2011–N–0655 for ''Animal Generic Drug User Fee Act.'' 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: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 2022, FDA published a notice announcing a public meeting and requesting comments on the proposed recommendations for the reauthorization of the AGDUFA IV for fiscal years 2024 through 2028.

Interested persons were originally given until November 9, 2022, to comment on the public meeting and request for comments. Due to a delay in the posting of the AGDUFA IV Performance Goals and Procedures Letter to our website at *https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings,* we are extending the comment period until November 14, 2022, to allow for a 30-day comment period.

Dated: October 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22744 Filed 10–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0401]

Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products; 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 final guidance for industry #254 entitled ''Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products.'' FDA's Center for Veterinary Medicine is issuing this guidance for sponsors, firms, individuals, and establishments that participate in the manufacture of, or perform any aspect of, the donor eligibility determination for animal cells, tissues, and cell- and tissue-based products (ACTPs). ACTPs that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or ACTPs intended to affect the structure or function of the animal generally meet the definition of a new animal drug under the Federal Food, Drug, and Cosmetic Act. Donor eligibility is a critical component of current good manufacturing practice (CGMP) when manufacturing ACTPs. A donor should be considered eligible to donate ACTPs only if screening of the donor shows that the donor is free from risk factors for, and clinical evidence of, infection with relevant disease agents and diseases, and the donor (and product/source material) test results for relevant disease agents are negative or nonreactive.

DATES: The announcement of the guidance is published in the **Federal Register** on October 20, 2022.

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–2021–D–0401 for ''Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products.'' 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: Lynne Boxer, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0611, *Lynne.Boxer@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 2021 (86 FR 52912), FDA published the notice of availability for a draft guidance entitled ''Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products'' giving interested persons until November 22, 2021, to comment on the draft guidance. FDA received two submissions that contained multiple comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity, for example, by making clear that the final guidance is intended to apply to allogeneic and xenogeneic ACTPs, as opposed to autologous ACTPs, and by providing additional, suggested donor screening and testing information that should be considered when determining an ACTP donor's eligibility. The guidance announced in this notice finalizes the draft guidance dated September 2021.

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 ''Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 been approved under OMB control number 0910–0032.

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: October 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22817 Filed 10–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0399]

Current Good Manufacturing Practice for Animal Cells, Tissues, and Cell- and Tissue-Based Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry #253 entitled ''Current Good Manufacturing Practice for Animal Cells, Tissues, and Cell- and Tissue-Based Products.'' FDA's Center for Veterinary Medicine (CVM) is issuing this guidance to provide establishments that manufacture animal cells, tissues, and cell- and tissue-based products (ACTPs) with recommendations for meeting requirements for current good manufacturing practice (CGMP). All new animal drugs, including ACTPs, are required to be manufactured in accordance with CGMP to ensure that such drugs meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as to safety, and have the identity, strength, quality, and purity characteristics, which they purport to or are represented to possess. This guidance also provides FDA's recommendations for those aspects of manufacturing specific to ACTPs in accordance with existing CGMP regulations, as applicable, and with the FD&C Act. In this guidance, we specifically address the methods, facilities, and controls used for manufacturing ACTPs.

DATES: The announcement of the guidance is published in the **Federal Register** on October 20, 2022.

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.