submit an application to CMS that describes how the entity meets all the requirements in the PACE program. An entity's application must be accompanied by an assurance from the SAA of the State in which the PO wishes to operate its PACE program. CMS accepts applications on a designated date four times per year (*i.e.,* on a quarterly basis, generally the last Friday of March, June, September and December). *Form Number:* CMS–10631 (OMB control number: 0938–1326); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Local or Tribal governments, Business or other for-profits; *Number of Respondents:* 72; *Total Annual Responses:* 130; *Total Annual Hours:* 7,271. (For policy questions regarding this collection contact Debbie Vanhoven at 410–786–6625.)

Dated: April 25, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–09164 Filed 4–28–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0140]

Ulcerative Colitis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Ulcerative Colitis: Developing Drugs for Treatment.'' This draft guidance addresses FDA's current thinking about necessary attributes of clinical trials for developing drugs for the treatment of ulcerative colitis in adults, including recommendations for trial population, trial design, and efficacy and safety considerations. This draft guidance replaces the draft guidance for industry entitled ''Ulcerative Colitis: Clinical Trial Endpoints,'' which is being withdrawn.

DATES: Submit either electronic or written comments on the draft guidance by June 28, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2022–D–0140 for ''Ulcerative Colitis: Developing Drugs for Treatment.'' 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kelly Richards, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5378, Silver Spring, MD 20993, 240–402–4276, or Stephen Ripley, Center for

Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Ulcerative Colitis: Developing Drugs for Treatment.'' This guidance addresses FDA's current thinking about necessary attributes of clinical trials for developing drugs for ulcerative colitis in adults including recommendations for trial population, trial design, and efficacy and safety considerations. This draft guidance replaces the draft guidance for industry entitled ''Ulcerative Colitis: Clinical Trial Endpoints,'' issued on August 8, 2016 (81 FR 52449), which is being withdrawn.

This 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 ''Ulcerative Colitis: Developing Drugs for Treatment.'' 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 312 have been approved under OMB control number 0910–0014. FDA receives information described in FDA's guidance entitled ''Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims'' to support the medical product's effectiveness and to support claims in approved medical product labeling; the collections of information in 21 CFR 314.50(d)(5) and 21 CFR 601.2 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively, and the collections of information in 21 CFR 201.56 and 201.57 for medical product labeling have been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 50 and 56 for protection of human subjects in clinical trials and institutional review board considerations have been approved under OMB control number 0910–0130.

III. Electronic Access

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

Dated: April 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09237 Filed 4–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that VEKLURY (remdesivir), manufactured by Gilead Sciences, Inc., meets the criteria for a material threat MCM priority review voucher.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Office of Counterterrorism and Emerging Threats, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8515, Fax: 301–796–8615, email: *EUA.OCET@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by the Cures Act (Pub. L. 114–255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that VEKLURY, manufactured by Gilead Sciences, Inc., meets the criteria for a material threat MCM priority review voucher. Remdesivir was approved on October 22, 2020, for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID–19 requiring hospitalization.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation.* For further information about VEKLURY, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09233 Filed 4–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5609]

Action Levels for Lead in Juice; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Action Levels for Lead in Juice: Guidance for Industry.'' The draft guidance, when finalized, would establish action levels of 10 parts per billion (ppb) for lead in single-strength (ready-to-drink) apple juice and 20 ppb for lead in all other single-strength juice types, including juice blends that contain apple juice.

DATES: Submit either electronic or written comments on the draft guidance by June 28, 2022 to ensure that we consider your comment on the draft