Dated: September 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20903 Filed 9–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2925]

Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #273 entitled ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals.'' This draft guidance document, when finalized, will provide recommendations on how sponsors may voluntarily establish defined durations of use for certain antimicrobial new animal drugs used in or on the medicated feed of food-producing animals that are currently approved with one or more indications that lack a defined duration of use. Establishing defined durations of use within the approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) is intended to mitigate development of antimicrobial resistance for these antimicrobial drugs, which are important to human medicine. It also, when finalized, will propose timelines for stakeholders wishing to voluntarily align their affected applications with this guidance.

DATES: Submit either electronic or written comments on the draft guidance by December 26, 2023, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2023–D–2925 for ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals.'' 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: John Mussman, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0589, *John.Mussman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #273 entitled ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals.'' This draft guidance, when finalized, will provide information to sponsors of certain antimicrobial animal drug products who are interested in establishing appropriately defined durations of therapeutic administration to food-producing animals where none currently exist. The draft guidance, when finalized, will also propose timelines for stakeholders wishing to comply voluntarily with this guidance.

In response to recommendations made by FDA in GFI #213,[1] as part of a strategy to address antimicrobial resistance associated with the use of antimicrobial drugs in animal agriculture, sponsors of all NADAs and ANADAs for antimicrobial drugs important to human medicine (medically important antimicrobial drugs) approved for use in or on the feed or in the drinking water of food-producing animals worked with FDA over a 3-year period from 2013 to 2016 to voluntarily withdraw approval of indications that were not considered necessary for ensuring animal health (production indications). In response to FDA recommendations made in GFI #263,[2] sponsors also voluntarily worked with FDA to change the marketing status of all remaining approved uses of such new animal drugs from over-the-counter (OTC) to either by veterinary prescription (Rx) or by veterinary feed directive, as applicable.

In September 2016, FDA announced that it intended to enter the next phase of its efforts to mitigate antimicrobial resistance by focusing on medically important antimicrobials used in animal feed or water that have at least one therapeutic indication without a defined duration of use. In a notice published in the **Federal Register** of September 14, 2016 (81 FR 63187), the Agency requested comments from the public about how to establish appropriately targeted durations of use for therapeutic products within the scope of GFI #213 with no currently defined duration of use. Public feedback received in response to that request for information was taken into consideration during subsequent development of a concept paper released in 2021.

On September 14, 2018, FDA released a 5-year action plan for supporting antimicrobial stewardship in veterinary settings.[3] This plan includes an action item intended ''to ensure that all medically important antimicrobial drugs used in the feed or drinking water of food-producing animals have an appropriately targeted duration of use.'' [4]

In a notice published in the **Federal Register** of January 11, 2021 (86 FR 1979), FDA requested comments from the public on a concept paper that outlined a potential framework for how sponsors of NADAs and ANADAs for products containing medically important antimicrobial drugs approved for use in or on the feed of food-producing animals could voluntarily work with FDA to change the approved conditions of use of these drugs to establish appropriately defined durations of use for those indications that currently have an undefined duration of use. The concept paper generated invaluable public comment; FDA considered all information and feedback received on the concept paper as it developed this draft guidance.

This level 1 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 ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

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.*

[1] See GFI #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' December 2013. (*https://www.fda.gov/media/83488/download*)

[2] See GFI #263, ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter,'' June 2021. (*https://www.fda.gov/media/130610/download*)

[3] See FDA's 5-year action plan entitled ''Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019–2023.'' (*https://www.fda.gov/media/115776/download*)

[4] See Action item 1.1.2 of the 5-year plan.

Dated: September 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20920 Filed 9–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0313–60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 27, 2023.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0313 and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: National Blood Collection & Utilization Survey (NBCUS).

Type of Collection: Revision.

OMB No.: 0990–0313 Office of the Assistant Secretary for Health/HHS.

Abstract: The Office of the Assistant Secretary for Health (OASH) is requesting approval for a three-year revised information collection request (ICR) titled ''National Blood Collection & Utilization Survey (NBCUS).'' The NBCUS is a biennial survey that