800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Timothy McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6426, Silver Spring, MD 20993–0002, 240–402–0477; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–4548, *Amanda.Roache@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, regulatory authorities and industry associations from around the world have participated in many important initiatives to promote international harmonization of regulatory requirements under the ICH. FDA has participated in several ICH meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and reduce differences in technical requirements for drug development among regulatory agencies.

ICH was established to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; FDA; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers. The Assembly is responsible for the endorsement of draft guidelines and adoption of final guidelines. FDA publishes ICH guidelines as FDA guidance.

In the **Federal Register** of December 24, 1997 (62 FR 67377), FDA published a notice announcing the availability of the ICH guidance for industry entitled ''Q3C Impurities: Residual Solvents.'' The guidance makes recommendations as to what amounts of residual solvents are considered toxicologically acceptable for some residual solvents, or permitted daily exposure. Upon issuance in 1997, the text and appendix 1 of the guidance contained several tables and a list of solvents categorizing residual solvents by toxicity, classes 1 through 3, with class 1 being the most toxic. The ICH Quality Expert Working Group (EWG) agreed that the PDEs could be modified if reliable and more relevant toxicity data were brought to the attention of the group and the modified PDE could result in a revision of the tables and list.

In 1999, ICH instituted a Q3C maintenance agreement and formed a maintenance EWG (the Q3C EWG). The agreement provided for the revisitation of solvent PDEs and allowed for minor changes to the tables and list that include the existing PDEs. The agreement also provided for new solvents and PDEs that could be added to the tables and list based on adequate toxicity data. In the **Federal Register** of February 12, 2002 (67 FR 6542), FDA briefly described the process for proposing future revisions to the PDEs. In the same notice, the Agency announced its decision to remove the link to the tables and list in the Q3C guidance and create a stand-alone document entitled ''Q3C: Tables and List'' to facilitate making changes recommended by ICH; the document is available at *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073395.pdf.* ''Q3C: Tables and List'' was updated in January 2017 to include the recommended PDE for triethylamine and methylisobutylketone.

In March 2020, the ICH Assembly endorsed the draft PDEs for three solvents—2-methyltetrahydrofuran, cyclopentyl methyl ether, and tert-butyl alcohol—and agreed that the guidance should be made available for public comment. The draft guidance is the product of the ICH Q3C EWG. Comments on this draft will be considered by FDA and the Quality EWG.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on the PDEs for 2-methyltetrahydrofuran, cyclopentyl methyl ether, and tert-butyl alcohol. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: May 19, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11280 Filed 5–26–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0421]

Agency Father Generic Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork

Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 27, 2020.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0421–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: ASPE Generic Clearance for the Collection of Qualitative Research and Assessment.

OMB No.: 0990–0421.

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting an extension for their generic clearance for purposes of conducting qualitative research. ASPE conducts qualitative research to gain a better understanding of emerging health policy issues, develop future intramural and extramural research projects, and to ensure HHS leadership, agencies and offices have recent data and information to inform program and policy decision-making. ASPE is requesting approval for at least four types of qualitative research: (a) Interviews, (b) focus groups, (c) questionnaires, and (d) other qualitative methods.

ASPE's mission is to advise the Secretary of the Department of Health and Human Services on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy. ASPE leads special initiatives, coordinates the Department's evaluation, research and demonstration activities, and manages cross-Department planning activities such as strategic planning, legislative planning, and review of regulations. Integral to this role, ASPE will use this mechanism to conduct qualitative research, evaluation, or assessment, conduct analyses, and understand needs, barriers, or facilitators for HHS-related programs.

Need and Proposed Use of the Information: ASPE is requesting comment on the burden for qualitative research aimed at understanding emerging health and human services policy issues. The goal of developing these activities is to identify emerging issues and research gaps to ensure the successful implementation of HHS programs. The participants may include health and human services experts; national, state, and local health or human services representatives; public health, human services, or healthcare providers; and representatives of other health or human services organizations. The increase in burden from 747 in 2014 to 1,300 respondents in 2017 reflects an increase in the number of research projects conducted over the estimate in 2014.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Health Policy Stakeholder	Qualitative Research	1,300	1	1	1,300

Dated: May 13, 2020.

Sherrette A. Funn,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2020–11289 Filed 5–26–20; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Step Up for Substance Use Disorders (SUD): A Drug Target Initiative for Scientists Engaged in Fundamental Research (U18—Clinical Trial Not Allowed).

Date: June 9, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neurosciences Center Building, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Trinh T. Tran, Scientific Research Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, (301) 827–5843, *trinh.tran@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 20, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11275 Filed 5–26–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.