addiction medicine; health disparities and social determinants of health.

Additional study section descriptive information can be found here:

Study Section Rosters: http://www.ahrq.gov/funding/process/study-section/peerrev.

Study Section Descriptions: http://www.ahrq.gov/funding/process/study-section/peerdesc.

Study Section Research Foci: http://www.ahrq.gov/funding/process/study-section/resfoci.

Interested individuals may nominate themselves, and organizations and individuals may nominate one or more qualified persons for study section membership. A diversity of perspectives is valuable to AHRQ's work. To help obtain a diversity of perspectives among nominees, AHRQ encourages nominations of women and members of minority groups. AHRQ also seeks broad geographic representation. All nominations must be submitted electronically, and should include:

1. A copy of the nominee's current curriculum vitae and contact information, including mailing address, phone number, and email address.

2. Preferred study section assignment.

Dated: May 3, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–09834 Filed 5–6–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0728]

Celgene Corporation and Teva Pharmaceutical Industries Ltd.; Withdrawal of Approval of Peripheral T-Cell Lymphoma Indication for ISTODAX (Romidepsin) for Injection and Romidepsin Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the peripheral T-cell lymphoma (PTCL) indication for ISTODAX (romidepsin) for injection, approved under new drug application (NDA) 022393, held by Celgene Corporation, 86 Morris Ave., Summit, NJ 07901 (Celgene). We are also announcing the withdrawal of approval of the same indication for Romidepsin injection, approved under NDA 208574, held by Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054 (Teva). Celgene and Teva have voluntarily requested that FDA withdraw approval of this indication and have waived their opportunity for a hearing.

DATES: Approval was withdrawn as of May 9, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 16, 2011, FDA approved an additional indication for Celgene's new drug application (NDA) 22393 for ISTODAX (romidepsin) for injection, 10 mg, specifically for treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of Celgene's ISTODAX (romidepsin) for injection for PTCL included a required postmarketing clinical trial intended to verify the clinical benefit of romidepsin (the Ro-CHOP study) for PTCL.

On March 13, 2020, FDA approved Teva's NDA 208574 for Romidepsin injection, 10 mg/2 milliliter, for treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of Teva's Romidepsin injection for PTCL also included a required postmarketing clinical trial intended to verify the clinical benefit of romidepsin for PTCL. Teva's Romidepsin injection product was approved under the 505(b)(2) approval pathway, and the listed drug relied upon is Celgene's NDA 22393, ISTODAX (romidepsin) for injection.

On August 6, 2020, Celgene submitted high level results from the Ro-CHOP study to FDA, which indicated the study failed to meet its primary endpoint of progression free survival. On May 14, 2021, Celgene informed FDA that after careful consideration, Celgene decided to voluntarily withdraw the PTCL indication from ISTODAX (romidepsin) for injection.

On June 17, 2021, Celgene submitted a supplemental NDA proposing to remove the PTCL indication. On July 14, 2021, Celgene submitted a letter asking FDA to withdraw approval of the PTCL indication pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing.

On August 27, 2021, Teva submitted a labeling supplement proposing to remove the PTCL indication. On September 12, 2021, the Agency requested Teva voluntarily request withdraw of the PTCL indication pursuant to § 314.150(d) and waive its opportunity for a hearing. On September 14, 2021, Teva amended its supplement by submitting a cover letter requesting withdrawal of approval of the PTCL indication pursuant to § 314.150(d) and waiving its opportunity for a hearing.

Therefore, under § 314.150(d), approval of the PTCL indications for ISTODAX (romidepsin) for injection, and Romidepsin injection, is withdrawn effective May 9, 2022. Withdrawal of approval of the PTCL indication does not affect any other approved indication(s) for ISTODAX (romidepsin) for injection or Romidepsin injection.

Dated: May 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09889 Filed 5–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0190]

Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Smokeless Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions associated with warning plans for smokeless tobacco products.

DATES: Submit either electronic or written comments on the collection of information by July 8, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 8, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 8, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2013–N–0190 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Warning Plans for Smokeless Tobacco Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Warning Plans for Smokeless Tobacco Products

OMB Control Number 0910–0671—Extension

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402) requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section (b)(3)(A) of 15 U.S.C. 4402 requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco ''in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer'' to, and approved by, FDA.

To implement these statutory requirements, warning plans are reviewed by FDA, upon submission by respondents. FDA published a draft guidance entitled ''Submission of

Warning Plans for Cigarettes and Smokeless Tobacco Products'' on September 9, 2011, which describes the information and format to be submitted for smokeless plans (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-warning-plans-cigarettes-and-smokeless-tobacco-products*). Submitters may also visit a web page that describes the smokeless tobacco labeling and warning statement requirements (*https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/smokeless-tobacco-labeling-and-warning-statement-requirements*). Additionally, FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan. Warning plans can be submitted either electronically or in paper format. The Center for Tobacco Products (CTP) Portal, available at *https://ctpportal.fda.gov/ctpportal/login.jsp,* provides a secure online system for electronically submitting documents and receiving messages from CTP.

Based on our experience with the information collection over the past 3 years, we retain our estimate of 60 hours to complete an initial rotational plan. We estimate half this time for preparing and submitting a supplement to an approved plan (30 hours).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of initial rotational plans for health warning statements	1	1	1	60	60
Supplement to approved plan	4	1	4	30	120
Total					180

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates a total of 1 respondent will submit a new original warning plan yearly and take 60 hours to complete a rotational warning plan for a total of 60 burden hours. In addition, FDA estimates a total of 4 respondents will submit a supplement to an approved warning plan at 30 hours per response for a total of 120 hours. After receiving the initial influx of original warnings plans, FDA does not expect to receive as many original warning plans annually. We expect that a few supplements will continue to be received as new products are marketed or as warning plans are revised. Therefore, we have decreased our estimate burden by 360 hours.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09885 Filed 5–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit and to Applied DNA Sciences, Inc., for the Linea COVID–19 Assay Kit. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit is revoked as of April 15, 2022. The Authorization for the Linea COVID–19 Assay Kit is revoked as of April 20, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On February 11, 2021, FDA issued an EUA to Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On May 13, 2020, FDA issued an EUA to Applied DNA Sciences, Inc. for the Linea COVID–19 Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria