

recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Pujita Vaidya (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients 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. They will be asked to send a brief summary of responses to the topic questions to [PatientFocused@fda.hhs.gov](mailto:PatientFocused@fda.hhs.gov). Panelists will be notified of their selection a few days after the close of registration on September 10, 2014. FDA will try to accommodate all patients and patient advocate participants who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

#### IV. Comments

Submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by November 26, 2014. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### V. Transcripts

As soon as a transcript is available, FDA will post it at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm395774.htm>.

Dated: July 2, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-15871 Filed 7-7-14; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0233]

#### Center for Drug Evaluation and Research; Use of Innovative Packaging, Storage, and/or Disposal Systems To Address the Misuse and Abuse of Opioid Analgesics; Reopening of the Comment Period

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

**ACTION:** Notice, reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the notice entitled "Center for Drug Evaluation and Research; Use of Innovative Packaging, Storage, and/or Disposal Systems to Address the Misuse and Abuse of Opioid Analgesics," which published in the **Federal Register** of April 9, 2014. FDA is reopening the comment period to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments by August 7, 2014.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Colleen Brennan, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Surveillance and Epidemiology, 10903 New Hampshire Ave., Bldg. 22, Rm. 4410, Silver Spring, MD 20993-0002, 301-796-2316, email: [Colleen.Brennan@fda.hhs.gov](mailto:Colleen.Brennan@fda.hhs.gov), with the subject line identified as "Packaging Abuse Deterrence Strategies."

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of April 9, 2014 (79 FR 19619), FDA announced the establishment of a docket to receive suggestions, recommendations, and comments on innovative packaging, storage and disposal systems, technologies or designs that could be used to prevent or deter misuse and abuse of opioid analgesics by patients and others. In the notice, FDA stated that comments about specific system or technology designs should include a description of the following: (1) Design features and functionality; (2) results of any formative or summative human

factors assessments conducted; (3) applications to date, including information on the effectiveness and acceptability of those applications (with literature references or other documentation); (4) recommendations for how the system/technology design could be applied or adapted (either alone and/or in combination with other systems/technologies) to help prevent or deter misuse and abuse, and any limitations of that application; (5) specific problems that could be addressed (e.g., serious complications such as addiction or overdose due to improper dosage and/or administration, improper disposal, accidental use by someone for whom the medication was not prescribed); and (6) to the extent possible, considerations for implementation into routine dispensing and clinical use (e.g., how the solution would impact the workflow in a retail pharmacy).

To help FDA prioritize among proposed approaches, the Agency is also interested in receiving feedback about methods that could be used to assess a system or technology's potential abuse-deterrent characteristics and real-world impact (e.g., actual ability to prevent or deter misuse and abuse, effect on access for appropriate patients, patient confidentiality, burden on the healthcare system, feasibility of implementation, whether the design could create unintended medication errors). Finally, FDA is interested in receiving feedback on methods for encouraging further research and development in this area, and, if promising technologies are identified, incentivizing the pharmaceutical industry (e.g. via patent extensions) to adopt such technologies.

Interested persons were given until June 9, 2014, to submit comments. On our own initiative, the Agency is reopening the comment period until August 7, 2014 to allow interested persons additional time to submit comments. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

##### II. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 1, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-15809 Filed 7-7-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request; Specimen Resource Locator (NCI)**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of 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. This proposed information collection was previously published in the **Federal Register** on April 8, 2014 (Vol. 79, P. 19345) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. 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.

**Direct Comments To OMB:** 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: NIH Desk Officer.

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

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Joanne Demchok, Program Director, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, 9609 Medical Center Drive, Rockville, Md. 20892 or call non-toll-free number 240-276-5959 or Email your request, including your address to: *peterjo@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

**Proposed Collection:** Specimen Resource Locator, Existing Collection in Use without OMB Control Number, National Cancer Institute (NCI), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The availability of specimens and associated data is critical to increase our knowledge of cancer biology, and to translate important research discoveries to clinical application. The discovery and validation of cancer prevention markers require access, by researchers, to quality clinical biospecimens. In response, to this need, the National Cancer Institute's (NCI) Cancer Diagnosis Program has developed, and is expanding, a searchable database: Specimen Resource Locator (SRL). The SRL allows scientist in the research community and the NCI to locate specimens needed for their research. The SRL will list all NCI supported repositories and their links. This administrative submission is an on-line form that will collect information to manage and improve a program and its resources for the use of all scientists. This submission does not involve any analysis.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 105.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hour
Private Sector .....	Initial Request .....	70	1	30/60	35
State Government .....	.....	70	1	30/60	35
Federal Government .....	.....	60	1	30/60	30
Private Sector .....	Annual Update .....	20	1	5/60	2
State Government .....	.....	20	1	5/60	2
Federal Government .....	.....	10	1	5/60	1

Dated: July 1, 2014.

**Karla Bailey,**

*NCI Project Clearance Liaison, National Institutes of Health.*

[FR Doc. 2014-15890 Filed 7-7-14; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; Assessment of Oncology Nursing Education and Training in Low and Middle Income Countries (NCI)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed

projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and