that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit (e.g., in early-stage breast cancer, an improvement in disease-free or overall survival), provided that the applicant conducts additional trials or collects additional data after approval to verify and describe the predicted clinical benefit. This guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pCR as a surrogate endpoint that could support approval under the accelerated approval regulations. The guidance provides acceptable definitions of pCR for regulatory purposes. The guidance also describes appropriate patient populations for inclusion in neoadjuvant trials conducted with regulatory intent. Finally, the guidance outlines critical design features of trials for both accelerated approval and confirmation of clinical benefit to support regular approval.

FDA recognizes that despite advances in adjuvant systemic therapy of breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. Developing highly effective new drugs for these populations is an FDA priority. In providing guidance on the use of pCR as a surrogate endpoint that could support accelerated approval in the neoadjuvant setting, FDA hopes to encourage industry innovation and expedite the development and widespread availability of highly effective novel therapies to treat high-risk early-stage breast cancer.

This guidance finalizes the draft guidance issued May 30, 2012 (77 FR 31858). The current version clarifies appropriate trial designs and development strategies to support accelerated approval in the neoadjuvant setting, defines acceptable endpoints for accelerated approval and confirmation of clinical benefit, standardizes the approach to postoperative systemic therapy, includes guidelines for evaluation of the axillary lymph nodes, and provides detailed recommendations for pathology standard operating procedures.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on use of pCR as an endpoint to support accelerated approval of drug and biological products to treat high-risk early-stage breast cancer patient populations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information for special protocol assessments have been approved under OMB control number 0910–0470.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23845 Filed 10–6–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1208]

Laboratory Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Tobacco Products' (CTP) Office of Science is announcing an invitation for participation in its Laboratory Site Tours Program. This program is intended to give CTP staff an opportunity to visit facilities involved in the testing and analysis of tobacco products and tobacco smoke. These visits are intended to provide CTP staff with the opportunity to gain a better understanding of tobacco science and laboratory operations and are not intended as regulatory inspections or facility visits for the purposes of developing Tobacco Product Manufacturing Practice regulations. The purpose of this notice is to invite parties interested in participating in the Laboratory Site Tours Program to submit their requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by December 8, 2014. The request should include a description of your facility, including, as applicable, a list of the types of testing and analyses of tobacco products and tobacco smoke performed. Please specify the physical address(es) of the site(s) for which you are submitting a request, along with a proposed 1-day tour agenda.

ADDRESSES: If your facility is interested in offering a site visit, submit either an electronic request to *http://www.regulations.gov* or a written request to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carolyn Dresler, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, rm. G335, Silver Spring, MD 20993–0002, 240–402–4067, *carolyn.dresler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing.

CTP's Office of Science is conducting the Laboratory Site Tours Program to provide its scientific and regulatory staff the opportunity to gain a better understanding of tobacco science and laboratory operations, to include tobacco product testing and analysis. CTP's goal for the Laboratory Site Tours Program is for its staff to gain: (1) Firsthand exposure to laboratories that perform tobacco product testing and (2)

knowledge of product analyses used by tobacco product manufacturers to ensure product consistency.

II. Description of Site Tours Program

In the Laboratory Site Tours Program, small groups of CTP staff plan to observe the operations of laboratories that perform testing and analyses of tobacco products and tobacco smoke relative to analytical chemistry, microbiology, toxicology, biomarkers of exposure or risk, and analytical method development. Please note that the Laboratory Site Tours Program is not intended to include official FDA inspections of facilities to determine compliance with the FD&C Act or for the purposes of developing Tobacco Product Manufacturing Practice regulations; rather, the program is meant to educate CTP staff and improve their understanding of laboratory testing and analyses used by the tobacco industry.

III. Site Selection

CTP plans to select a wide variety of laboratories that include academic, private, and those affiliated with tobacco manufacturers. All travel expenses associated with the site tours will be the responsibility of CTP. Final site selections will be based on the availability of CTP funds and resources for the relevant fiscal year, as well as the following factors, if applicable: (1) Compliance status of the requesting facility and affiliated firm, (2) whether the requesting facility is in arrears for user fees, and (3) whether the requesting facility or affiliated firm has a significant request or marketing application or submission pending with FDA.

IV. Requests for Participation

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23844 Filed 10–6–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; NIMH Database of Cognitive Training and Remediation Studies (DCTRS) (NIMH)

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 15, 2014, pages 21250–21252 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 Institute of Mental Health (NIMH), 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.

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: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *nimhprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection

NIMH Database of Cognitive Training and Remediation Studies (DCTRS)—New—National Institute of Mental Health (NIMH), National Institute of Health (NIH).

Need and Use of Information Collection: The NIMH Database of Cognitive Training and Remediation Studies (DCTRS) is an integrated database that includes study- and subject-level data from studies of cognitive remediation (CR) in schizophrenia. DCTRS will allow NIMH staff and interested investigators to examine the ways in which various patient characteristics, intervention approaches and features, and treatment combinations affect responses to remediation. The DCTRS Study Information Form and Data Submission Agreement are necessary for the ''Submitter'' to request permission to submit study data to the NIMH DCTRS for general research purposes. The primary use of this information is to collect submitter information and study information for inclusion in the NIMH DCTRS database. The DCTRS data submission agreement includes two forms: (1) The data submission form that includes the terms, agreement, submitter information and certifications, and (2) the study information form which collects de-identified data for each study.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 60.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
Data Submission Agreement	Principal Investigators/Physicians	12	1	5	60