TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 1, subpart M	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response [2]	Total hours
AB applications. renewals, notifications, revocations.	25	11.36	284	3.18	903
CB certifications, regulatory audits and assessments, notifications.	208	147.29	30,638	0.25 (15 minutes)	7,661
CB applications for direct accreditation & renewal.	1	1	1	90	90
Total			30,923		8,654

[1] We estimate no capital costs or operating and maintenance costs for the information collection.
[2] Figures rounded to the nearest one, one-hundred as calculated based on total number of records and hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping [2]	Total hours
AB documenting certification procedures; maintaining applicable records.	25	426.56	10,664	0.25 (~15 minutes)	2,677
AB establishing and updating public list of CBs	25	1	25	52.8	1,320
CB documenting procedures for accreditation; maintaining applicable records (audits, certifications, serious risks).	208	112.72	23,446	0.35 (~20 minutes)	8,228
CB establishing & updating public list of eligible entities.	208	1.31	273	44.19	12,064
Contract modification [2]	7	9	63	2	126
Total			34,471		24,415

[1] We estimate no capital costs, or operating and maintenance costs for the information collection.
[2] Figures rounded to the nearest one, one-hundred as calculated based on total number of records and hours.

We include in our estimate reporting burden attributable to required submissions, including notifications, to FDA; and recordkeeping burden attributable to the time we assume necessary for searching data sources, and preparing and maintaining records described in the applicable regulations. We estimate that 25 ABs will accredit CBs who conduct food safety audits of foreign eligible entities that offer food for import to the United States. We also estimate the 208 accredited CBs will participate in the third-party program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA. Finally, we attribute nominal burden to recordkeeping attendant to contractual modifications that may be part of accreditation.

Based on a review of the information collection since last OMB approval, we have made only nominal adjustments to our burden estimate.

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03306 Filed 2–15–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1305]

Antimicrobial Drug Use in Companion Animals; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is soliciting comments from the public on antimicrobial drug use practices in companion animals and the potential impacts of such uses on antimicrobial resistance in both humans and animals. We are issuing this notice as part of our objective to engage with our stakeholders to develop and implement a strategy for promoting antimicrobial stewardship in companion animals. Specific questions and information requests are included in this notice to help guide input from stakeholders and other members of the public. FDA's Center for Veterinary Medicine (CVM) intends to use the information provided to assist in the development of strategies to promote antimicrobial stewardship in companion animals.

DATES: Submit either electronic or written comments on the notice by June 16, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 16, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 16, 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.

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–2021–N–1305 for ''Antimicrobial Drug Use in Companion Animals, Request for Comments.'' 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: Barbara Leotta, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0605, *Barbara.Leotta@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial drugs [1] have been widely used in human and veterinary medicine for more than 80 years, with tremendous benefits to both human and animal health. The development of resistance [2] to this important class of drugs, and the resulting loss of the drugs' effectiveness, poses a serious threat to human and animal health. Because antimicrobial drug use can contribute to the emergence of drug-resistant organisms, these drugs should be used judiciously in both human and veterinary medicine to slow the development of resistance and preserve their utility. While judicious use efforts often focus on antimicrobial drug use in food-producing animal species (*e.g.,* cattle, swine, chickens, and turkeys), there is also a need to better understand how the use of antimicrobial drugs to treat companion animals (*e.g.,* dogs, cats, and horses) might contribute to populations of resistant bacteria in these species and the humans exposed to them.

As part of its regulatory mission, CVM is responsible for ensuring the safety and effectiveness of animal drugs, including antimicrobial drugs, and has taken important steps to update the approved use conditions of medically important antimicrobial drugs (*i.e.,* antimicrobial drugs important for treating human disease) to support their judicious use in animals. CVM believes that the concept of antimicrobial stewardship encompasses several important principles of judicious use that are critical to slowing the rate at which bacteria develop resistance to antimicrobial drugs. In simple terms, we believe medically important antimicrobial drugs should only be used in animals when necessary to treat, control, or prevent disease. In addition, when such use is necessary, these antimicrobial drugs should be used in an optimal manner under the oversight of a licensed veterinarian. We acknowledge and support the many efforts that multiple stakeholders and animal health organizations have already taken to promote antimicrobial stewardship practices. For example, the American Veterinary Medical Association defined antimicrobial stewardship as ''the actions veterinarians take individually and as a profession to preserve the effectiveness and availability of antimicrobial drugs through conscientious oversight and responsible medical decision making while safeguarding animal, public, and environmental health.'' [3]

In September of 2018, CVM published a five-year action plan entitled ''Supporting Antimicrobial Stewardship in Veterinary Settings, Goals for Fiscal Years 2019–2023,'' [4] which outlines goals and objectives for promoting the judicious use of antimicrobial drugs in animals and includes specific actions CVM intends to undertake in order to carry out those goals and objectives. The purpose of this notice is to address Goal 1 of the five-year action plan, ''Align Antimicrobial Drug Product Use with the Principles of Antimicrobial Stewardship,'' which includes an

[1] The term ''antimicrobial'' refers broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites. Antimicrobial drugs that have specific activity against bacteria are referred to as antibacterial or antibiotic drugs. The broader term ''antimicrobial,'' however, commonly used in reference to drugs with activity against bacteria, is used in this document interchangeably with the terms antibacterial or antibiotic.

