

to complete the baseline survey and three quarterly surveys, regardless of how the respondent chooses to complete it (*i.e.*, self-administered

online or NASTAD staff-administered by phone or videoconferencing). CDC requests OMB approval for an estimated 233 annual burden hours. There is no

cost to survey participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondent | Form | Number of respondents | Number of responses per respondent | Average burden per response (hours) |
|------------------------------|---|-----------------------|------------------------------------|-------------------------------------|
| All participating SSPs | Strengthening Syringe Services Programs Baseline Survey. | 200 | 1 | 25/60 |
| All participating SSPs | Strengthening Syringe Services Programs Quarterly Survey. | 200 | 3 | 15/60 |

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Board of Scientific Counselors, National Center for Injury Prevention and Control

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of open and closed meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC). This meeting will take place in person and virtually and is partially open to the public.

DATES: The meeting will be held on June 5, 2024, from 1 p.m. to 4 p.m., EDT (Closed); and June 6, 2024, from 10 a.m. to 3:30 p.m., EDT (Open). The public comment period will be at the end of the open session of the meeting on June 6, 2024, from 3:10 p.m. to 3:25 p.m., EDT.

ADDRESSES: Centers for Disease Control and Prevention, Chamblee Campus, Building 106, Conference Room 1-B, 4770 Buford Highway NE, Atlanta, Georgia 30341. The conference room will have seating for approximately 100 people for the open session of the meeting.

Please note that the meeting location is a federal facility and in-person access is limited to United States citizens unless prior authorizations, taking up to 30 to 60 days, have been made. Visitors must follow all directions for access to CDC facilities. Directions for visitors to CDC, including safety requirements related to COVID-19, are available at <https://www.cdc.gov/screening/visitors.html>.

If you wish to attend the open session of the meeting in person, please submit a request by email to Mrs. Tonia Lindley at TLindley@cdc.gov at least 5 business days in advance of the meeting.

If you wish to attend the open session of the meeting virtually, please register in advance by accessing the link at: https://cdc.zoomgov.com/webinar/register/WN_X5RXABmES3u_tsbMjdSjkg. Instructions to access the Zoom virtual meeting will be provided in the link following registration.

FOR FURTHER INFORMATION CONTACT:

Christopher R. Harper, Ph.D., Designated Federal Officer, Board of Scientific Counselors, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S-1069, Atlanta, Georgia 30341. Telephone: (404) 718-8330; Email: ncipcbsc@cdc.gov.

SUPPLEMENTARY INFORMATION: Portions of the meeting referenced above will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention (CDC), pursuant to 5 U.S.C. 1009(d) (Pub. L. 92-463, as amended).

Purpose: The Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC) will: (1) conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific

institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes and strategies related to the prevention of injury, overdose, and violence; (2) assist States and other entities in preventing intentional and unintentional injuries, and to promote health and well-being; and (3) make recommendations of grants and cooperative agreements for research and prevention activities related to injury, overdose, and violence. The BSC, NCIPC makes recommendations regarding policies, strategies, objectives, and priorities and reviews progress toward injury, overdose, and violence prevention. The Board also provides advice on the appropriate balance of intramural and extramural research and provides guidance on the needs, structure, progress, and performance of intramural programs. Further, the Board provides guidance on extramural scientific program matters. Additionally, the Board provides second-level scientific and programmatic review of applications for research grants, cooperative agreements, and training grants related to injury, overdose, and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Board also provides feedback and input on strategic plans, resources, and priority publications related to injury, overdose, and violence prevention.

Matters to be Considered: The closed session of the meeting (Day 1) will focus on the secondary peer review of extramural research grant applications received in response to three (3) Notices of Funding Opportunity: RFA-CE-22-003—“Rigorously Evaluating Programs and Policies to Prevent Child Sexual Abuse (CSA)””; RFA-CE-24-012—“Rigorous Evaluation of Policy-Level Interventions to Prevent Overdose (R01)””; and RFA-CE-24-030—“Research Grants for Preventing

Violence and Violence Related Injury (R01).” The open session of the meeting (Day 2) will include discussions on Enhancing CDC’s Efforts to Promote Mental Health and Reduce Overdose and Suicide; CDC’s New Behavioral Health Coordinating Unit; the 2024 National Strategy for Suicide Prevention and Action Plan; Updated Sexual Violence Research Priorities; Leveraging High-Quality Data from the Violence Against Children and Youth Survey to Demonstrate Reductions in Population Prevalence of Violence against Children; and Division of Overdose Prevention Portfolio Review, 2018–2023; Informing the 2025 Update to the Overdose Prevention Research Priorities. Agenda items are subject to change as priorities dictate.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–1984; FDA–2022–E–1986]

Determination of Regulatory Review Period for Purposes of Patent Extension; JEMPERLI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for JEMPERLI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by July 12, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 12, 2024. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 12, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 Nos. FDA–2022–E–1984 and FDA–2022–E–1986 for “Determination of Regulatory Review Period for Purposes of Patent Extension; JEMPERLI.” 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 § 10.20 (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.