ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Applications	47	1	24	1,128
State Plans	47	1	40	1,880
Performance Progress Reports	47	2	16	1,504

Estimated Total Annual Burden Hours: 4,512.

Authority: Section 510 of the Social Security Act (42 U.S.C. 710), as amended by section 50502 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) and extended by Division CC, title III, section 303 of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–20758 Filed 9–25–23; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0001]

Advancing the Development of Pediatric Therapeutics on Drug Dosing in Pediatric Patients With Renal Impairment; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT 8) on Drug Dosing in Pediatric Patients With Renal Impairment.'' The purpose of the public workshop is to discuss the current landscape of drug dosing in pediatric patients with renal impairment, understand the gaps in knowledge, and consider innovative approaches to improve the current paradigm for dosing in pediatric patients with renal impairment.

DATES: The public workshop will be held on November 30, 2023, and December 1, 2023, from 9 a.m. to 5 p.m. eastern time each day. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus Great Room and online. Entrance for the registered public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Julie Levin, Office of New Drugs Public Meeting Support, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6481, Silver Spring, MD 20993–0002, 202–567–7565, *ONDPublicMTGSupport@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The pharmacokinetics of drugs excreted by the kidneys may be altered by renal (kidney) impairment, requiring dosing adjustments. However, the majority of drugs that are predominantly renally excreted and have dosage recommendations for adults with renal impairment lack dose adjustment recommendations for pediatric patients with renal impairment. This is largely due to the lack of generation of pharmacokinetic data in pediatric patients with renal impairment, which is attributable to both the ethical and the practical limitations of conducting dedicated renal impairment studies in pediatric patients, as well as the exclusion of pediatric patients with renal impairment from most clinical efficacy and safety studies. For drugs that are renally cleared, exposures can be impacted by both the maturation of kidney function and the renal impairment due to kidney disease.

II. Topics for Discussion at the Public Workshop

The main objective of the ''Advancing the Development of Pediatric Therapeutics (ADEPT 8) on Drug Dosing in Pediatric Patients With Renal Impairment'' workshop is to discuss current approaches to classifying renal impairment in the pediatric population, identify data gaps, and explore scientifically supported approaches and methods for providing information on dosing adjustment. The workshop will specifically focus on measurements of renal function, extrapolation of adult data, and approaches to generating clinical trial data to assess the impact of renal impairment on the pharmacokinetics of drugs in pediatric patients. In addition, the workshop will allow for an open dialogue around the use of these approaches among regulators, industry, academia, and patient organizations.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.eventbrite.com/e/adept-8-pediatric-renal-impairment-workshop-tickets-687423571407.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by November 15, 2023, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Julie Levin at *ONDPublicMTGSupport@fda.hhs.gov* no later than November 15, 2023.

Streaming Webcast of the Public Workshop: This public workshop will also be via Zoom. A link will be provided via email to registered participants. If you have never attended a Zoom event before, test your internet connection by joining a test meeting at *https://zoom.us/test.* FDA has verified the website addresses in this document, as of the date this document is published in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that when a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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.