[2] Antimicrobial resistance is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to treat bacterial infections.

[3] American Veterinary Medical Association, ''Antimicrobial Stewardship Definition and Core Principles,'' 2018, *https://www.avma.org/KB/Policies/Pages/Antimicrobial-Stewardship-Definition-and-Core-Principles.aspx,* accessed November 4, 2021.

[4] *https://www.fda.gov/media/115776/download.*

objective to engage with our stakeholders to develop and implement a strategy for promoting antimicrobial stewardship in companion animals.[5] One of the actions related to this objective (Action 1.2.1 under Phase 1 Actions [6]) is to obtain public input regarding antimicrobial use practices in companion animals and the impact of such use practices on the development of resistance.

II. Questions for Consideration

CVM seeks input on the following questions and information requests:

1. Please describe if antimicrobial use practices in companion animals have impacted the development of antimicrobial resistance in bacterial pathogens of companion animals. Please provide information, data, and/or references to support your response.

2. Please describe if antimicrobial use practices in companion animals, including extralabel use, have impacted the development of antimicrobial resistance in human bacterial pathogens. If possible, please describe whether the impact was the result of direct or indirect contact between humans and the treated companion animals. Are there specific concerns about the development of antimicrobial resistance in human bacterial pathogens when particular antimicrobial drugs or drug classes are used in companion animals? Please provide information, data, and/or references to support your response.

3. How should the human medical importance of particular antimicrobial drugs or drug classes be considered when deciding whether, or under what conditions, to use such drugs in companion animals?

4. How can CVM best engage with our stakeholders on promoting antimicrobial stewardship for companion animals? Examples of stakeholders include other government agencies, the pharmaceutical industry, public health organizations (both public and private entities), veterinary professional organizations, veterinary schools, veterinarians, pet owners, and veterinary diagnostic laboratories.

5. How can CVM encourage the development of antimicrobial drugs consistent with the principles of antimicrobial stewardship for the treatment of infectious diseases in companion animals for which there are no FDA-approved animal drugs?

a. What bacterial diseases affecting companion animals are most in need of an FDA-approved animal antimicrobial drug?

b. What safety and effectiveness study design considerations present challenges for developing antimicrobial drugs to address specific infectious diseases in companion animals (*e.g.,* Lyme disease, sepsis, or osteomyelitis)? Are there alternative study designs that would address these challenges? If not, what role(s) could the stakeholder groups identified in question 4 play in developing such alternative study designs?

c. Are there specific infectious diseases in companion animals for which topical formulations of antimicrobial drugs (*e.g.,* medicated shampoos, rinses, or ointments) may be a better alternative than using systemic antimicrobial drugs from the perspective of antimicrobial stewardship? If so, what role(s) could the stakeholder groups identified in question 4 play toward fostering the use of such topical antimicrobial formulations?

6. Labeling:

a. What information on currently approved animal drug labeling helps the veterinarian prescribe or use an antimicrobial drug in a manner consistent with the principles of antimicrobial stewardship?

b. What additional information could be added to the approved animal drug labeling to improve the veterinarian's ability to prescribe or use an antimicrobial drug in a manner consistent with the principles of antimicrobial stewardship?

c. Is there a need for materials containing labeling information and/or information about antimicrobial stewardship that veterinarians could provide to the client when they prescribe an antimicrobial drug (*e.g.,* client information sheets or other educational handouts)?

7. With respect to the use of antimicrobial drugs in companion animals, what other actions should CVM consider taking to foster greater antimicrobial stewardship?

Dated: February 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03245 Filed 2–15–22; 8:45 am]

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[5] As a part of the plan, CVM established three goals, which include: (1) Align antimicrobial drug product use with the principles of antimicrobial stewardship; (2) foster stewardship of antimicrobials in veterinary settings; and (3) enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals. See the five-year action plan at p. 5.

[6] CVM intends to initiate the actions outlined in the plan in two phases, with Phase 1 activities being initiated between FY 2019 and FY 2021 and Phase 2 activities being initiated between FY 2022 and FY 2023. See the five-year action plan at pp. 5–6.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held virtually on March 10, 2022, from 10 a.m. to 1:30 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: *https://youtu.be/silb2C_Ro8I.*

FOR FURTHER INFORMATION CONTACT: Christina Vert or Tonica Burke, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993–0002, 240–402–8054, *ctgtac@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before joining the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On March 10,