may examine the EASA AD in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–1113.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Austro Engine Mandatory Service Bulletin No. MSB–E4–025, Rev. No. 3, dated January 8, 2019.

(ii) [Reserved]

(3) For Austro Engine GmbH service information identified in this AD, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A–2700 Weiner Neustadt, Austria; phone: +43 2622 23000; fax: +43 2622 23000–2711; website: *www.austroengine.at.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call 781–238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on July 9, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–15606 Filed 7–20–20; 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–2017–D–6146]

Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry and FDA staff entitled ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' The guidance does not alter FDA's current thinking on the regulatory criteria of minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based product (HCT/P). The guidance announced in this notice supersedes the guidance of the same title dated November 2017 and corrected December 2017. The guidance revises section V of the November 2017 guidance to communicate that the Agency is extending the period of time during which FDA intends to exercise enforcement discretion regarding certain regulatory requirements for certain HCT/Ps; this time period will run through May 31, 2021, instead of November 30, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on July 21, 2020.

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–2017–D–6146 for ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' 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 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 the 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Walker Udechukwu, 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; or Andrew Yeatts, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5510, Silver Spring, MD 20993–0002, 301–796–4539; or Leigh Hayes, Office of Combination Products, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5127, Silver Spring, MD 20993–0002, 301–796–8938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Regulatory Considerations for Human Cells, Tissues, Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The Agency is soliciting public comment, but is implementing this guidance immediately, because the Agency has determined that prior public participation is not feasible or appropriate. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation.

The guidance does not alter FDA's current thinking on the regulatory criteria of minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based product (HCT/P) as described in the November 2017 guidance of the same name and corrected in December 2017. The only substantive change to this guidance is to revise section V of the November 2017 guidance to communicate that FDA intends to exercise enforcement discretion for certain regulatory requirements for certain HCT/Ps for a longer period of time, *i.e.,* through May 31, 2021, instead of November 30, 2020. This will give manufacturers additional time to determine if they need to submit an investigational new drug (IND) or marketing application and, if such an application is needed, to prepare the IND or marketing application. Such additional time is warranted in light of the Coronavirus Disease 2019 (COVID–19) public health emergency, which has presented unique challenges in recruiting clinical trial participants and carrying out clinical trials.

As described in the guidance, FDA generally intends to exercise enforcement discretion with respect to the IND and the premarket approval requirements for HCT/Ps that do not meet one or more of the 21 CFR 1271.10(a) criteria, provided that use of the HCT/P does not raise reported safety concerns or potential significant safety concerns. FDA intends to continue to focus enforcement actions on products with higher risk, including based on the route and site of administration.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115(g)(2)). The guidance represents the current thinking of FDA on ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' 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

This guidance contains no collection 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.

However, this guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances; https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products; https://www.fda.gov/combination-products/guidance-regulatory-information;* or *https://www.regulations.gov.*

Dated: July 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15718 Filed 7–20–20; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA–HQ–OW–2018–0780, EPA–HQ–OW–2008–0692, EPA–HQ–OW–2009–0297; FRL–10011–21–OW]

RIN 2040–AF28

Drinking Water: Final Action on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is announcing its withdrawal of the 2011 determination to regulate perchlorate in accordance with the Safe Drinking Water Act, (SDWA). On February 11, 2011, the EPA published a **Federal Register** document in which the Agency determined that perchlorate met the SDWA's criteria for regulating a contaminant. On June 26, 2019, the EPA published a proposed national primary drinking water regulation (NPDWR) for perchlorate and requested public comments on multiple alternative actions, including the alternative of withdrawing the 2011 regulatory determination for perchlorate. The EPA received approximately 1,500 comments on the proposed rulemaking. The EPA has considered these public comments and based on the best available information the Agency is withdrawing the 2011 regulatory determination and is making a final determination not to regulate perchlorate. The EPA has determined that perchlorate does not occur ''with a frequency and at levels of public health concern'' within the meaning of the SDWA. In addition, in the judgment of the EPA Administrator, regulation of perchlorate does not present a ''meaningful opportunity for health risk reduction for persons served by public water systems.'' Accordingly, the EPA is