SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled ''Evaluating the Pressor Effects of Drugs.'' This public workshop is convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA. The purpose of this public workshop is to bring the stakeholder community together to discuss the premarketing assessment of a drug's effect on blood pressure. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Agency staff will present findings related to the use of ambulatory blood pressure monitoring to assess treatment effects.

DATES: The public workshop will be held on Monday, February 4, 2019 from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at 1777 F Street NW, Washington, DC 20006. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.*

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4166, Silver Spring, MD 20903, 301–796–2240, email: *Norman.Stockbridge@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding FDA's assessment of the pressor effects of drugs. Elevated blood pressure is known to increase the risk of stroke, heart attack, and death. The effect of a drug on blood pressure may therefore be an important consideration in benefit-risk assessment. Following FDA's announcement in the **Federal Register** of the availability of a draft guidance for industry entitled ''Assessment of Pressor Effects of Drugs'' (May 31, 2018, 83 FR 25013), FDA is convening this public meeting in collaboration with the Duke-Margolis Center for Health Policy to discuss the Agency's current thinking with expert stakeholders and to consider public comments.

II. Topics for Discussion at the Public Workshop

Topics for discussion during this meeting include:

- Risk associated with blood pressure change
- Aspects and FDA analyses related to ambulatory blood pressure monitoring
- Evaluating a drug's effect on blood pressure and understanding the optimal regulatory approach to assigning risk

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by Thursday, January 31, 2019, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. Duke-Margolis will post on its website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (202–791–9561, email: *sarah.supsiri@duke.edu*) no later than November 29, 2018.

Streaming webcast of the public workshop: This public workshop will be webcast live. Persons interested in viewing the live webcast may register ahead of the event by visiting *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.* The live webcast will also be available at the website above on the day of the event without preregistration. Archived video footage will be available at the Duke-Margolis website following the workshop.

All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website *https://healthpolicy.duke.edu/events/evaluating-pressor-effects-drugs-ambulatory-blood-pressure-monitoring-studies.*

Dated: November 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24961 Filed 11–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No.: DHS–2018–0063]

First Responders Community of Practice (FRCoP)

AGENCY: Science and Technology Directorate, Department of Homeland Security.

ACTION: 30-Day Notice of Information Collection; request for comment. (Re-instatement of a Currently Approved Collection, 1640–0016).

SUMMARY: The Department of Homeland Security (DHS), Science and Technology (S&T) is proposing to reinstate OMB 1640–0016, an information collection, by inviting the public to comment on the collection: First Responders Community of Practice (FRCoP) User Registration Page (DHS Form 10059 (9/09)). The FRCoP web based tool collects profile information from first responders and select authorized non-first responder users to facilitate networking and formation of online communities. All users are required to authenticate prior to entering the site. In addition, the tool provides members the capability to create wikis, discussion threads, blogs, documents, etc., allowing them to enter and upload content in accordance with the site's Rules of Behavior. Members are able to participate in threaded discussions and comment on other members' content. The FRCoP program is responsible for providing a collaborative environment for the first responder community to share information, best practices, and lessons learned. The Homeland Security Act of 2002 established this requirement. Interested persons may receive a copy of the collection by contacting the DHS S&T Paperwork Reduction Act (PRA) Coordinator.

DATES: Comments are encouraged and accepted until December 17, 2018.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0063, at:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Mail and hand delivery or commercial delivery:* Science and

Technology Directorate, ATTN: Chief Information Office—Mary Cantey, 245 Murray Drive, Mail Stop 0202, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number DHS–2018–0063. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: DHS/S&T/FRG System Owner: Marc Caplan, *Marc.Caplan@HQ.DHS.GOV,* (202) 254–6134 (Not a toll free number).

SUPPLEMENTARY INFORMATION: DHS, in accordance with the PRA (6 U.S.C. 193), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collection of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provides the requested data in the desired format. DHS is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Homeland Security is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: First Responders Community of Practice User Registration Page (DHS Form 10059 (9/09)).

Prior OMB Control Number: 1640–0016.

Prior ***Federal Register*** *Document:* 2018–0035, August 2, 2018.

Type of Review: An extension of an information collection.

Respondents/Affected Public: Federal, State, Local, and Tribal Governments.

Frequency of Collection: Once per respondent.

Average Burden per Response: 30 minutes.

Total Estimated Number of Annual Responses: 2,000.

Total Estimated Number of Annual Burden Hours: 1,000.

Gregg Piermarini,

Deputy Chief Information Officer, Science and Technology Directorate.

[FR Doc. 2018–24907 Filed 11–14–18; 8:45 am]

BILLING CODE 9110–9F–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2018–0038]

Science and Technology Collection of Qualitative Feedback

AGENCY: Science and Technology Directorate (S&T), Department of Homeland Security (DHS).

ACTION: 60-Day notice of information collection; new request for comment.

SUMMARY: S&T will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery.

DATES: Comments are encouraged and accepted until January 14, 2019.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0038, at:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Mail and hand delivery or commercial delivery:* Science and Technology Directorate, ATTN: Chief Information Office—Mary Cantey, 245 Murray Drive, Mail Stop 0202, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number DHS–2018–0038. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: DHS/S&T/OCIO Program Manager: Mary Cantey, *Mary.K.Cantey@hq.dhs.gov* or 202–254–5367 (Not a toll free number).

SUPPLEMENTARY INFORMATION: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the S&T's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between S&T and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of S&T's program management. Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results. DHS, in accordance with the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. DHS is soliciting comments on the proposed Information Collection Request (ICR) that is described below. DHS is