In table 1, we estimate 1,457 sponsors of clinical trials of human drugs will develop approximately 1,457 quality management systems per year (as described in ICH E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We assume it will take respondents 60 hours to develop and implement each quality management system, totaling 87,420 hours annually. The estimated number of sponsors who will develop a quality management system as described in ICH E6(R2) is based on the number of annual investigational new drug applications (INDs) and new drug applications (NDAs) submitted to FDA's Center for Drug Evaluation and Research. The estimated number of hours we assume it takes to develop a quality management system is based on informal interactions with industry about activities that support drug development plans.

In table 2, we estimate 1,457 sponsors of clinical trials of human drugs will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in the clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 4.6 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 20,106 reporting hours annually. These estimates are based on our past experiences with INDs and NDAs.

In table 3, we estimate 423 sponsors of clinical trials of biological products will develop 423 quality management systems per year (as described in ICH E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We assume it will take respondents 60 hours to develop and implement each quality management system, totaling 25,380 hours annually. The estimated number of sponsors who will develop a quality management system as described in ICH E6(R2) is based on the number of annual INDs and biologics license applications (BLAs) submitted to FDA's Center for Biologics Evaluation and Research. The estimated number of hours we assume it takes to develop a quality management system is based on informal interactions with industry about activities that support drug development plans.

In table 4, we estimate 423 sponsors of clinical trials of biological products will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in a clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 660 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 1,980 reporting hours annually. As described previously, these estimates are based on past experiences with INDs and BLAs submitted to FDA.

Although our estimated burden for the information collection reflects an overall decrease of 433 hours, we have increased the estimate by 861 records. We are making this adjustment based on an increase in the number of submissions we received over the last few years.

Dated: August 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19113 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The National Institutes of Health (NIH) Sexual & Gender Minority Research Listening Session

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) Sexual & Gender Minority Research Office (SGMRO) will be holding a listening session with the Sexual & Gender Minority (SGM) community. The primary objectives of the NIH's listening session are: (1) To hear from community stakeholders about what issues are on their minds with regard to SGM-related research and related activities at the NIH, and (2) to use these individual viewpoints to help inform the development of the NIH SGM Research FY 2021–2025 strategic plan. The goal is to hold a listening session every year, to provide different SGM focused organizations an opportunity to join a session in person.

DATES: The listening session with the SGM community will be held on October 22, 2019 at 11:00 a.m. ET.

ADDRESSES: The meeting will be held at the National Institutes of Health, Building 1, Wilson Hall, Bethesda, MD 20892 for invited participants; the meeting will be open to the public remotely at 1–877–951–0634, Passcode: 6617257#.

FOR FURTHER INFORMATION CONTACT: Karen Parker, Ph.D., MSW, Director, Sexual & Gender Minority Research Office (SGMRO), 6555 Rock Spring Drive, Rm 2SE31K, Bethesda, MD 20817, *klparker@mail.nih.gov,* 301–451–2055.

SUPPLEMENTARY INFORMATION: ''Sexual and gender minority'' is an umbrella term that includes, but is not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, two-spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.

The Sexual and Gender Minority Research Office (SGMRO) coordinates sexual and gender minority (SGM)–related research and activities by working directly with the NIH Institutes, Centers, and Offices. The Office was officially established in September 2015 within the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the Office of the Director.

The SGMRO has the following research-related goals: (1) Expand the knowledge base of SGM health and well-being through NIH-supported research; (2) Remove barriers to planning, conducting, and reporting NIH-supported research about SGM health and well-being; (3) Strengthen the community of researchers and scholars who conduct research relevant to SGM health and well-being; and (4) Evaluate progress on advancing SGM research.

Listening Session Details

The listening session event will be a trans-NIH effort, with representation from several NIH Institutes, Centers, and Offices. The listening session will be open to the public to listen in; comments submitted via email will be accepted post-listening session. Comments, questions, or feedback can be shared with *SGMRO@nih.gov.* SGMRO will invite approximately 20 SGM focused organizations to attend the listening session in-person. Selection of the organizations will be based on the diversity of their missions and efforts.

Dated: August 27, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–19085 Filed 9–4–19; 8:45 am]

BILLING CODE 4140–01–P