ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal PREP Plan	10	1	40	400

Estimated Total Annual Burden Hours: 400.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–00595 Filed 1–13–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4809]

Patient and Medical Professional Perspectives on the Return of Genetic Test Results and Interpretations; 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 the following public workshop entitled ''Patient and Medical Professional Perspectives on the Return of Genetic Test Results.'' The purpose of this public workshop is to understand patient and provider perspectives on receiving potentially medically relevant genetic test results. The topic(s) to be discussed will focus on better defining the specific information patients and providers prefer to receive, with an emphasis on the type(s) and amount of evidence available to interpret the results for medical purposes, how those results should be returned, and what information is needed to understand the results in the event that they could effectively aid in medical decision making.

DATES: The public workshop will be held on March 2, 2016, from 8 a.m. to 4 p.m. Submit either electronic or written comments on the public workshop by March 31, 2016.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting 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–4809 for ''Patient and Medical Professional Perspectives on the Return of Genetic Test Results; Public Workshop; Request for Comments.'' 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: Cara Tenenbaum, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 5563, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8456, *cara.tenenbaum@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In his State of the Union address on January 20, 2015, President Obama launched the Precision Medicine Initiative (PMI),[1] in order to empower health care providers to tailor treatment and prevention strategies to an individual's unique characteristics. This may include analysis of genetic information, including information gathered through Next Generation Sequencing (NGS). As part of PMI, FDA is considering new approaches in its regulation of NGS. FDA is interested in promoting innovation while ensuring that patients have access to cutting edge technologies that are accurate and provide meaningful information to inform their health care decisions.

NGS produces significant amounts of information, including some that may be difficult for patients and health care professionals to interpret with presently available scientific knowledge. In some cases, the evidence for association of many genetic variants with particular diseases is limited because of the rarity of the variant or because it partially contributes to a disease in combination with other factors. In other cases, the evidence may be contradictory or not be available currently, but may be clearer in the future. Additionally, some findings may be unexpected or incidental to what a physician is looking for. FDA seeks to learn, when results are generated in a CLIA-compliant laboratory, which results are of importance to patients and providers, how those results should be returned, and how much and what types of evidence supporting interpretation of those results is necessary. Thus, FDA is seeking public input from patients and health care professionals to inform its approach regarding the return of results of genetic tests.

II. Topics for Discussion at the Public Workshop

In response to President Obama's PMI, the public workshop will consider the different uses of genetic testing. For example, tests that determine the risk of developing a condition, tests that diagnose hereditary genetic disorders, and tests that can guide treatment or therapeutic interventions. Additionally, the workshop and invited speakers will cover various topics, including which results (*e.g.,* variants or mutations) and interpretations are useful to patients when undergoing genetic testing; what types of results patients would want to receive when there is no medical action that can be taken; how best can results of genetic test be presented; patients' preference in receiving results that are supported by limited or conflicting evidence and how best such results should be presented; how information can be best presented to ease integration into clinical care and health care provider workflow; what providers want to know about results that are supported by limited or conflicting evidence; what information should be included in test reports and how it should be presented; and what specific information providers can do without.

FDA will present case studies as a starting point for discussion, which will be available on the meeting Web page in advance of the public meeting. Furthermore, the following will be considered in the context of different uses of genetic testing: Health literacy/numeracy of patients; genetics/genomics literacy of health care practitioners; the personal utility of knowing about the presence of a mutation or variant whether it is actionable or not; that a mutation or variant may have limited evidence at the time the test is initially run but evidence may be gathered that changes the interpretation of the mutation or variant; privacy concerns; demographic information and subpopulations; undiagnosed patients; and underserved populations.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by February 24, 2016, 4 p.m. Early registration is recommended because space is 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 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, email: *susan.monahan@fda.hhs.gov,* phone: 301–796–5661, no later than February 20, 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 contact for special accommodations). 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. 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, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes public comment and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session. FDA has

[1] The Precision Medicine Initiative found on the White House's Web site at: *https://www.whitehouse.gov/precision-medicine.*

included general topics for discussion in this document. If you do request to present public comments, please list which topics you wish to address. FDA will do its best to accommodate requests to make public comment. Following the close of registration, 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 24, 2016. All requests to make oral presentations must be received by the close of registration on February 24, 2016, at 4 p.m. If selected for presentation, any presentation materials must be emailed to Cara Tenenbaum (see **FURTHER INFORMATION CONTACT**) no later than February 26, 2016. No commercial promotional material will be permitted to be presented or distributed at the 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.)

Dated: January 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00540 Filed 1–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0307]

Revised Preventive Measures To Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry.'' The guidance document provides blood collecting establishments and manufacturers of plasma derivatives with comprehensive recommendations intended to minimize the possible risk of transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) from blood and blood products. The guidance amends the guidance document entitled ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products'' dated May 2010 (2010 guidance) by finalizing and incorporating the recommendations from the draft document entitled ''Draft Guidance for Industry: Amendment to 'Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products''' dated June 2012 (2012 draft guidance).

DATES: Submit either electronic or written comments on Agency guidances at any time.

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

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- 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–D–0307 for Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry. 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