ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Overdose Data to Action funded jurisdictions (State—territories—counties and cities) and their designated delegates.	Evaluation and Performance Measuring Plan Template—Initial Population.	22	1	12	264
	Evaluation and Performance Measuring Plan Template—Annual reporting.	66	1	4	264
	Overdose Prevention Capacity Assessment Tool.	66	1	1	66
	Activity Progress Report and Work Plan Tool—Initial Population.	22	1	20	440
	Activity Progress Report and Work Plan Tool—Annual Reporting.	66	1	4	264
	Surveillance Data Dissemination Plan.	22	1	1	22
Total					1,320

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–15819 Filed 7–24–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–1125]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Ingress/egress and work boot outsole wear investigation at surface mines'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 20, 2019 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Ingress/egress and work boot outsole wear investigation at surface mines—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety & health at work for all people through research and prevention. NIOSH, under Public Law 91–173 as amended by Public Law 95–164 (Federal Mine Safety and Health Act of 1977) has the responsibility to conduct research to improve working conditions and to prevent accidents and occupational diseases in the U.S. mining sector. The goal of the proposed project is to investigate how ingress/egress systems on mobile equipment, and personal protective footwear (boots) used by miners may lead to slips, trips and falls at stone, sand and gravel surface mining facilities. NIOSH is requesting a two-year extension for this data collection.

The project objective will be achieved through two studies. The first study aims to: identify elements of ingress/egress systems on haulage trucks and front end loaders that pose a risk of slips, trips, and falls (STFs) and could lead to STF related injuries; to determine worker behavior associated with STF incidents; and to learn how purchasing/maintenance decisions are made for ingress/egress systems. In the surface mining industry, it is still unclear which component of the ingress/egress system poses the greatest risk for STF. Hence, there is a need to understand where, how, and why STF incidents occur during ingress/egress on mobile equipment.

NIOSH will conduct semi-structured interviews and focus groups with mobile equipment operators, and interviews will be conducted with mine management to explore the issues

identified above. Focus groups will be conducted in a private setting with 4–6 participants using a predefined list of questions to help guide the discussion. Semi-structured interviews will be conducted either in person or over the telephone. Two separate interview guides will be used for mobile equipment operators and mine management to guide the discussion.

For the focus groups and semi-structured interviews, NIOSH will collect basic demographic information including years of mining experience, years of experience with haul trucks/front end loaders, and models of haul trucks/front end loaders operated most often in the past year. The semi-structured interviews and focus groups will be audio recorded for further analysis of the discussion. The semi-structured interviews will last no longer than 60 minutes and the focus groups will last no longer than 90 minutes.

The second study aims to identify changes in tread (wear) on the work boot outsoles and other outsole characteristics of the boot outsole that will be used to develop guidelines for work boot replacement based on measureable features of boot outsoles. This information will also be used in further analysis to determine desirable and undesirable features of work boots based on mine characteristics or job activities. Most mining companies replace footwear at a pre-determined interval or based on appearance and comfort with little knowledge on the actual condition of the boot outsole and its influence on the likelihood of a STF incident. Although there have been attempts to quantify shoe outsole wear in industrial work when the shoe was ready for disposal, there is a lack of knowledge in the mining industry on how quickly the outsoles of work boots wear, what sorts of wear occurs, and how wear patterns influence the likelihood of a STF. This study aims to address this concern through two parts: A longitudinal study of boot outsole wear characteristics and a cross-sectional evaluation of boot outsole characteristics.

For the longitudinal study, NIOSH will provide participants with a pair of new work boots of their choice, in accordance with their respective mine requirements and policies. Afterwards, participants will complete a preliminary survey and provide some basic demographic information, details of their current work boots, and details of STF incidents in the past 3 months. Participants will be requested to wear the supplied boots at work and treat the boots as they would any pair of work boots they would commonly wear at work.

NIOSH researchers will scan the boot outsoles longitudinally, at two to three month intervals for the length of the study. To better understand wear patterns and risks, participants will complete a recurring survey that records hours worked, locations commonly visited, and tasks performed along with details of any near miss or STF events. These self-reports will be collected via survey on a bi-weekly basis. Participants will be offered multiple modalities to respond to the survey (in-person, on paper, over the telephone, via email or using an online survey) to increase response rates. When a participant feels their boots need to be replaced (or when the end of the two-year tracking period has been reached), and at the end of the study, they will complete a final survey assessing why the boots were at the end of their life and will return their boots to NIOSH researchers for further analysis.

For the cross-sectional study, participants' current work boots will be scanned and participants will complete the preliminary survey that includes basic demographic information, details of current work boots, and details of STF events in the past three months.

The results of these research studies will have very different applications, but one goal: Reducing the risks of STF accidents at surface mining facilities. The methods adopted were adequate to address the research questions, and based on a thematic analysis of the data, NIOSH will be able to identify elements of ingress/egress systems on mobile equipment that pose a risk of STFs. The findings of this work were validated against findings from an analysis of MSHA injury data related to front-end loaders (Nasarwanji, Pollard & Porter, 2018). A publication will be drafted based on the results that also includes ways to make mobile equipment.

The extension is requested to help complete data collection for the boot outsole wear study. The results of the boot outsole wear study will be used to inform mine policy and practices by providing miners and mine managers with the knowledge to determine when to replace footwear based on measurable features of the boot outsoles. The total estimated burden hours are 643. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mobile equipment Operators	Mobile equipment operators focus group guide.	25	1	75/60
Mobile equipment operators	Mobile equipment operator interview guide	10	1	45/60
Mine Management	Mine Management Interview Guide	15	1	45/60
Mine Worker	Screening Questionnaire	50	1	6/60
Mine Worker	Informed consent form(Longitudinal boot outsole study).	50	1	12/60
Mine Worker	Preliminary survey	150	1	15/60
Mine Worker	Recurring survey	50	52	12/60
Mine Worker	Final Survey	50	1	6/60
Mine Worker	Talent and consent waiver	150	1	6/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–15818 Filed 7–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2769]

21st Century Cures: Announcing the Establishment of the BEST Resource Taxonomy; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to receive comments from interested parties (including academic institutions, regulated industry, and patient groups) on the Agency's publication of a glossary of terms which is part of the BEST (Biomarkers, EndpointS, and other Tools) Resource Taxonomy. FDA has developed a web page that describes the BEST Resource Taxonomy and links out to the official National Library of Medicine web page for the BEST glossary of terms. Comments on the BEST Resource Taxonomy will help FDA enhance its utility and may assist FDA in developing future versions of this resource and identifying best methods for conveying information about biomarkers, endpoints, and other drug development tools to the general public.

DATES: Submit either electronic or written comments on this notice by September 23, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 23, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 23, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–N–2769 for ''21st Century Cures: Announcing the Establishment of the BEST Resource Taxonomy.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017, *Christopher.Leptak@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3011 of the 21st Century Cures Act (Pub. L. 114–255) added a new section 507 to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357). Section 3011(b)(3)(A) requires FDA to collaborate with biomedical research consortia and other interested parties to ''establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.'' FDA is meeting this legislative requirement through updates to the BEST Resource on the National Library of Medicine website, available at *https://www.ncbi.nlm.nih.gov/books/NBK326791/,* is FDA's response to this