variability of employer costs in the case studies.

If the WWGP is effective at improving worker health, reducing WC claims and demonstrating a positive economic return, then other employers and insurance carriers may develop similar programs and drive the optimization of integrated OSH-wellness approaches. NIOSH expects to complete data collection in 2017. It is estimated that a maximum of 100 individuals will be interviewed (up to 50 for the semi-structured economic interviews and up to 100 for the annual case study verification interviews). The hour-burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and participating in the interview. There are no costs to interviewees other than their time. The total estimated annual burden hours are 150.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Wellness Program Coordinators.	Employers interview on cost of wellness and occupational safety and health program.	25	1	2
Occupational Safety and Health Specialists.	Employers interview on cost of wellness and occupational safety and health program.	25	1	2
The person in charge of the employer's wellness program.	Annual case study verification interview	100	1	30/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–00383 Filed 1–11–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4990]

Next Generation Sequencing-Based Oncology Panels; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Next Generation Sequencing-Based Oncology Panels.'' The purpose of this workshop is to obtain feedback on analytical and clinical validation approaches for next generation sequencing (NGS)-based oncology panels. Comments and suggestions generated through this workshop will help guide the development of appropriate regulatory standards for evaluation of NGS-based oncology panels in cancer patient management.

DATES: The public workshop will be held on February 25, 2016, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on the public workshop by March 28, 2016.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 B and C (the Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–4990 for ''Next Generation Sequencing-Based Oncology Panels.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer Dickey, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 5648, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5028, *Jennifer.Dickey@fda.hhs.gov*.

I. Background

A number of oncology therapeutic products have been approved with corresponding companion diagnostics (Ref. 1). To date, approved companion diagnostic assays assess a single analyte or prespecified mutations associated with therapeutic response; however, NGS technology can interrogate a patient's tumor specimen for numerous biomarkers concurrently, introducing challenges to the current companion diagnostic paradigm. Additionally, NGS tumor panels are increasingly employed for use in similar oncology applications because the technology can be used to screen a cancer patient's specimen for many relevant mutations simultaneously.

FDA is holding this public workshop to solicit input from external stakeholders on approaches to establish performance characteristics of NGS-based oncology panels that include variants that are intended to be used as companion diagnostics, as well as other variants that may be used for alternative therapeutic management of patients who have already been considered for all appropriate therapies. The Agency is requesting public input on strategies for establishing performance characteristics for NGS-based oncology panels for rare variants across tumor types, follow-on companion diagnostic claims, and post-approval assay modifications. Further details to be considered and discussed at the workshop will be outlined in a discussion paper that will be posted publicly and available prior to the workshop at the following site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.)

II. Topics for Discussion at the Public Workshop

This public workshop will consist of brief presentations to provide information to frame the goals of the workshop and interactive discussions via several panel sessions. Following the presentations, there will be a moderated discussion where speakers and additional panelists will be asked to provide their individual perspectives. The presentations and discussions will focus on several topics, including a description of a hypothetical NGS-based oncology panel test and its general intended use; considerations for pre-analytical and quality metric approaches; challenges in analytical validation and the potential for development of a flexible approach for post-approval assay modifications; and the framework for clinical and follow-on companion diagnostic claims. In advance of the meeting, FDA plans to post a discussion paper outlining FDA's current thinking for NGS-based oncology panels and the issues for discussion at the workshop at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.) FDA will place the discussion paper on file in the public docket (docket number found in brackets in the heading of this document) and will post it at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. The deadline for submitting comments on this document for presentation at the public workshop is February 2, 2016, although comments related to this document can be submitted until March 28, 2016. A detailed agenda will be posted on this Web site in advance of the workshop.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on February 17, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication and Education, phone 301–796–5661, email: *mailto:Susan.Monahan@fda.hhs.gov* no later than 4 p.m. on February 11, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see special accommodations contact). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web page after February 17, 2016. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this meeting/public workshop from the posted events list.) If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview*. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document which will be addressed in greater detail in a

subsequent discussion paper (see **SUPPLEMENTARY INFORMATION**). FDA will do its best to accommodate requests to make public comment. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by February 2, 2016. FDA 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 February 8, 2016. If selected for presentation, any presentation materials must be emailed to Jennifer Dickey (see **FOR FURTHER INFORMATION CONTACT**) no later than February 16, 2016, at 4 p.m. No commercial promotional material will be permitted to be presented or distributed at this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information Office address is available on the Agency's Web site at *http://www.fda.gov*. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.)

III. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov*. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Please refer to FDA's Web site on companion diagnostics, available at *http://www.fda.gov/companiondiagnostics*.

Dated: January 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00328 Filed 1–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0977]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.

DATES: Submit either electronic or written comments on the collection of information by March 14, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2012–N–0977 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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