populations in the United States, such as Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and Other Pacific Islanders, and other persons of color. Adequate representation in clinical trial(s) and studies supporting regulatory submissions helps ensure that the data generated in the development program reflects the racial and ethnic diversity of intended use population for the medical product, if approved, and may potentially identify safety or efficacy outcomes that may be associated with, or occurring more frequently, within these populations. This is one of many efforts by FDA to help address the participation of underrepresented populations in clinical trials relating to FDA regulated products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Diversity Plans to Improve Enrollment of Participants from Unrepresented Racial and Ethnic Populations in Clinical Trials.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 800 have been approved under OMB control number 0910–0625; and the collections of information pertaining to submission of a biologics license application under section 351(k) of the Public Health Service Act have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07978 Filed 4–13–22; 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; Guidance for Industry; Availability

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 final guidance for industry (GFI) #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' This guidance describes FDA's current thinking about compounding animal drugs from bulk drug substances, identifies our enforcement priorities with respect to drugs compounded from bulk drug substances, and describes circumstances under which FDA generally does not intend to take action against veterinarians or pharmacists in either State-licensed pharmacies or Federal facilities, who compound animal drugs from bulk drug substances. We are also 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 (PRA).

DATES: The announcement of the guidance is published in the **Federal Register** on April 14, 2022. Submit written comments (including recommendations) on the collection of information by May 16, 2022.

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–NEW. Also include the FDA docket number found in brackets in the heading of this document.

You may submit either electronic or written comments on Agency guidances 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.'' 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 (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Office of Surveillance and Compliance (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7011.

Regarding the proposed collection of information: 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:

I. Background

In the **Federal Register** of November 20, 2019 (84 FR 64085), FDA published the notice of availability for draft GFI #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances'' with a 90-day comment period. In response to requests from interested parties, we extended the comment period to July 17, 2020, and then to October 15, 2020. We requested comments on the draft guidance with respect to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment option exists. This final GFI #256 describes FDA's current thinking about compounding animal drugs from bulk drug substances, identifies our enforcement priorities with respect to drugs compounded from bulk drug substances, and describes circumstances under which FDA generally does not intend to take action against veterinarians or pharmacists in either State-licensed pharmacies or Federal facilities, who compound animal drugs from bulk drug substances. FDA does not intend to take action under sections 501(a)(2)(B) and (a)(5), 502(f), and 512(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B) and (a)(5), 352(f), and 360(b)) under the circumstances described in GFI #256.

FDA received numerous comments on the draft guidance, which were considered as the guidance was finalized. Changes made in response to comments include identifying compliance with relevant State and local laws as the standard for compounding methods and eliminating references to United States Pharmacopeia and National Formulary Chapters <795> ''Pharmaceutical Compounding—Nonsterile Preparations'' and <797> ''Pharmaceutical Compounding—Sterile Preparations.'' We also revised the recommended label statement regarding reporting of adverse events to include reporting to the pharmacy as well as FDA.

We also made a number of changes related to recommendations for copies of approved products. We simplified the definition of ''copy'' used in the guidance and clarified that ''clinical difference'' includes issues affecting patient compliance and the safety of these who administer the drug, but excludes cost differences between approved and compounded products. The final guidance includes examples of how to briefly describe the medical rationale for making a copy, such as the compounding pharmacist contacting the prescribing veterinarian to obtain the rationale and noting it in the compounding records as an alternative to the veterinarian noting the rationale on the prescription. It also provides examples of rationales to explain why an approved drug cannot be used in a legal extralabel manner to compound a drug with the same active moiety.

We also made changes to lists of bulk drug substances for compounding office stock for nonfood-producing animals or antidotes for food-producing animals. As outlined in the Appendix to the final guidance,[1] we streamlined the nomination process for these bulk drug substances, reducing the information requested by FDA to support a nomination. The list of bulk substances to compound drugs for use in food-producing animals has been expanded to encompass nominations of sedatives or anesthetics for free-ranging wildlife species.

In addition, editorial changes were made to improve clarity in the final guidance. The guidance announced in this notice finalizes the draft guidance dated November 2019. However, as explained in section II of this notice, the information collection recommendations footnoted with an asterisk are subject to OMB review and approval and are not for current implementation.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on compounding animal drugs from bulk drug substances. 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.

[1] Elsewhere in this issue of the **Federal Register**, FDA is requesting nominations or renominations for bulk drug substances to be included on the ''Lists of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species'' for inclusion on a list of bulk drug substances for compounding certain animal drugs without a patient specific prescription (*i.e.,* office stock) for use in nonfood-producing animals or for inclusion on a list of compounded drugs for use as antidotes for food-producing animals or for use as sedatives or anesthetics for free-ranging wildlife species as described in GFI #256. That **Federal Register** notice describes information requested by FDA to evaluate nominations and explains when FDA will include bulk drug substances on a list. Such nominations will be collected in a separate docket.

II. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. FDA is issuing this guidance as final, footnoting with an asterisk recommendation that include information collection subject to review and approval by OMB under the PRA. FDA will implement the information collection recommendations if OMB approves them. At that time, FDA will announce OMB approval in the **Federal Register** and update the guidance to reflect this approval.

Title: Compounding Animal Drugs from Bulk Drug Substances (OMB Control Number 0910–NEW).

Description of Respondents: The respondents to the information collection are pharmacists in either State-licensed pharmacies or Federal facilities, or veterinarians who compound animal drugs from bulk drug substances.

Description: The Center for Veterinary Medicine has developed GFI #256 to address a need for Agency guidance in its work with the animal health industry. The guidance describes FDA's current thinking, based on our current understanding of the risks of animal drugs compounded from bulk drug substances, and describes the 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 November 20, 2019 (84 FR 64085), we published a notice of availability announcing draft guidance GFI #256, including an analysis under the PRA, and solicited public comment on the proposed collection of information. Comments regarding the information collection included concerns that the guidance document will impose requirements not placed on other prescribers. In any other setting, the comments suggested, the prescription itself serves as documentation of the veterinarian's determination of clinical need. We disagree with these comments suggesting that a prescription serves the same purpose as the medical rationale documentation recommended in GFI #256. The documentation of the medical rationale by the compounding pharmacist is recommended for copies of approved products because a prescription demonstrates an animal's need for a prescription drug but does not explain why an approved product could not be used legally to treat the animal. The medical rationale addresses the clinical need for an animal drug compounded from a bulk drug substance when there is an approved product available.

Our exercise of discretion is dependent upon our ability to assess whether the circumstances under which FDA intends to exercise such discretion, as described in the 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 the recommendations that compounders document rationales for prescribing a compounded product from a bulk drug substance, routine business records kept by pharmacists who compound animal drugs from bulk drug substances and veterinarians who compound animal drugs from bulk drug substances, as well as veterinarians prescribing compounded animal drugs within a valid veterinarian-client-patient relationship, should be adequate to demonstrate that the circumstances described in the guidance exist. While we believe it is usual and customary business practice for veterinarians to document medical rationales for prescribing a compounded product as recommended in the guidance, we acknowledge that documenting this information by the pharmacist compounder, as well as documenting the rationale for using a bulk drug substance as the source of the active ingredient by the veterinarian/pharmacist compounder, may not be usual and customary practice. We have therefore included an estimate for recordkeeping to account for burden beyond that which may be usual and customary for respondents who follow the recommended documentation of rationales for compounding the drug product from bulk drug substance as discussed in the guidance.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping	Total hours
Documenting rationales by licensed veterinarian/pharmacist compounder.	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.
[2] Rounded to the nearest whole number.

We have revised figures from our 60-day notice to reflect a more recent review of our experience with the information collection.

Sections III.A.5 and III.A.6 of the guidance describe circumstances under which FDA recommends veterinarian and pharmacist compounders document the prescribing veterinarian's medical rationale and the reason that a bulk drug substance 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. According to the American Pharmacists Association, of the approximately 56,000 community-based pharmacies in the United States, about 7,500 pharmacies specialize in compounding services.[2] We assume 11,339,400 prescriptions will be written for compounded animal drugs annually. Based on our experience with the regulation of compounded animal drugs, we assume 50 to 75 percent of these prescriptions will result in documenting rationales as discussed in the guidance. Using the upper-bound estimate of 75 percent, approximately 8,504,550 prescriptions (0.75 ×

[2] American Pharmacists Association, ''Frequently Asked Questions About Pharmaceutical Compounding,'' n.d., *https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs* (accessed September 15, 2021).

We currently have no data on the number of veterinarians who compound drugs for individual patients, specifically, compound drugs from bulk drug substances for individual patients; therefore, we are including this class of respondents in our burden estimate.

11,339,400 prescriptions) will necessitate documenting rationales. Averaging this figure equally among 7,500 compounding pharmacies, 1,134 (rounded to the nearest whole number) rationales will be documented annually, for a total of 8,505,000 records. We estimate it will take 1 minute (0.017 hours) to document the rationales described in the guidance, for a total of 144,585 hours, as reported in table 1.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply 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).

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.6, the guidance recommends basic information that pharmacists and veterinarians should include on the label of the compounded drug, such as the name and strength of the drug and the name, address, and contact information for the compounding pharmacy or compounding veterinarian. We believe that it is usual and customary for pharmacists and veterinarians 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 the guidance also recommend compounders (pharmacists and veterinarians) 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 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.*

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08092 Filed 4–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0470]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cellular, Tissue and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on scientific issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 9, 2022, from 10 a.m. to 6 p.m. and June 10, 2022, from 10 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

The online web conference meeting will be available at the following link on the day of the meeting: Day 1 June 9 link: *https://youtu.be/RvtTK3KNl5g* and Day 2 June 10 link: *https://youtu.be/Eo2BXnGienc.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0470. The docket will close on June 8, 2022. Submit either electronic or written comments on this public meeting on or before June 8, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 8, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before June 2, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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