ANNUAL BURDEN ESTIMATES

Instrument	Estimated total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Semi-Structured Discussions and Focus Groups	3,000	1	2	6,000
Interviews	1,500	1	1	1,500
Questionnaires/Surveys	1,125	1	.5	563

Estimated Total Annual Burden Hours: 8,063

Authority: Social Security Act, Sec. 1110 [42 U.S.C. 1310].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–00209 Filed 1–8–21; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2635]

Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed: A Concept Paper; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is requesting comments on a document entitled ''Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed: A Concept Paper.'' The concept paper outlines a potential framework for how sponsors of new animal drug products containing medically important antimicrobial drugs approved for use in or on animal feed might voluntarily establish appropriately defined durations of therapeutic administration to food-producing animals where none currently exist. Establishing appropriately defined durations of use to mitigate development of antimicrobial resistance would be consistent with previous efforts by FDA to protect public health by promoting the judicious use of these drugs in food-producing animals.

DATES: Submit either electronic or written comments by April 12, 2021.

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 April 12, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 12, 2021. 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–2016–D–2635 for ''Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed: A Concept Paper.'' 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.

Submit written requests for single copies of the concept paper 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 concept paper.

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

In response to recommendations made by FDA in Guidance for Industry (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 new animal drugs containing 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 assuring animal health (production indications) and to voluntarily change the marketing status of all remaining approved uses of such new animal drugs from ''over the counter'' to either by veterinary prescription 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 antimicrobial drugs 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** on September 14, 2016 (81 FR 63187), the Agency requested information from the public about how to establish appropriately targeted durations of use for therapeutic products affected by GFI #213 with no defined duration of use. Public feedback received in response to that request for information was taken into consideration during development of this concept paper.

On September 14, 2018, FDA released a 5-year action plan for supporting antimicrobial stewardship in veterinary settings.[2] This plan includes an action item intended to ensure that all medically important antimicrobial drugs used in or on the feed or drinking water of food-producing animals have an appropriately targeted duration of use.[3]

II. Request for Comments

We are requesting early input and comments from the public on a concept paper that outlines a potential framework for how sponsors of approved new animal drug applications and abbreviated new animal drug applications for products containing medically important antimicrobial drugs for use in or on the feed of food-producing animals could voluntarily 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. A copy of the concept paper may be obtained as described in section III below.

For the purpose of this potential framework, the term ''undefined duration of use'' means that for one or more of the indications for which the drug is approved, the product's labeling either includes no information regarding the duration of administration or otherwise does not provide an appropriately targeted duration of use. Although FDA's 5-year action plan for supporting antimicrobial stewardship that issued in September 2018 included an action item calling for the Agency to develop a strategy for establishing appropriately defined durations of use for medically important antimicrobial drugs used in or on the feed or drinking water of food-producing animals, the Center for Veterinary Medicine later determined that all of the approved uses of medically important antimicrobial drugs in dosage forms other than feed already have appropriately defined durations of use. For this reason, the scope of the concept paper is limited to those drugs that are approved for use in or on medicated feed.

The concept paper is intended to outline for sponsors and other stakeholders a potential process framework for how to make voluntary changes to the approved conditions of use of their medically important antimicrobial drugs administered in or on the medicated feed of food-producing animals to establish appropriately defined durations of use where none currently exist. Establishing appropriately defined durations of use to mitigate the development of antimicrobial resistance would be consistent with previous efforts by FDA to protect public health by promoting the judicious use of these drugs in food-producing animals.

Under the potential framework described in the concept paper, the process for revising the conditions of use would include making changes to the approved labeling for the product to appropriately define duration of use and, when appropriate, providing additional information to be included on the product's labeling that would be relevant to the veterinarian in determining when drug administration should be initiated or stopped in accordance with the approved labeling and consistent with the principles of judicious use of antimicrobials. In addition, were the potential framework later to be adopted through guidance, sponsors who choose to voluntarily establish appropriately defined durations of use for their products would be expected to submit data or other information supporting effectiveness at the shortest duration of use proposed for the labeling.

