Addendum to ICH M7; Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk,'' available at *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*. The notice gave interested persons an opportunity to submit comments by November 27, 2015.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory Agencies in June 2017.

This final guidance provides guidance on acceptable intake limits derived for some chemicals that are considered to be mutagenic carcinogens and are also commonly used in the synthesis of pharmaceuticals or are useful examples to illustrate the principles for deriving compound-specific intakes described in the ICH M7 guidance. This guidance is intended to provide guidance for new drug substances and new drug products during their clinical development and subsequent applications for marketing. The default method from ICH M7 of linear extrapolation from the cancer potency estimate, TD_{50} is used as the primary method to derive the acceptable intakes for carcinogens with likely mutagenic mode of action. After consideration of the comments received, hydroxylamine monograph was deleted from the final guidance. Relevant editorial changes were also made to improve clarity and to incorporate the ICH M7(R1) Addendum guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

Dated: March 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05118 Filed 3–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Changes to the Graduate Psychology Education Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Request for Public Comment on the Graduate Psychology Education Program.

SUMMARY: The Graduate Psychology Education (GPE) Program is authorized by section 756 of the Public Health Service Act and administered by HRSA. The program provides financial support to organizations and institutions that train doctoral-level psychologists. This notice seeks public comment to inform and guide policy and planning associated with the GPE Program.

DATES: Individuals and organizations interested in providing information must submit written comments no later than April 13, 2018. To receive consideration, comments must be received no later than 11:59 p.m. Eastern Time on that date.

ADDRESSES: Interested parties should submit their comments to Cynthia Harne, Public Health Analyst and Project Officer for the GPE Program, Division of Nursing and Public Health, Behavioral and Public Health Branch, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 11N–90C, Rockville, Maryland 20857; phone (301) 443–7661; fax (301) 443–0791; or email *charne@hrsa.gov*. Please include the title of this notice, ''Request for Comment: GPE Program'' in the subject line of the email. Response to this request is voluntary. Responders are free to address any or all of the questions listed below. This request is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the federal government. All submitted comments will be available to the public by request in their entirety.

FOR FURTHER INFORMATION CONTACT: Cynthia Harne, Public Health Analyst, Division of Nursing and Public Health, Behavioral and Public Health Branch, Bureau of Health Workforce, Health Resources and Services Administration, at the contact information listed above.

SUPPLEMENTARY INFORMATION: The GPE Program was established in 2002 to assist American Psychological Association (APA) accredited doctoral programs and internships in meeting the costs to plan, develop, operate, or maintain graduate psychology education programs to train health service psychologists to work with vulnerable populations. The purpose of the current program (Funding Opportunity Announcement HRSA–16–059) is to prepare doctoral-level psychologists to provide behavioral health care, including mental health and substance use disorder prevention and treatment services, in settings that provide integrated primary and behavioral health services to underserved and/or rural populations. The program is designed to foster an integrated and interprofessional approach to address access to behavioral health care for underserved and/or rural populations.

Given the value of feedback from stakeholders, HRSA is seeking comments from interested parties including current and former grant recipients, former applicants to the program, doctoral psychology schools and programs, and health care delivery sites that provide behavioral health experiential training to students. The purpose is to identify doctoral-level health service psychologist training needs, salient issues and challenges in the delivery of behavioral health services, including substance use, and to provide individual recommendations to maximize the reach, capacity and success of the GPE Program in addressing Opioid Use Disorder and other behavioral health concerns. This information may be used by HRSA will consider the input as it develops future technical assistance and funding opportunities, and strategic planning to meet the training demands of the behavioral health workforce.

Graduate Psychology Program in FY 2019—Proposal for Public Comment

HRSA seeks comments on how the GPE program (and the students it supports) can help address the opioid epidemic. In your comments, please address one or more of the following:

1. What do you see as the most prevalent behavioral health and public health trends or concerns that should be addressed in developing the psychologist workforce?

2. What do you see as the role for doctoral-level health psychologists in addressing the opioid epidemic?

3. What are the didactic and experiential training needs in preparing

doctoral-level health psychologists to effectively address substance use disorder (SUD) including opioid use?

4. If your institution has received in the past, is currently receiving, or applied for but did not receive GPE funding, what features or requirements of the GPE Program were easy to incorporate and/or beneficial in the development and implementation of your program, and which ones posed challenges? Please provide specific examples. If your institution did not apply for GPE funding, what features or requirements of the GPE Program posed challenges to the development of your program or dissuaded your institution from applying to the program?

5. What health workforce training strategies within the experiential training sites could the GPE Program address to increase access to integrated behavioral health/primary care services in underserved and/or rural populations? Please provide a description of practice.

6. Type and site including geographic locations (*e.g.,* large health system, private practices, group practices, Federally Qualified Health Center, etc.).

Dated: March 8, 2018.

George Sigounas,

Administrator.

[FR Doc. 2018–05064 Filed 3–13–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary (OS), Department of Health and Human Services (HHS).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, HHS is altering an existing department-wide system of records, ''Records About Restricted Dataset Requesters,'' System Number 09–90–1401. This system of records covers records about individuals within and outside HHS who request restricted datasets and software products from HHS (*e.g.,* for health-related scientific research and study purposes), when HHS maintains the requester records in a system from which they are retrieved directly by an individual requester's name or other personal identifier. The system of records currently covers records maintained by three HHS Operating Divisions. It is being altered to include records maintained by a fourth Operating Division, the National Institutes of Health (NIH), and to include three revised and five new routine uses, some of which will apply to all records in the system and some of which will apply to only NIH's records. The alterations affect the System Locations, Legal Authorities, Purposes, Retention, System Manager, and Routine Uses sections of the System of Records Notice (SORN).

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is applicable March 14, 2018, subject to a 30-day period in which to comment on the new and revised routine uses, described below. Please submit any comments by April 13, 2018.

ADDRESSES: The public should submit written comments, by mail or email, to Beth Kramer, HHS Privacy Act Officer, 200 Independence Avenue SW, Suite 729H, Washington, DC 20201, or *beth.kramer@hhs.gov.* Comments received will be available for review at this location without redaction, unless otherwise advised by the commenter. To review comments in person, please contact Beth Kramer at *beth.kramer@hhs.gov* or (202) 690–6941.

FOR FURTHER INFORMATION CONTACT: General questions about the system of records should be submitted by mail, email, or phone to Beth Kramer, HHS Privacy Act Officer, at 200 Independence Avenue SW, Suite 729H, Washington, DC 20201; *beth.kramer@hhs.gov* or (202) 690–6941.

SUPPLEMENTARY INFORMATION: This department-wide system of records was established April 2015 (see 80 FR 17447) and has not been previously revised. It covers records about individuals within and outside HHS who request restricted datasets and software products from HHS, when HHS maintains the requester records in a system from which they are retrieved directly by an individual requester's name or other personal identifier. It currently includes records maintained by three HHS Operating Divisions. It is being revised to add records maintained by a fourth Operating Division, the National Institutes of Health (NIH), which NIH plans to begin retrieving directly by personal identifier, and to include three revised and five new routine uses, some of which will apply to all records in the system and some of which will apply to only NIH's records.

The alterations made to add NIH's records affect the System Location, Legal Authorities, Purposes, Retention, System Manager, and Routine Uses sections of the System of Records Notice (SORN). One new purpose was added to the ''Purposes'' section, which will apply to all records, not just NIH records, stating that records may be used to evaluate accomplishment of HHS functions related to the purposes of this system of records and to evaluate performance of contractors utilized by HHS to accomplish those functions. Minor wording and formatting changes have been made throughout the SORN to conform to the SORN template prescribed in OMB Circular A–108. The new and revised routine uses are as follows:

- Routine use 1 has been revised to add ''including ancillary functions, such as compiling reports and evaluating program effectiveness and contractor performance.''
- Routine use 2 has been revised to add ''including ancillary functions'' and to add a last sentence stating: ''For example, disclosure may be made to qualified experts not within the definition of HHS employees as prescribed in HHS regulations, for opinions as a part of the controlled data access process.''
- Routine use 10 has been revised to use wording prescribed in OMB Memorandum M–17–12 issued January 3, 2017.
- Routine uses 11 through 15 are new. Routine use 11 is a new routine use prescribed by OMB Memorandum M–17–12.

''Restricted'' datasets and software products are those that HHS makes affirmatively available to qualified members of the public but provides subject to restrictions, because they contain identifiable data and/or anonymized data that has the potential, when combined with other data, to identify the particular individuals, such as patients or providers, whose information is represented in the data. The datasets and products are made available through an on-line or paper-based ordering and delivery system that provides them to qualified requesters electronically or by mail.

The restrictions are necessary to protect the privacy of individuals whose information is represented in the datasets or software products. The restrictions typically limit the data requester to using the data for research, analysis, study, and aggregate statistical reporting; prohibit any attempt to identify any individual or establishment represented in the data; and require specific security measures to safeguard the data from unauthorized access. HHS is required by law to impose, monitor, and enforce the restrictions (see, for example, provisions in the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), 44 U.S.C. 3501 at note). To impose and