2. Besides prescription medical treatments, are there other treatments or therapies that you currently use to address your OUD? If so, please describe. How well do these treatments or therapies help address the effects of OUD that are most bothersome to you?

3. Of all treatments, therapies, or other steps that you have taken to address your OUD, what have you found to be most effective in helping you manage your OUD?

4. What are the biggest factors that you take into account when making decisions about seeking out or using treatments for OUD?

5. What specific things would you look for in an ideal treatment for OUD?

6. If you had the opportunity to consider participating in a clinical trial studying experimental treatments for OUD, what factors would you consider when deciding whether or not to participate?

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit *https://www.eventbrite.com/e/public-meeting-for-patient-focused-drug-development-on-opioid-use-disorder-oud-registration-42531194949.* Please register by April 11, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Persons without access to the internet can call 240–402–6525 to register. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by April 11, 2018. 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 time and space permit, onsite registration on the day of the public meeting will be provided beginning at 9 a.m.

If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) no later than April 11, 2018.

Panelist Selection: Patients or patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients or patient representatives also will be asked to send *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by April 2, 2018. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Open Public Comment: There will be time allotted during the meeting for open public comment. Sign-up for this session will be on a first-come, first-serve basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the webcast by visiting *https://www.eventbrite.com/e/public-meeting-for-patient-focused-drug-development-on-opioid-use-disorder-oud-registration-42531194949.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm591290.htm.*

Dated: March 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05119 Filed 3–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0740]

M7(R1): Assessment and Control of Deoxyribonucleic Acid Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled ''M7(R1): Assessment and Control of Deoxyribonucleic Acid (DNA) Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' This guidance updates and replaces the May 2015 guidance for industry ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' This guidance finalizes the draft guidance ''M7(R1) Addendum to ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk,'' issued September 28, 2015 (80 FR 58261).

The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. This M7(R1) document provides guidance on acceptable intakes (AIs), or permissible daily exposures (PDEs), derived for some chemicals that are considered to be mutagens and 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 ICH M7. This document is intended to provide guidance for new drug substances and new drug products during their clinical development and subsequent applications for marketing.

DATES: The announcement of the guidance is published in the **Federal Register** on March 14, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 No. FDA–2018–D–0740 for ''M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk.'' Received comments 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 office between 9 a.m. and 4 p.m., Monday through Friday.

• 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 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.gpo.gov/fdsys/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.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Aisar Atrakchi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4118, Silver Spring, MD 20993–0002, 301–796–1036; or Anne Pilaro, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 4025, Silver Spring, MD 20993–0002, 240–402–8341.

Regarding the ICH: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993–0002, 301–796–4548.

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 FDA is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then 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; the 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 September 28, 2015 (80 FR 58261), FDA published a notice announcing the availability of a draft guidance entitled ''M7(R1)

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