regulatory submissions. In 2018, FDA created an RWE Framework and Program (Program) to evaluate the potential use of RWE to help support the approval of a new indication for a drug already approved under the FD&C Act or to help to support or satisfy postapproval study requirements. In late 2021, FDA utilized the Program to issue draft guidances outlining considerations for the use of RWD and RWE in regulatory decision-making to help satisfy the Cures Act mandate and the PDUFA VI commitment.

This guidance finalizes the draft guidance entitled ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data'' issued on October 22, 2021 (86 FR 58672). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification of FDA's understanding of challenges when using currently supported data standards for RWD sources and elaboration of available FDA resources for consultation about the use of data standards for study data submitted to FDA. In addition, editorial changes were made to improve clarity, including the movement of concepts from glossary entries to footnotes to the main document text.

This 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 ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data.'' 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 (Applications for FDA Approval to Market a New Drug) have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 (Investigational New Drug Regulations) have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 (Good Laboratory Practice Regulations for Nonclinical Laboratory Studies) have been approved under OMB control number 0910–0119; and the collections of information in 21 CFR part 601 (General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension) have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *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: December 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28291 Filed 12–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1997–D–0444]

Special Considerations, Incentives, and Programs To Support the Approval of New Animal Drugs for Minor Uses and for Minor Species; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry (GFI) #61 entitled ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This guidance is intended to assist those interested in pursuing FDA approval of new animal drugs intended for minor uses in major species or for use in minor species (MUMS drugs). It outlines the basic statutory and regulatory requirements and special considerations for these approvals and describes the incentives available to encourage the development of MUMS drugs.

DATES: The announcement of the guidance is published in the **Federal Register** on December 22, 2023.

ADDRESSES: 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–1997–D–0444 for ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' 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: Dorothy Bailey, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0565, *dorothy.bailey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 15, 2020 (85 FR 42876), FDA published the notice of availability for draft GFI #61 entitled ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species'' giving interested persons until November 12, 2020, to comment on the draft guidance. In response to a request for an extension, the comment period was extended to January 11, 2021 (85 FR 71659). FDA received 14 comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the final guidance include the following:

- In our draft guidance we referred to Minor Use Determinations. Our experience has shown that our stakeholders frequently confuse ''MUMS Determination'' with ''MUMS Designation.'' Therefore, the final guidance substitutes the word ''Assessment'' for the word ''Determination.''
- Section XII.C.3.a.i. ''Anthelmintics and Ectoparasiticides for Terrestrial Minor Species'' has been added to the final guidance in response to comments received requesting additional detail on this subject. This section also references the relevant ''International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)'' guidance.
- CVM received many comments pertaining to aquaculture species grouping. Due to the complexity of this topic, CVM has removed examples of aquaculture species groupings in the final guidance. We continue to consider this topic and intend to work with individual drug sponsors wishing to use species groupings for new animal drug approvals to identify an appropriate species grouping strategy and subsequent data needs for specific projects.

In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated July 2020.

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 ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' 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 21 CFR part 511 have been approved under OMB control number 0910–0117; the collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0284; and the collections of information in 21 CFR part 516 have been approved under OMB control numbers 0910–0605.

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: December 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28287 Filed 12–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–N–1157; FDA–2022–D–0109; FDA–2020–N–0908; FDA–2022–D–0814; FDA–2022–D–0745; FDA–2023–N–1006; FDA–2023–N–1053; FDA–2023–N–2286; FDA–2023–N–1661; FDA–2013–N–1119; FDA–2023–N–2986; FDA–2009–N–0582; FDA–2023–N–1272; FDA–2023–N–2030; FDA–2023–N–1189]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).