212), we announced the availability of final GFI #256, entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' GFI #256 describes circumstances under which FDA generally does not intend to take enforcement action for violations of the FD&C Act against either veterinarians or pharmacists who compound certain types of animal drugs from BDS in either State-licensed pharmacies or Federal facilities. The enforcement discretion in GFI #256 applies to State-licensed pharmacies as well as federal government facilities.

GFI #256B is intended to provide recommendations for an additional type of compounder, federally-registered facilities that operate in compliance with state laws and regulations governing drugs, pharmacy, and veterinary medicine but that may not be State-licensed pharmacies (*e.g.,* the state has a different license for outsourcing facilities). ''Federally-registered facilities'' are defined in draft GFI #256B as facilities that are registered with FDA under section 503B(b) (21 U.S.C. 353b(b)) or section 510(b) (21 U.S.C. 360(b)) of the FD&C Act.

Draft GFI #256B, when finalized, will describe the circumstances with respect to federally-registered facilities under which FDA does not intend to take enforcement action against the compounding of animal drug products from BDS for nonfood-producing animals, either with or without patient-specific prescriptions, and for the use of certain BDS for compounding animal drugs for use as antidotes for food-producing animals or as sedatives and anesthetics for free-ranging wildlife species, provided that certain circumstances are present. We will combine this draft guidance, when finalized, with our final GFI #256, ''Compounding Animal Drugs from Bulk Drug Substances.'' In draft GFI #256B, we have made minor changes and clarifications to recommendations that were originally in GFI #256. If any of these are adopted when GFI #256B is finalized, we consider them level 2 changes to GFI #256, and we will make conforming changes as appropriate.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Compounding Animal Drugs from Bulk Drug Substances: Compounding under CGMP in Federally-Registered Facilities.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each 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.

Title: Compounding Animal Drugs from Bulk Substances; OMB control number 0910–0904–Revision.

Description of Respondents: The respondents are pharmacists in State-licensed pharmacies, pharmacists in Federal government facilities, veterinarians, and pharmacists at federally-registered facilities who compound animal drugs from BDS.

Description: This information collection supports recommendations discussed in Food and Drug Administration guidance. In the **Federal Register** of April 14, 2022 (87 FR 22212), we announced the availability of final GFI #256, entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' GFI #256 describes circumstances under which FDA generally does not intend to take enforcement action against veterinarians or pharmacists who compound certain types of animal drugs from BDS in either State-licensed pharmacies or Federal facilities for violations of the FD&C Act.

Draft GFI #256B, when finalized, will describe the circumstances with respect to federally-registered facilities under which FDA does not intend to take enforcement action against the compounding of animal drugs from BDS for nonfood-producing animals, either with or without patient-specific prescriptions, and for the use of certain BDS for compounding animal drugs for use as antidotes for food-producing animals or as sedatives and anesthetics for free-ranging wildlife species, provided that certain conditions are met. We will incorporate this draft guidance, when finalized, into our final GFI #256, ''Compounding Animal Drugs from Bulk Drug Substances.''

We note also related reporting, recordkeeping, and disclosure requirements applicable under the Controlled Substances Act, for which currently active information collection approvals are maintained by the Department of Justice's Drug Enforcement Administration. For purposes of this information collection request, however, we have characterized the burden that may be associated with recommendations discussed in the guidance document as recordkeeping burden.

Our exercise of discretion depends on our ability to assess whether the circumstances under which FDA would intend to exercise such discretion, as described in this draft guidance, exist. FDA staff may use pharmacy and veterinary records, among other things, to determine the circumstances surrounding the compounding activity. Except with regard to one proposed item, the routine business records kept by pharmacists who compound animal drugs from BDS who compound animal drugs from BDS, as well as veterinarians prescribing compounded animal drugs within a valid veterinarian-client-patient relationship, should be adequate to ascertain if the circumstances described in the draft guidance exist.

