U.S. FOOD & DRUG ADMINISTRATION

October 5, 2023

Donald C. Hall, Jr. Ph.D.
Director of Operations
Drexel Medicine Diagnostics
College of Medicine, Drexel University
245 N. 15th Street, Room 5108
Philadelphia, PA 19102

Re: Revocation of EUA220099

Dear Dr. Hall:

This letter is in response to the request from Drexel University College of Medicine, in an email received September 29, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, issued on April 19, 2021. Drexel University College of Medicine indicated that they have discontinued use of the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay at Drexel University, Drexel Medicine Diagnostics, located at 245 N. 15th Street, Room 5401, Philadelphia, PA 19102.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Drexel University College of Medicine has requested that FDA withdraw the EUA for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA220099 for the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-CoV-2 DUCoM-PDL Modified Tetracore Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Date: February 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02356 Filed 2–5–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1031]

Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; 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 final guidance for industry entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability.'' This guidance addresses the process through which registrants of drug establishments should submit reports to FDA on the amount of each listed drug manufactured, prepared,

propagated, compounded, or processed for commercial distribution, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance finalizes the draft guidance of the same title published on November 1, 2021. To allow for the transition of technical updates to the NextGen Portal, FDA will delay implementation of the final guidance until February 26, 2024. The draft guidance will remain available until that date.

DATES: The announcement of the guidance is published in the **Federal Register** on February 6, 2024. Implementation of this guidance will be delayed until February 26, 2024, to allow for the transition of technical updates to the NextGen Portal.

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–2021–D–1031 for ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act.'' 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 this 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 to 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Neil Stiber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4128, Silver Spring, MD 20993–0002, 301–796–8944; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7226, Silver Spring, MD 20993–0002, 240–402–5923; or Linda Walter-Grimm, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–240), Rockville, MD 20855, 240–753–3173.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.'' On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136) was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019 (COVID–19). In addition, the CARES Act included authorities to enhance FDA's ability to assess, prevent, and mitigate possible drug shortages by, among other things, improving FDA's visibility into drug supply chains. Section 3112(e) of the CARES Act added section 510(j)(3) of the FD&C Act (21 U.S.C. 360(j)(3)), which requires that each person (including repackers and relabelers) who registers with FDA under section 510 of the FD&C Act with regard to a drug must report annually to FDA the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.

This guidance describes the process that should be used for such reporting by each person who registers with FDA under section 510 of the FD&C Act with regard to a listed drug (including a drug

product that is in finished package form, a drug product that is not in finished package form, an active pharmaceutical ingredient, and other types of listed drugs, except for biological products or categories thereof exempted by an order under section 510(j)(3)(B) of the FD&C Act). Listed drugs subject to reporting include human drug products (including non-exempt biological products) marketed under an approved application, animal drug products marketed under an approved application, medical gases, homeopathic products, products marketed in accordance with requirements under section 505G of the FD&C Act (21 U.S.C. 355h), often referred to as over-the-counter monograph drugs, and animal drug products that are not approved, conditionally approved, or indexed under sections 512, 571, and 572 of the FD&C Act (21 U.S.C. 360b, 360ccc, and 360ccc–1).

This guidance finalizes the draft guidance entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act'' published on November 1, 2021 (86 FR 60249). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include changes to the recommended timeframe for report submission, as well as changes to the recommended units for the reporting of drugs that are not drug products in finished package form. These changes were made in response to public comments received and in the interest of facilitating drug amount data submission and improving data accuracy. Revisions also were made to clarify the reporting requirements applicable to registrants of listed drugs across the drug supply chain, including contract manufacturers. Further revisions were made to clarify and further detail how FDA plans to use data derived from the drug amount reporting program, including data submitted by each registrant in the drug supply chain.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 207 pertaining to registration of producers of drugs and listing of drugs in commercial distribution have been approved under OMB control number 0910–0045. The collections of information in 21 CFR parts 314 and 601 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collections of information pertaining to notifications of discontinuance or interruption in manufacturing under 21 CFR 310.306 and 314.81(b)(3)(iii) have been approved under OMB control number 0910–0001. The collections of information relating to 21 CFR 600.81 and 600.82 have been approved under OMB control number 0910–0308. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 514.80 have been approved under OMB control number 0910–0284. The collections of information in 21 CFR 514.87 have been approved under OMB control number 0910–0659.

III. Electronic Access

Persons with access to the internet may obtain the 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/biologics-guidances, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry,* or *https://www.regulations.gov.*

Dated: February 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02369 Filed 2–5–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Pediatric Mental Health Care Access Program National Impact Study

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 8, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Pediatric Mental Health Care Access Program National Impact Study, OMB No. 0915–xxxx—[New].

Abstract: This notice describes an information collection request for one of HRSA's Maternal and Child Health Bureau programs, the Pediatric Mental Health Care Access (PMHCA) Program. The PMHCA Program aims to promote behavioral health integration into pediatric primary care by supporting the development of state, regional, and tribal pediatric mental health care teleconsultation access programs. The PMHCA Program supports pediatric health professionals (HPs) [1] in their

[1] Health professionals may include but are not limited to pediatricians, family physicians,