The potential framework includes a possible timeline for sponsors, with two phases: Phase 1, reassessing the existing data used to support the original approval of the affected product indications, considering what additional data or information might be needed, and formulating plans to obtain such data or information; and Phase 2, taking steps to obtain approval of revisions to conditions of use for their affected products. The potential framework also includes possible timelines for making labeling changes to combination proprietary free-choice medicated feeds and generic products, as well as a possible timeline for sponsors who intend to voluntarily withdraw the approval of an indication or an entire application rather than submit data or other information to define a duration of use.

We do not intend for the concept paper described in this notice to produce any decisions or new positions on specific regulatory issues or processes. Rather, the intent is to gather

[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/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed*)

[2] 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*)

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

information and obtain early input from the public on a potential framework for how sponsors may voluntarily change the approved conditions of use of medically important antimicrobial drugs used in or on the medicated feed of food-producing animals to establish an appropriately defined duration of use for those indications that currently have an undefined duration of use. The concept paper does not contain recommendations and does not constitute draft or final guidance by FDA. It should not be used for any purpose other than to facilitate public comment. FDA intends to consider all information and comments received on the concept paper before issuing draft guidance for additional comment.

We are specifically interested in receiving public comments on the following questions:

1. Are the potential timeframes outlined in the concept paper reasonable to achieve the goals described in the concept paper? If not, are there specific scientific or administrative barriers that would prevent sponsors from meeting these timeframes?

2. Are the potential processes for revising the applications described in the concept paper reasonable? If not, what specific adjustments could be made to improve these processes?

3. Are there other factors we should consider regarding this potential framework? If so, what are they?

III. Electronic Access

Persons with access to the internet may obtain the concept paper at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: January 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–00189 Filed 1–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HHS–NIH–CDC–SBIR PHS 2021–1 Phase I: Reagents for Immunologic Analysis of Non-Mammalian and Underrepresented Mammalian Models (Topic 094) (For SBIRs Phase I)

Date: January 28, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Virtual Meeting),

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240–669–5067, *kelly.hudspeth@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HHS–NIH–CDC–SBIR PHS 2021–1 Phase II: Reagents for Immunologic Analysis of Non-Mammalian and Underrepresented Mammalian Models (Topic 094) (For SBIRs Phase II).

Date: January 29, 2021.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240–669–5067, *kelly.hudspeth@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 5, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–00219 Filed 1–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Communities of Practice Webinar on Non-Animal Approaches for Mixtures Assessment; Notice of Public Webinar; Registration Information

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces a public webinar ''Non-animal Approaches for Mixtures Assessment.'' The webinar is organized on behalf of ICCVAM by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Interested persons may participate via WebEx. Time will be allotted for questions from the audience. Information about the webinar and registration are available at *https://ntp.niehs.nih.gov/go/commprac-2021.*

DATES:

Webinar: January 26, 2021, 9:00 a.m. to approximately 11:00 a.m. EST.

Registration for Webinar: January 4, 2021, until 11:00 a.m. EST January 26, 2021.

Registration to view the webinar is required.

ADDRESSES: Webinar web page *https://ntp.niehs.nih.gov/go/commprac-2021.*

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Acting Director, NICEATM, Division of NTP, NIEHS, P.O. Box 12233, K2–16 Research Triangle Park, NC 27709. Phone: 984–287–3150, Email: *Nicole.kleinstreuer@nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2032, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM promotes the development and validation of toxicity testing methods that protect human health and the environment while replacing, reducing, or refining animal use. ICCVAM also provides guidance to test method developers and facilitates collaborations that promote the development of new test methods. To address these goals, ICCVAM will hold a Communities of Practice webinar on ''Non-animal Approaches for Mixtures Assessment.''

While most available toxicity data are for single chemicals, humans are often