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Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of Recombinant Deoxyribonucleic Acid Origin; Draft Guidance for Industry; Availability.''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

NIH. The ODP fulfills this mission by providing leadership for the development, coordination, and implementation of prevention research in collaboration with NIH Institutes, Centers, and Offices and other partners. The first ODP strategic plan was released in February 2014 and charted new directions and, at the same time, built upon and expanded existing programs. The Office has made considerable progress on the priorities identified in the initial plan, and the ODP remains committed to playing an integral role in advancing trans-NIH prevention-related activities. Input received from this Request for Information will inform the development of the final FY 2019–2023 Strategic Plan, which will outline activities coordinated by the ODP to assess, facilitate, and stimulate research in disease prevention, and disseminate the results of this research to improve public health.

The ODP is seeking input on the following strategic priorities:

- Strategic Priority I: Systematically monitor NIH investments in prevention research and the progress and results of that research.
- Strategic Priority II: Identify prevention research areas for investment or expanded effort by the NIH.
- Strategic Priority III: Promote the use of the best available methods in prevention research and support the development of better methods.
- Strategic Priority IV: Promote collaborative prevention research projects and facilitate coordination of such projects across the NIH and with other public and private entities.
- Strategic Priority V: Advance the understanding of prevention research, increase the availability of prevention research resources and programs, and enhance ODP's stakeholder engagement.

The ODP is also seeking input on the following questions:

- What new strategic priorities should the ODP consider adding to its plan?
- What opportunities or challenges in disease prevention research and methods could the ODP help to address?
- Who should the ODP partner with to address pressing needs in disease prevention research and methods?
- What areas transcend disease prevention research that the ODP should consider as it develops its new plan?

The definition of prevention research used by the ODP to guide its work and decision-making encompasses research designed to yield results directly applicable to identifying and assessing risk, developing interventions for preventing or ameliorating high-risk behaviors and exposures, the occurrence of a disease, disorder, or injury, or the progression of detectable but asymptomatic disease. Prevention research also includes research studies to develop and evaluate disease prevention, health promotion recommendations, and public health programs. The ODP definition of prevention includes the following categories of research:

- Identification of modifiable risk and protective factors for diseases/disorders/injuries
- Studies on assessment of risk, including genetic susceptibility
- Development of methods for screening and identification of markers for those at risk for onset or progression of asymptomatic diseases/disorders, or those at risk for adverse, high-risk behaviors/injuries
- Development and evaluation of interventions to promote health for groups of individuals without recognized signs or symptoms of the target condition
- Translation of proven effective prevention interventions into practice
- Effectiveness studies that examine factors related to the organization, management, financing, and adoption of prevention services and practices
- Methodological and statistical procedures for assessing risk and measuring the effects of preventive interventions.

Responses to this RFI are voluntary and may be submitted anonymously. Please do not include any personally identifiable or other information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in responses. Comments submitted will be compiled for discussion and incorporated into the strategic plan as appropriate. Any personal identifiers (personal names, email addresses, etc.) will be removed when responses are compiled.

This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the United States (U.S.) Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any information submitted or for use of that information.

Dated: December 1, 2017.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2017–26453 Filed 12–7–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Amy Williams, Director of the Office of Advocacy Relations (OAR), NCI, NIH, 31 Center Drive, Bldg. 31, Room 10A28, MSC 2580, Bethesda, MD 20892, call non-toll-free number 240–781–3406, or email your request, including your address, to *amy.williams@nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on October 2, 2017, page 45870 (82 FR 45870) and allowed 60 days for public comment. No public comments were received. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National