child care programs working directly with children in classrooms (Center-based Classroom Staff [Workforce] Interview) as of 2019 and who participated in the 2019 NSECE.

Respondents: Home-based providers as of 2019 serving children under 13 years (listed and unlisted paid)—regardless of their status serving children in 2020–2022, center-based child care providers as of 2019 serving children ages 0 through 5 years of age (not yet in kindergarten)—regardless of their status serving children in 2020–2022, and classroom-assigned instructional staff members working with children ages 0 through 5 years of age (not yet in kindergarten) in center-based child care providers as of 2019, regardless of their employment status in 2020–2022.

Annual Burden Estimates: This request is for an extension through spring 2022.

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)
Home-based Provider Interview, Wave 2—In ECE during focal week	2,025	1	0.35	709
Home-based Provider Interview, Wave 2—Not in ECE during focal week	506	1	0.25	126
Center-based Provider Interview, Wave 2 spring or fall; in ECE during focal week	3,291	1	0.38	1,251
Center-based Provider Interview, Wave 2 spring or fall; not in ECE during focal week	1,097	1	0.22	241
Center-based Provider Fall 2021 Funding Receipt Supplement	1,255	1	0.20	251
Center-based Provider Interview Wave 2 fall; Centers completing in Wave 2 spring also	1,136	1	0.29	329
(Center-based) Workforce Interview—Wave 2; In ECE during Focal Week	1,775	1	0.37	657
(Center-based) Workforce Interview—Wave 2; Not in ECE during Focal Week	874	1	0.24	210

Estimated Total Burden Hours: 3,774.

Authority: Child Care and Development Block Grant (CCDBG) Act of 1990 as amended by the CCDBG Act of 2014 (Pub. L. 113–186).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–20573 Filed 9–22–21; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0399]

Good Manufacturing Practices for Animal Cells, Tissues, and Cell- and Tissue-Based Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry #253 entitled ''Good Manufacturing Practices for Animal Cells, Tissues, and Cell- and Tissue-Based Products.''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) meeting the definition of new animal drugs with recommendations for meeting requirements for current good manufacturing practices (CGMPs). 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 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: 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–0399 for ''Good Manufacturing Practices 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) #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