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FDA is announcing the availability of a draft guidance for industry entitled ''Ulcerative Colitis: Developing Drugs for Treatment.''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 This draft guidance replaces the draft guidance for industry entitled ''Ulcerative Colitis: Clinical Trial Endpoints,'' issued on August 8, 2016 (81 FR 52449), which is being withdrawn.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Ulcerative Colitis: Developing Drugs for Treatment.''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

guidance before we begin 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–2019–D–5609 for ''Action Levels for Lead in Juice: Guidance for Industry.'' 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.'' We will review this copy, including the claimed confidential information, in our 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 Office of Food Safety, Division of Plant Products and Beverages, Beverages Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Eileen Abt, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1700; or Katherine Collins, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Action Levels for Lead in Juice: Guidance for Industry.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations.

This draft guidance when finalized, would, in accordance with 21 CFR 109.6(d), establish action levels for lead of 10 ppb for 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. Consistent with 21 CFR 109.4, these action levels would define the levels of lead contamination that may cause the juice products described in the guidance to be regarded as adulterated. We intend to consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov*

because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. FDA, 2004. ''Guidance for Industry: Juice HACCP Hazards and Controls Guidance First Edition; Final Guidance.'' Available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm.*
2. Codex Alimentarius, 2021. Revision of the Code of Practice for the Prevention and Reduction of Lead Contamination in Foods.
3. HHS, National Toxicology Program, 2012. NTP Monograph on Health Effects of Low-Level Lead. Available at: *https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.*
4. Flannery, B.M., L.C. Dolan, D. Hoffman-Pennesi, A. Gavelek, et al., 2020. U.S. Food and Drug Administration's Interim Reference Levels for Dietary Lead Exposure in Children and Women of Childbearing Age.'' *Regulatory Toxicology and Pharmacology.* 110:1–20.
5. WHO/FAO Joint Expert Committee on Food Additives, 2011. Evaluation of Certain Contaminants in Food, 73rd Report of the World Health Organization/Food and Agriculture Organization of the United Nations Joint Expert Committee on Food Additives. WHO Technical Report Series 960. Available at *https://apps.who.int/iris/bitstream/handle/10665/44515/WHO_TRS_960_eng.pdf?sequence=1.*
6. Codex Alimentarius, 2021. General Standard for Contaminants and Toxins in Food and Feed, CXS 193–1995. *http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-14%252FINFO-DOC%252FCF14_INF01x.pdf.*
* 7. FDA, 2021. Closer to Zero: Action Plan for Baby Foods. Available at *https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods.*
* 8. FDA, 2022b. Draft Supporting Document for Establishing FDA's Action Levels for Lead in Juice. Available at *https://www.fda.gov.*

Dated: April 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09255 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–2021–P–1188]

Determination That Cupric Sulfate Injection, Equivalent to 0.4 Milligram Copper/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Cupric Sulfate Injection, equivalent to (EQ) 0.4 milligram (mg) copper/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Cupric Sulfate Injection, EQ 0.4 mg copper/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 240–825–9944, *Kaetochi.Okemgbo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Cupric Sulfate Injection, EQ 0.4 mg copper/mL, is the subject of NDA 019350, held by Abraxis Pharmaceutical Products, and initially approved on May 5, 1987. Cupric Sulfate Injection is indicated for use as a supplement to intravenous solutions given for total parenteral nutrition, to prevent and treat copper deficiency.

In a letter dated April 17, 1995, Fujisawa USA, Inc. (the applicant at that time), notified FDA that Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was being discontinued, and requested withdrawal of NDA 019350. FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of June 21, 2017 (82 FR 28322), FDA announced that it was withdrawing approval of NDA 019350, effective June 21, 2017.

Arent Fox LLP submitted a citizen petition dated November 2, 2021 (Docket No. FDA–2021–P–1188), under 21 CFR 10.30, requesting that the Agency determine whether Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Cupric Sulfate Injection, EQ 0.4 mg copper/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.