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DATES: Approval was withdrawn as of May 9, 2022.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