301–796–1125, email: *Tamy.Kim@fda.hhs.gov.*

## I. Background

FDA announces the establishment of a public docket and a public listening session for the OCE. As a part of 21st Century Cures Act (Cures Act), section 3073, the ''Secretary shall establish one or more Intercenter Institutes within the Agency for a major disease area or areas'' and ''shall provide a period for public comment during the time that each Institute is being implemented'' (section 1014 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 399g)). The OCE is the Agency's first Intercenter Institute.

Under the Cures Act, the purpose of an Intercenter Institute is to coordinate activities among FDA Centers, applicable to the major disease area, including coordination of staff, streamlining of review activities, promotion of scientific programs, staff recruitment and development, enhancement of interactions, and facilitation of collaborative relationships within the Department of Health and Human Services.

FDA is establishing a docket for public comment for written comments and will hold a listening session for parties who are interested in commenting verbally. This will serve as the public comment period identified under the Cures Act (section 1014(b) of the FD&C Act).

## II. Topics for Discussion at the Public Meeting

The docket for public comments and public listening session will discuss the structure, function, regulatory purview, and activities of the OCE and solicit comments regarding how the public would like the OCE to be structured and what function the OCE should serve as an Intercenter Institute.

The public docket and listening session are intended to be a part of the period of public comment during the implementation of the Oncology Center of Excellence, the first Intercenter Institute at FDA. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the meeting, and the background material will be posted on FDA's Web site after the meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced meeting detail cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's Oncology Center of Excellence Web site at *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/oce/ucm544496.htm* and scroll down to the appropriate meeting link.

## III. Participating in the Public Meeting

*Registration:* To register for the public meeting, persons interested in attending this public meeting must register online by February 15, 2018. Please visit the following Web site to register: *https://fdaoce.formstack.com/forms/ocelisteningsession.* 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 meeting must register by February 15, 2018, midnight Eastern Time. 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 need special accommodations due to a disability, please contact Tamy Kim (see **FOR FURTHER INFORMATION CONTACT**) no later than March 1, 2018.

*Requests for Oral Presentations:* During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by March 1, 2018. All requests to make oral presentations must be received by the close of registration on February 15, 2018. If selected for presentation, any presentation materials must be emailed to Tamy Kim (see **FOR FURTHER INFORMATION CONTACT**) no later than March 12, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Dated: December 4, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–26440 Filed 12–7–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–D–5767]**

### Abbreviated New Drug Applications for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of Recombinant Deoxyribonucleic Acid Origin; Draft Guidance for Industry; Availability; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of October 3, 2017. In the notice of availability, FDA requested comments on the draft guidance for industry entitled ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' The Agency is taking this action in response to public interest in the draft guidance and to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the notice of availability published October 3, 2017 (82 FR 46075). Submit either electronic or written comments on the draft guidance by February 4, 2018, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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–2017–D–5767 for ''Abbreviated New Drug Applications for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of Recombinant Deoxyribonucleic Acid Origin; Draft Guidance for Industry; Availability.'' 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 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.

**FOR FURTHER INFORMATION CONTACT:** Gail Schmerfeld, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1672, Silver Spring, MD 20993–0002, 301–796–9291, *Gail.Schmerfeld@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 3, 2017, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry entitled ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the submission of ANDAs for certain highly purified synthetic peptide drug products that refer to listed drugs of rDNA origin. 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 draft guidance is not subject to Executive Order 12866.

Based on public interest in the draft guidance, FDA is extending the comment period for the notice of availability for 60 days, until February 4, 2018. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

Dated: December 4, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–26436 Filed 12–7–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Request for Information on the Office of Disease Prevention Strategic Plan for Fiscal Years (FY) 2019–2023

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This Request for Information (RFI) is intended to gather broad public input on the FY 2019–2023 Strategic Plan for the Office of Disease Prevention (ODP) in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), National Institutes of Health (NIH). The ODP invites input from prevention researchers in academia and industry, health care professionals, patient advocates and advocacy organizations, scientific or professional organizations, federal agencies, and other interested members of the public. Organizations are strongly encouraged to submit a single response that reflects the views of their organization and membership as a whole.

**DATES:** The ODP's Request for Information is open for public comment for a period of 45 days. Comments must be received by January 22, 2018 to ensure consideration.

**ADDRESSES:** Comments must be submitted electronically using the web-based form available at *https://prevention.nih.gov/strategic-plan/request-for-information.*

**FOR FURTHER INFORMATION CONTACT:** Please direct all inquiries to Wilma Peterman Cross, M.S.; Deputy Director, Office of Disease Prevention, National Institutes of Health; Phone: 301–827–5561; email: *prevention@mail.nih.gov.*

**SUPPLEMENTARY INFORMATION:** To ensure consideration, responses must be submitted electronically using the web-based form available at *https://prevention.nih.gov/strategic-plan/request-for-information.* The web form will provide confirmation of response submission, but respondents will not receive individualized feedback. All respondents are encouraged to sign up for the ODP email list at *http://prevention.nih.gov/subscribe* to receive information related to Office activities, including updates on the development and release of the final strategic plan.

The mission of the Office of Disease Prevention (ODP) is to improve the public health by increasing the scope, quality, dissemination, and impact of prevention research supported by the