Requests for Oral Comments: During online registration you may indicate if you wish to provide a statement during the Open Public Comment Period. We will do our best to accommodate requests to make public comments based on time allocated for public comment. Individuals and organizations with common interests are urged to consolidate or coordinate their comments, and request time for a joint presentation. Following the close of registration date, we will determine the amount of time allotted to each commenter and the approximate time each oral comment is scheduled to begin; commenters should arrive ahead of their scheduled time in case the agenda moves ahead of schedule so as to be sure not to forfeit their speaking time. All requests to make oral comments must be received by the close of registration on May 1, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Additional information will be made available regarding accessing the Webcast 2 days prior to the public workshop at *http://www.fda.gov/Drugs/NewsEvents/ucm538047.htm.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see ADDRESSES). A link to the transcript will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm538047.htm.*

Dated: April 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–07821 Filed 4–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1989]

Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, in co-sponsorship with the Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium, is announcing a public workshop entitled ''Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials.'' The purpose of the public workshop is to provide a forum for collaborative multidisciplinary discussion to identify opportunities and address challenges for clinical outcome assessments, particularly patient-reported outcome (PRO) assessments, in oncology drug development. In this public workshop, a broad array of international stakeholders involved in oncology drug development and PRO measurement will provide perspectives on the role of PRO measures to provide complementary clinical data on the symptomatic side effects of anti-cancer agents. Speakers and panelists will explore the utility of information derived from existing and emerging PRO measures and discuss potential ways to improve the collection, analysis, and presentation of the data to support drug development and better inform treatment decisions. In addition, workshop participants will discuss possible approaches to the patient-reported assessment of an investigational drug's overall side effect burden as a clinical trial endpoint. This public workshop will include speakers and panelists from regulatory agencies, academia, patient advocacy groups, and the medical product industry.

DATES: The public workshop will be held on April 25, 2017, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Ave., Bethesda, MD 20814, 301–657–1234.

FOR FURTHER INFORMATION CONTACT: Theresa Hall, Patient-Reported Outcome Consortium, Critical Path Institute, 1730 East River Road, Tucson, AZ 85718, 520–777–2875, FAX: 525–547–3456, email: *thall@c-path.org;* and Valerie Vashio, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3710, FAX: 301–796–9909, email: *valerie.vashio@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Clinical outcome assessment (COA) tools are intended to capture how patients experience a disease and its treatment by assessing symptoms, function, and other aspects of a patient's health-related quality of life (HRQL). PRO measures are one important type of COA tool. There is growing interest in optimizing the use of PRO measures to better incorporate the patient perspective into oncology drug development. While PRO measures can be used to evaluate the efficacy of cancer treatments, there is increasing interest in the use of PRO tools to assess symptomatic side effects of treatment. New PRO item banks and libraries are becoming available that can provide needed flexibility to tailor the PRO assessment to the wide range of side effects seen with the various mechanistic classes utilized in contemporary drug development. FDA is interested in gaining feedback on methods to integrate the patient into the assessment of safety and tolerability of cancer drugs through systematic patient-reporting of side effects during clinical trials. This public workshop will discuss standard clinician reporting of adverse events, the development and implementation of the PRO-Common Terminology Criteria for Adverse Events (CTCAE) assessment tool, and explore different analysis and presentation methods for longitudinal patient-reported adverse event data.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this public workshop. The registration fee is charged to help defray the costs of the public workshop facility, speaker and panelist expenses, audiovisual equipment, materials, and food. Persons interested in attending this public workshop must register by April 21, 2017. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. Seats are limited, and registration will be on a first-come, first-served basis.

To register for the public workshop, please complete registration online at *https://www.cvent.com/events/second-annual-workshop-on-clinical-outcome-assessments-coas-in-cancer-clinical-trials/registration-270d8a5ee3ae4a108938851e2a7d0ea7.aspx.* (FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives.	$400.
Charitable Nonprofit/ Academic.	$100 (Contact C-Path).

Category	Cost
Government	$100 (Contact C-Path).

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814, are eligible for a reduced rate of $249 per night, not including applicable taxes. To receive the reduced rate, please contact the hotel directly at 301–657–1234 and reference the Critical Path Institute April 2017 workshop or book online at: *https://aws.passkey.com/event/15624700/owner/14877/landing?gtid=8d00149fbdf860c0e824aee45de33531.*

If you need special accommodations due to a disability, please contact the Hyatt Regency Bethesda at least 7 days in advance.

III. Transcripts

Transcripts will not be available. Presentations and associated audio files will be available on the C-Path Web site approximately 30 days after the public workshop at *https://c-path.org/category/events/.*

Dated: April 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–07766 Filed 4–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 0937–0198–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number <OCN>, scheduled to expire on <expiration date>. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before May 18, 2017.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 795–7714.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0937–0198 and document identifier 0937–0198–30D for reference.

Information Collection Request Title: Public Health Service Polices on Research Misconduct (42 CFR part 93)—OMB No. 0937–0198—Extension—Office of Resource Integrity.

OMB No.: 0937–0198.

Abstract: This is a request to extend the currently approved collection, OMB No. 0937–0198, which involves two forms: PHS–6349 and PHS–6315. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form (PHS–6349) is to provide data on the amount of research misconduct activity occurring in institutions conducting PHS-supported research, as well as providing an annual assurance that those institutions have established and will follow administrative policies and procedures for responding to allegations of research misconduct that comply with the Public Health Service (PHS) Regulations on Research Misconduct (42 CFR part 93). The purpose of the Assurance of Compliance by Sub-Award Recipients form (PHS–6315) is to establish a similar assurance of compliance with 42 CFR part 93 for sub-awardee institutions, as well as provide data on the amount of research misconduct activity occurring in those sub-awardee institutions. Research misconduct is defined as receipt of an allegation of research misconduct and/or the conduct of an inquiry and/or investigation into such allegations. These data enable the ORI to monitor institutional compliance with the PHS regulation. Lastly, the forms will be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

Need and Proposed Use of the Information: Public Health Service Polices on Research Misconduct (42 CFR part 93)—OMB No. 0937–0198—Extension—Office of Research Integrity.

Likely Respondents: PHS awardee and sub-awardee institutions.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
PHS–6349	5,435	1	10/60	906
PHS–6315	200	1	5/60	17
Total	.....	.....	.....	923

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2017–07787 Filed 4–17–17; 8:45 am]

BILLING CODE 4150–31–P