The draft guidance provides recommendations for the compounding of animal drugs from bulk drug substances at ''federally-registered facilities,'' that is, facilities that are registered with FDA under section 503B(b) (21 U.S.C. 353b(b)) or section 510(b) (21 U.S.C. 360(b)) of the FD&C Act. Section III.A.4 of the draft guidance explains that when the compounded drug is a copy of a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug, there should be a difference between the compounded drug and the FDA-approved, conditionally approved, or indexed animal drug or the FDA-approved human drug that will produce a clinical difference in the identified patient. We tentatively conclude that it is usual and customary for veterinarians to document their medical rationale for using such a compounded product as a matter of maintaining an adequate medical record in routine practice; therefore, no burden has been estimated for the time it would take for a veterinarian to make this record.

Section III.A.5 of the draft guidance explains that when the compounded drug contains the same active moiety as a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug (which includes drugs containing the same active ingredient and those with a different salt, ester, or other noncovalent derivative), there should be a difference between the compounded drug and the marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug that will produce a clinical difference in the identified patient. In such a case, the medical rationale is documented in the prescription or noted in the patient's medical record. We tentatively conclude that it is usual and customary for veterinarians to document their medical rationale for using such a compounded product as a matter of maintaining an adequate medical record in routine practice; therefore, no burden has been estimated for the time it would take for a veterinarian to make this record.

Sections III.A.5 and III.A.6 of the draft guidance describe circumstances under which FDA recommends pharmacist compounders document the prescribing veterinarian's medical rationale and the reason that a BDS is being used as the source of the active ingredient. Based on our evaluation, we believe it is usual and customary business practice for veterinarians to document the medical rationale, as recommended in the guidance. However, we believe pharmacist compounders may not document the information recommended in the guidance as a usual and customary business practice.

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

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

Recommended information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Documenting rationales by licensed veterinarian/pharmacist compounders in state-licensed pharmacies or Federal Facilities.	7,500	741	5,556,306	0.02 (1 minute)	111,126
Documenting rationales by facilities registered under section 503B(b) or section 510(b) (21 U.S.C. 360(b)(2) of the FD&C Act.	8	741	5,928	0.02 (1 minute)	119
Total	7,508	.....	5,562,234	.....	111,245

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Sums may not total due to rounding.

Our estimated burden for the information collection reflects an overall decrease of 58,855 hours and a corresponding decrease of 393 records/recordkeeper. We attribute this adjustment to a decrease in our estimate of the percentage of prescriptions that are subject to the recommendation related to medical rationale, plus the inclusion of federally-registered facilities. Of the approximately 98 federally-registered facilities that perform any compounding in the United States, about 8 specialize in both human and animal compounding. We do not have data on the number of patient-specific prescriptions filled at these facilities and therefore use the same assumptions we use for other compounders. We seek information about percentage of patient specific animal drug prescriptions sold by these facilities, and the percentage of those prescriptions that meet the guidance's definition of copy. GFI 256B makes recommendations that apply not only to outsourcing facilities registered under

section 503B(b), but also to ''traditional'' animal drug manufacturers registered under section 510(b). At present, to our knowledge, no facilities registered under section 510(b) compound patient-specific prescriptions. Therefore, we do not count them in our estimated number of recordkeepers and estimate 0 recordkeeping burden for those firms at this time.

At the time of its initial publication, we originally assumed the guidance's recommendations regarding medical rationales would apply to 50 to 75 percent of all prescriptions. However, since the publication of GFI 256, FDA has conducted additional inspections of animal drug compounders and has a better understanding of current industry practices. Based on our additional experience with the regulation of compounded animal drugs, we now estimate that 49% of all prescriptions for compounded animal drugs would fall within the medical rationale recommendation. We note that our medical rationale recommendation does not apply to several significant categories of compounded animal drugs, namely, all drugs not compounded from BDS, all drugs sold as office stock, and all drugs which do not meet the guidance's definition of a copy (such as compounded drugs with a different active moiety and/or route of administration). We do not have additional information about our other estimates (*e.g.,* the estimated number of recordkeepers) and therefore continue to use our original estimates for those values. Therefore, recalculating using 49% as the number of prescriptions that fall within the medical rationale recommendation, we estimate the total number of recordkeeping hours for veterinarians, pharmacies and federal government facilities under GFI 256 to be 111,126.

