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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: 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

FDA is announcing the availability of a draft guidance for industry (GFI) #253 entitled ''Good Manufacturing Practices for Animal Cells, Tissues, and Cell- and Tissue-Based Products.'' CVM is issuing this guidance to provide establishments that manufacture ACTPs with recommendations for meeting CGMP requirements. All new animal drugs, including ACTPs, are required to be manufactured in accordance with CGMPS to ensure that such drugs meet the requirements of the FD&C Act as to safety and have the identity, strength, quality, and purity characteristics that they purport to or are represented to possess. The CGMP requirements for new animal drugs are found in Title 21 parts 210 and 211 of the Code of Federal Regulations (parts 210 and 211 (21 CFR parts 210 and 211)). The CGMP regulations in parts 210 and 211 are broad in scope, and we recognize that these regulations do not specifically or fully address all aspects of the manufacture of ACTPs, including early stages of the manufacturing process. This guidance provides our recommendations for complying with section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) for those aspects of manufacturing specific to ACTPs.

ACTPs that meet the definition of a new animal drug are subject to the same statutory and regulatory requirements found under the FD&C Act and Title 21 of the CFR. Sponsors are responsible for ensuring that their products are manufactured in accordance with Federal law, including parts 210 and 211 and section 501(a)(2)(B) of the FD&C Act. New animal drugs not manufactured in conformity with CGMPs are adulterated under the relevant provisions of the FD&C Act.

This guidance specifically addresses the methods, facilities, and controls used for manufacturing ACTPs, including steps in recovery, processing, storage, labeling, packaging, and distribution. We refer to our recommendations for meeting CGMPs in the manufacture of ACTPs as ACTP CGMPs. These ACTP CGMPs should be applied to consistently produce quality and to ensure that ACTPs are not contaminated and do not become contaminated during manufacturing.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on good manufacturing practices 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 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/FederalRegister/default.htm,* or *https://www.regulations.gov.*

Dated: September 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20514 Filed 9–22–21; 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; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency or we) is announcing the availability of a draft guidance for industry #254 entitled ''Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products.'' FDA's Center for Veterinary Medicine (CVM) 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), which meet the definition of new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Donor eligibility is a critical component of current good manufacturing practices (CGMPs) 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: Submit either electronic or written comments on the draft guidance by November 22, 2021 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–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 draft 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

FDA is announcing the availability of a draft guidance for industry (GFI) #254 entitled ''Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products.'' This draft guidance is for sponsors, firms, individuals, and establishments that participate in the manufacture of, or perform any aspect of, the donor eligibility determination for ACTPs, which meet the definition of new animal drugs under section 201(v) of the FD&C Act (21 U.S.C. 321(v)). ACTPs that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or are intended to affect the structure or function of the animal generally meet the definition of a new animal drug. All new animal drugs, including ACTPs, are required to be manufactured in accordance with CGMPs to ensure that such drugs meet the requirements of the FD&C Act as to safety, and have the identity, strength, quality, and purity characteristics that they purport to or are represented to possess. Advances in the field of veterinary regenerative medicine have resulted in increasing research into veterinary applications for ACTPs, and many of these products are intended for use as new animal drugs.

Donor eligibility is a critical component of CGMPs when manufacturing ACTPs. Selecting appropriate donors is critical to product quality and compliance with ACTP CGMPs. Establishments performing any function related to donor eligibility should comply with the ACTP CGMPs related to that function. 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. To prevent transmission of disease when manufacturing ACTPs, it is necessary to determine that donors are healthy and free from relevant disease agents. Transmission of relevant disease agents by an ACTP may be the result of the presence of relevant disease agents in the donated cells/tissues (either within the cells/tissues, within other accompanying cells/tissues, or in the extracellular components of the product).

The CGMP requirements for new animal drugs are found in Title 21 parts 210 and 211 of the Code of Federal Regulations (21 CFR parts 210 and 211). These regulations are broad in scope, and FDA recognizes that they do not specifically or fully address some aspects of the manufacture of ACTPs, including donor eligibility determinations. This guidance offers FDA's recommendations for determining that a donor is free from relevant disease agents and is an eligible source of cells, tissues, or both, used in the manufacture of allogeneic or xenogeneic ACTPs. We encourage sponsors and manufacturers of ACTPs to contact CVM early in the product development process to discuss considerations specific to approval of a new animal drug product.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *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: September 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20517 Filed 9–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–XXXX]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: SHIP COVID–19 Testing and Mitigation Program Data Collection—New, Emergency

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 4, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: SHIP COVID–19 Testing and Mitigation Program Data Collection, OMB No. 0906–XXXX—New, Emergency.

Abstract: The American Rescue Plan Act of 2021 (Pub. L. 117–2) provided one-time funding for awards that will be carried out under Section 711 of the Social Security Act (42 U.S.C. 912(b)(5)). The Small Rural Hospital Improvement Program (SHIP) is requesting approval of an emergency ICR. State grantees will improve health care in rural areas by using the funding to provide support to eligible rural hospitals to increase COVID–19 testing efforts, expand access to testing in rural communities, and expand the range of mitigation activities.

Need and Proposed Use of the Information: The terms and conditions for this program specify that, ''hospitals will be required to report on the number of tests provided and categories in which the funding is spent.'' The data will allow HRSA to ensure SHIP COVID–19 recipients are meeting the terms and conditions of their funding, while providing HRSA with information on the effectiveness of funds distributed through this program.

Likely Respondents: The respondents will be hospital staff and designated representatives.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.