projects;
- Fund-raising experience;
- Fiscal management experience, including management of the flow of funds among the partners.

This RFI is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of HHS. HHS does not intend to award a grant or contract to pay for the preparation of any information submitted or for the use of such information by HHS. Acknowledgment of receipt of responses may not be made, nor will respondents be notified of the evaluation by HHS of the information received. No basis for claims against HHS shall arise as a result of a response to this request for information or to the use of such information by HHS as either part of our evaluation process or in developing specifications for any subsequent announcement. Any proprietary information submitted should be clearly marked for confidentiality.

Dated: April 20, 2011.

James J. Berger,

Associate Public Health Advisor for Blood, Organ, and Tissue Safety.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–11–0020]

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 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Coal Workers' Health Surveillance Program (CWHSP)—OMB 0920–0020–Reinstatement With Change—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This submission will incorporate the National Coal Workers' X-Ray Surveillance Program 42 CFR 37 (0920–0020) and National Coal Workers' Autopsy Study 42 CFR part 37.204 (0920–0021) into one complete package which will be called the Coal Workers' Health Surveillance Program (CWHSP). Upon OMB approval, 0920–0021 will be discontinued. CWHSP is a congressionally-mandated medical examination program for monitoring the health of underground coal miners, established under the Federal Coal Mine Health and Safety Act of 1969, as amended in 1977 and 2006, PL–91–173 (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which includes both a health surveillance and an autopsy component, has been useful in providing tools for protecting the health of miners (whose participation is entirely voluntary), and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines. During the early 1970s, one out of every three miners examined through the CWHSP who had worked at least 25 years underground had evidence of pneumoconiosis on their chest x-ray. An analysis among over 25,000 miners who participated in the x-ray Programs from 1996 to 2002 indicated that the proportion of affected individuals had decreased to about one in 20. However, recent surveillance analyses and research studies have confirmed that the prevalence of 'black lung' disease is increasing, there is regional clustering of rapidly progressive pneumoconiosis cases, and coal miners have a higher risk of disease if they perform certain jobs, work in smaller mines, or are from certain geographic areas. Importantly, young coal miners are developing the disabling and lethal forms of 'black lung'.

Demographic and logistical information is gathered from coal mine operators and participating x-ray facilities. Participating miners also provide health and work histories, and participating physicians report radiographic findings. The Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, WV 26505, also called the Appalachian Laboratory for Occupational Safety and Health (ALOSH), is charged with administration of this Program.

From October 1, 1999 through September 30, 2002, the Mine Safety and Health Administration (MSHA), in consultation with NIOSH, conducted a pilot health surveillance program for both underground and surface miners (The Miners' Choice Program). The Miners' Choice Program has been continued as an extension of the CWHSP (currently called the Enhanced Coal Workers' Health Surveillance Program—ECWHSP). This extension of the CWHSP currently operates utilizing a mobile examination unit which travels to mining regions to provide locally accessible and more comprehensive health surveillance, including chest radiography, spirometry, and blood pressure screening.

Under the Act, the provision of periodic chest x-ray examinations is specifically mandated, and the x-rays are to be supplemented by such other tests as the Secretary deems necessary. In addition to radiographically-apparent pneumoconiosis, miners are at risk for the development of chronic obstructive pulmonary disease (COPD). Chest radiographs alone cannot provide a measure of airflow obstruction and therefore often miss important lung disease. For this reason, spirometry, a simple breathing test, is an additional component that is particularly useful for the health assessment of miners. Periodic medical history and spirometry tests have been recommended by NIOSH for both surface and underground coal miners since 1995, to facilitate preventive actions, increase miners' participation in programs for early detection of disease, and improve the derivation of representative estimates of the burden, distribution, and determinants of occupational lung disease in relation to coal mining in the U.S. Finally, unrecognized hypertension has previously been observed among many miners, and the ECWHSP offers blood pressure screening as a safe, simple, and inexpensive test, which can help target initiation of proven health conserving medications.

The National Coal Workers' Autopsy Study (NCWAS) provides standardized lung specimens for ongoing scientific research as well as information to the next-of-kin regarding the presence and extent of coal workers' pneumoconiosis (black lung) in the lungs of the deceased miner. The Consent Release and History Form is primarily used to obtain written authorization from the next-of-kin to perform an autopsy on the deceased miner. Because a basic reason for the post-mortem examination is research (both epidemiological and clinical), a minimum of essential information is collected regarding the deceased miner,

including occupational history and smoking history. The data collected are used by scientists for research purposes in defining the diagnostic criteria for pneumoconiosis and in correlating pathologic changes with exposures and x-ray findings.

There are no costs of the NCWAS to respondents other than their time. The total estimated burden hours are 4,470.

Type of respondent	Form name	Number of respondents	Responses per respondent	Average burden per response (in hours)
Physicians B Readers	Roentgenographic Interpretation Form—CDC/NIOSH (M) 2.8.	10,000	1	3/60
	Interpreting Physician Certification Document—CDC/NIOSH (M) 2.12.	300	1	10/60
Miners	Miner Identification Document—CDC/NIOSH (M) 2.9	5,000	1	20/60
	No form—X-ray	5,000	1	15/60
	No form—Spirometry	2,500	1	20/60
Coal Mine Operators	Coal Mine Operator's Plan—CDC/NIOSH (M) 2.10	200	1	30/60
Supervisor at X-ray Facilities	Facility Certification Document—CDC/NIOSH (M) 2.11	100	1	30/60
Pathologist	No form—Invoice	50	1	5/60
	No form—Final Diagnosis Report	50	1	5/60
Next-of-Kin	Consent, Release, and History Form—CDC/NIOSH (M) 2.6	50	1	15/60

Daniel Holcomb,

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–2011–D–0125]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007." This draft guidance provides information on how a manufacturer may demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007. In this draft guidance, FDA provides recommendations on the evidence that a manufacturer may use to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007. This draft guidance is not final nor is it in effect at this time.

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 of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 24, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" 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 guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments 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.

FOR FURTHER INFORMATION CONTACT: With regard to the draft guidance: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, e-mail: *annette.marthaler@fda.hhs.gov.*

With regard to the proposed collection of information: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, e-mail: *Jonnalynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. In this draft guidance, FDA provides recommendations on the information that a manufacturer may use to establish that a tobacco product was commercially marketed in the United States on February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review requirements. In the draft guidance document, FDA recommends that this information may include, among other things, dated copies of advertisements, dated catalog pages, and dated promotional material.

II. Significance of Guidance

This draft guidance is being issued 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 "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007." 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. Electronic Access

An electronic version of the draft guidance document is available on the Internet at *http://www.regulations.gov*