With respect to draft GFI #256B, we estimate it will take 1 minute (0.02 hours) per record for federally-registered facilities to document the rationales described in the draft guidance, for a total of 119 hours attributable to the new respondents in draft GFI 256B, as reported in Table 1.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities are usual and customary because they would occur in the normal course of activities. If the compounded drug is compounded for use as an antidote for food-producing animals or for use as a sedative or anesthetic for free-ranging wildlife species, section III.C.3 of the guidance recommends that the veterinarian establishes and documents a scientifically based withdrawal time that ensures residues of the: (1) Antidote and the underlying toxin or (2) sedative or anesthetic are not present in the animal at the time of slaughter or harvest or the veterinarian ensures the animal does not enter the food supply. We believe that it is usual and customary for veterinarians to establish and document a scientifically based withdrawal time as a matter of maintaining an adequate medical record in routine practice and, therefore, estimate no burden for the time it would take for a veterinarian to make this record. See 5 CFR 1320.3(b)(2).

We believe any information collection pertaining to enforcement activities would involve administrative actions to which the Federal government is a party or that occur after an administrative case file has been opened regarding a particular individual or entity and would be exempt from OMB review and approval under the PRA. See 44 U.S.C. 3518(c)(1)(B); 5 CFR 1320.4(a)(2), (c).

In addition, the guidance makes a number of recommendations regarding the labeling of animal drugs compounded from bulk drug substances. In sections III.A.8, III.B.6, and III.C.8, the guidance recommends basic information that pharmacists should include on the label of the compounded drug, such as the name and strength of the drug, species, directions for use, and the name, address, and contact information for the compounder. We believe that it is usual and customary for pharmacists to include such information on the labels of compounded animal drugs in the normal course of their activities, and therefore, estimate no burden for the time it would take to prepare such labeling. See 5 CFR 1320.3(b)(2). Sections III.A.8, III.B.6, and III.C.6 of GFI #256 and III.A.9, III.B.7, and III.C.9 of GFI #256 also recommend compounders include several specific statements on the label of animal drugs compounded from bulk drug substances (*e.g.,* ''This is a compounded drug. Not an FDA approved or indexed drug''). Because these recommended labeling statements are public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)), they are exempt from OMB review and approval under the PRA.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

IV. Other Issues for Consideration

Although this draft guidance proposes to extend a similar enforcement policy to all federally-registered facilities as is currently applicable to State licensed pharmacies and Federal government facilities, FDA is interested in which, if any, alterations should be made to better tailor this policy to account for the quality advantages of drugs that are produced in accordance with CGMP, as opposed to those compounded under the enforcement discretion policy of GFI #256, which are not made under CGMP conditions. FDA therefore requests the following additional information and comments on the options. FDA may adopt any of these changes in the final document without reissuance of a new draft guidance. For all data provided in response to these questions, we request the respondent do its best to identify the source of the data (*e.g.,* data from 503B facilities vs. data from other non-federally registered compounders vs. combined data).

1. FDA seeks comment on whether it should expand the recommendations in this guidance to additional drugs that are not currently on ''The List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals'' (available at *https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals*). FDA remains concerned that compounded office stock potentially exposes large numbers of animals to drugs of unproven safety and effectiveness but notes that production in accordance with CGMP would present fewer quality concerns than drugs compounding under non-CGMP conditions per GFI #256. Unapproved drugs made in accordance with CGMP can still present additional quality risks compared to approved products because, while both are made according to CGMP, the latter undergo a product-specific Chemistry Manufacturing and Controls review during their application review. FDA is interested in the effects of extending the enforcement discretion policy related to office stock made in federally-registered establishments to additional categories of drugs, such as all office stock that does not meet the definition of a copy (*i.e.,* the enforcement discretion policy would include compounding office stock on ''The List of Bulk Drug Substances for

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.