ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondent	Number of respondents	Responses per respondent	Average burden per respondent (in hours)	Total burden (in hours)
School, school district or public health department	100	1	5/60	8
Total				8

Dated: October 27, 2009.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–26398 Filed 11–2–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–09BD]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Field Evaluation of Prototype Kneel-assist Devices in Low-seam Mining—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH, under Public Law 91–596, Sections 20 and 22 (Section 20–22, Occupational Safety and Health Act of 1970) has the responsibility to conduct research relating to innovative methods, techniques, and approaches dealing with occupational safety and health problems.

According to the Mining Safety and Health Administration (MSHA) injury database, 227 knee injuries were reported in underground coal mining in 2007. With data from the National Institute for Occupational Safety and Health (NIOSH), it can be estimated that the financial burden of knee injuries was nearly three million dollars in 2007.

Typically, mine workers utilize kneepads to better distribute the pressures at the knee. The effectiveness of these kneepads was only recently investigated in a study by NIOSH that has not yet been published. The results of this study demonstrated that kneepads do decrease the maximum stress applied to the knee albeit not drastically. Additionally, the average pressure across the knee remains similar to the case where subjects wore no kneepads at all. Thus, the injury data and the results of this study suggest the need for the improved design of kneel-assist devices such as kneepads. NIOSH is currently undertaking the task of designing more effective kneel-assist devices such as a kneepad and a padded support worn at the ankle where mine workers can comfortably rest their body weight.

These devices must also be field tested to verify they do not result in body discomfort or inadvertent accidents. It is also important to determine how usable and durable these devices are in the harsh mining environment. In order to quantitatively demonstrate that these prototype devices are superior to their predecessors, mine workers using these prototypes must be interviewed. Their feedback will identify any necessary changes to the design of the devices such that NIOSH can ensure the prototypes will be well-accepted by the mining community.

To collect this type of information, a field study must be conducted where kneel-assist devices currently used in the mining industry (i.e. kneepads) are compared to the new prototype designs. The study suggested here would take approximately 13 months.

Phase I of this study will evaluate the prototype kneel-assist device by mine workers after being used for one month. Iterative changes will be made to the design based on the feedback obtained during Phase I. Data will be collected via interviews with individual mine workers and through a focus group where all mine workers come together to express their opinions about the devices. If the prototype kneel-assist devices do not appear to be successful, the data collected will be used to adequately redesign them and the above described process will begin again. If the prototype kneel-assist devices appear to be successful, Phase II of the study will commence.

Once Phase II of the study is ready to commence, cooperating mines will be identified. Every month, the section foreman at the cooperating mines will be asked to supply some information regarding the current mine environment.

Initially, the mine workers will be given a control kneel-assist device. Currently, mine workers only utilize kneepads as a kneel-assist device. Therefore, only a control kneepad will be provided. They will then be asked some basic demographics information such as their age and time in the mining industry. Additional data will then be collected at 1, 3, and 6 months after the study commences. The mine workers will be asked to provide their feedback regarding factors such as body part discomfort, usability, durability, and ease of movement with respect to the control kneepad. After evaluating the control kneepad, mine workers will then be given the prototype kneel-assist device that was finalized in Phase I of the study. The same questions that were asked about the control kneepad will again be asked at 1, 3, and 6 months after usage begins of the prototype. Thus, Phase II of the study will last 12 months.

There will be no cost to the respondents/subjects other than their time. The total burden hours are estimated to be 182.

ESTIMATED ANNUALIZED BURDEN HOURS

	Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Phase I	Section Foreman	Phase I Section Foreman Form.	1	1	10/60
	Mine Workers	Phase I Baseline Form	9	1	20/60
	Mine Workers	Phase I 1 month form	9	1	30/60
	Mine Workers	Phase I Focus Group Questions.	9	1	1
Phase II	Section Foreman	Phase II Section Foreman Form.	6	12	10/60
	Mine Workers	Phase II Baseline Form	54	1	20/60
	Mine Workers	Phase II 1, 3, and 6 months forms.	54	6	25/60

Dated: October 28, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0524]

Draft Guidance for Industry on Listing of Ingredients in Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Listing of Ingredients in Tobacco Products.'' The draft guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by section 904 of the Federal Food, Drug, and Cosmetic Act (the act) as added by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 13, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Listing of Ingredients in Tobacco Products'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 301–796–4800, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Tobacco Control act (Public Law 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq*.) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 904(a)(1) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.'' Since the Tobacco Control act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. While electronic submission of ingredient listing information is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for ingredient listing. This tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions.

II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Listing of Ingredients in Tobacco Products.'' 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 statute and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance