published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the Ohio Patient Safety Institute to voluntarily relinquish its status as a PSO. Accordingly, the Ohio Patient Safety Institute, PSO number P0041, was delisted effective at 12:00 Midnight ET (2400) on April 30, 2022.

Ohio Patient Safety Institute has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov*.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–09843 Filed 5–6–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for Membership To Serve on Initial Review Group for Scientific Peer Review

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for nominations for membership to serve on initial review group for scientific peer review.

SUMMARY: This is to invite the public to nominate members to the Agency for Healthcare Research and Quality (AHRQ) Initial Review Group (IRG) responsible for the scientific peer review of AHRQ grant applications. The AHRQ IRG conducts scientific and technical review for health services research grant applications and is comprised of five subcommittees or study sections, each with a particular research focus. AHRQ is seeking nominations for scientific reviewers in specific competency domains to evaluate grant applications.

DATES: Nominations should be received on or before June 1, 2022.

ADDRESSES: Nominations should be submitted by email to *dsr@ahrq.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Celeste Torio, Ph.D., MPH., AHRQ, (301) 427–1664 or by email at *celeste.torio@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: This is to invite the public to nominate members to the Agency for Healthcare Research and Quality (AHRQ) Initial Review Group (IRG) responsible for the scientific peer review of AHRQ grant applications. AHRQ is required to conduct appropriate scientific peer review of grant applications pursuant to *42 U.S.C. 299c–1.* The AHRQ IRG conducts scientific and technical review for health services research grant applications and is comprised of five subcommittees or study sections, each with a particular research focus. AHRQ is seeking nominations for scientific reviewers in specific competency domains to evaluate grant applications.

AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services (DHHS) and with other partners to make sure that the evidence is understood and used. AHRQ works to fulfill its mission by supporting health services research, evaluation, demonstration, dissemination, and training grants.

The peer review of AHRQ grant applications involves an assessment conducted by panels of qualified experts established according to scientific disciplines or medical specialty areas. Members of the IRG will be selected based upon their training and experience in relevant scientific and technical fields, taking in account, among other factors: (1) The level of formal education and pertinent expertise and experience; (2) extent of engagement in relevant research; (3) extent of professional recognition; (4) need for specialization in relevant field; and (5) appropriate representation based on gender, racial/ethnic origin, and geography. See *42 CFR 67.15(a)(2).*

The IRG is comprised of five subcommittees, or study sections, each with a particular emphasis around which peer reviewer expertise is assembled. AHRQ seeks nominations for each of the subcommittee competency domains described below:

Health Care Effectiveness and Outcomes Research: End-stage renal disease; cardiovascular disease; pediatrics; pharmacologist in opioid management; biostatisticians in health services research; health disparities and social determinants of health.

Healthcare Safety and Quality Improvement Research: Pharmacists with expertise in informatics; infectious diseases specialists; geriatricians; surgeons with a specialty in diagnostic error; health disparities and social determinants of health.

Healthcare Information Technology Research: Biomedical and consumer health informatics; family medicine; health care data analysis; health information technology; health services research in patient-oriented research; electronic health record and data for research; population-based studies in medicine; epidemiology; telehealth/telemedicine; emergency medicine; insurance benefit design; chronic condition care; natural language processing and machine learning; social networking and its determinants of health; health disparities and social determinants of health.

Healthcare Systems and Value Research: Health statistics; health care outcome research; evaluation and survey methods; health system and service research; health care policy research; health economics research; large database analysis; private health insurance/Medicaid and Medicare; learning laboratory development; health disparities and social determinants of health.

Health Care Research Training: Clinicians with knowledge of health policy; Medicare and Medicaid;

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.