

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FDA is announcing the availability of a draft guidance for industry entitled “Ulcerative Colitis: Developing Drugs for Treatment.”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 This draft guidance replaces the draft guidance for industry entitled “Ulcerative Colitis: Clinical Trial Endpoints,” issued on August 8, 2016 (81 FR 52449), which is being withdrawn.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Ulcerative Colitis: Developing Drugs for Treatment.”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.

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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.O CET@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.

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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