JOVOM, AK	WP	(Lat. 60°07′40.55″ N, long. 143°42′56.99″ W)
OXUGE, AK	WP	(Lat. 60°06′15.81″ N, long. 144°13′28.54″ W)
KATAT, AK	FIX	(Lat. 60°15′29.17″ N, long. 144°42′18.77″ W)
Johnstone Point, AK (JOH)	VOR/DME	(Lat. 60°28′51.43″ N, long. 146°35′57.61″ W)
Anchorage, AK (TED)	VOR/DME	(Lat. 61°10′04.32″ N, long. 149°57′36.51″ W)
MKLUK, AK	WP	(Lat. 60°26′40.04″ N, long. 165°55′17.28″ W)

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Issued in Washington, DC, on October 25, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–23536 Filed 10–31–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2022–D–0563]

Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products: Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled ''Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is intended to help small entity establishments that manufacture HCT/Ps better understand the comprehensive regulatory framework for HCT/Ps set forth in the regulations and comply with certain HCT/P-related final rules. The SECG announced in this notice supersedes the SECG of the same title dated August 2007.

DATES: The announcement of the guidance is published in the **Federal Register** on November 1, 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–2022–D–0563 for ''Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Small Entity Compliance Guide.'' 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 SECG to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Small Entity Compliance Guide.'' The SECG is intended to help small entity establishments that manufacture HCT/Ps better understand the comprehensive regulatory framework for HCT/Ps, set forth in part 1271 (21 CFR part 1271). The SECG announced in this notice supersedes the SECG of the same title dated August 2007.

The SECG reflects the amendments of part 1271 based on the following: (1) the final rule published in the **Federal Register** of June 22, 2016 (81 FR 40512), which amended certain regulations regarding donor eligibility, including the screening and testing of donors of particular HCT/Ps; and (2) the final rule published in the **Federal Register** of August 31, 2016 (81 FR 60170), which amended the regulations governing drug establishment registration and drug listing and included amendments to certain establishment registration and listing regulations for HCT/Ps.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to explain the actions that a small entity must take to comply with the final rules.

We are issuing the SECG as level 2 guidance consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. 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 207 have been approved under OMB control number 0910–0045; the collections of information in 21 CFR part 607 have been approved under OMB control number 0910–0052; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0625; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the SECG at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23573 Filed 10–31–22; 8:45 am]

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