and safety managers, mine foremen, maintenance supervisors, production coordinators and operators of equipment with installed noise controls. The proposed time schedule for conducting these assessments is before installation of a control and on a predetermined schedule for the duration of the life of the control. For example, one noise control may have an expected performance life of 6 months. In that case the interviews will occur before installation, 2 weeks, 6 weeks, 14 weeks, and 24 weeks post installation.

Although we plan to follow this general time table, due to the nature of the mining industry, slight deviation may occur. No noise control will require greater than 5 interviews per respondent. The goal is to achieve 6 mines and 6 individuals per mine per noise control.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| Managers Foreman Supervisors Coordinators Operators. | Assessment of the Urethane-Coated Chain for Continuous Mining Machines. | 36 | 5 | 20/60 | 60 |
| Managers Foreman Supervisors Coordinators Operators. | Assessment of the Roof Bolting Machine Noise Control Products. | 36 | 5 | 20/60 | 60 |
| Managers Foreman Supervisors Coordinators Operators. | Assessment for the Enclosure for Vibrating Screen. | 36 | 5 | 20/60 | 60 |
| Total | | 108 | | | 180 |

Dated: February 22, 2010.

**Maryam I. Daneshvar,**

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

[FR Doc. 2010–3999 Filed 2–25–10; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0373]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mental Models Study of Recruitment and Retention of Pregnant Women Into An Asthma Pregnancy Registry

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 29, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title Mental Models Study of Recruitment and Retention of Pregnant Women Into An Asthma Pregnancy Registry. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Mental Models Study of Recruitment and Retention of Pregnant Women Into An Asthma Pregnancy Registry—(OMB Control Number 0910)—NEW

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The proposed information collection will help FDA advance public health by identifying priorities, perceptions, and communication needs about how pregnant women and their health care providers make decisions about participation in a pregnancy registry. Understanding these priorities, perceptions, and communication needs will foster more effective approaches to recruitment of pregnant women into pregnancy registries and full retention of those women until the end of the registry study period. Ultimately, early enrollment and complete followup of women in pregnancy registries will strengthen the quality of safety data about use of needed medications during pregnancy.

Before a medication is approved by FDA for sale in the United States, pregnant women are rarely included in experimental research studies of the medication because of concerns that the experimental treatment may harm the developing fetus and/or the pregnant woman. As a result, when a medication is approved for marketing in the United States, little systematically collected human data are available to define the chance of serious side effects in pregnant women and/or their developing fetuses from use of the medication during pregnancy.

A pregnancy registry is a research study conducted after a medication has been approved, during which pregnant women being treated with the medication are observed to identify possible harms to the woman and/or to her developing fetus. Pregnant women voluntarily enroll in a pregnancy registry; data about the pregnancy, labor, delivery, and newborn are collected and analyzed to identify any serious adverse outcomes and consider whether use of the medication may be linked to any observed harm. The quality of pregnancy registry data is enhanced by enrollment of women early in their pregnancy and by complete followup of all enrolled pregnancies to the end of the registry study period. Ultimately, high quality human

pregnancy data gathered through a pregnancy registry and incorporated into medical product labeling will provide patients and their health care providers useful information so they may make informed medical treatment decisions during pregnancy. Data collected from this mental models study will be incorporated into recommendations for improvement of the quality of pregnancy registries, ultimately improving medical treatment decisions, and potentially improving pregnancy outcomes.

FDA engages in various regulatory and communication activities to support and at times require collection of safety data through establishment of a pregnancy registry. Pregnancy exposure registries are a major source of human pregnancy data for product labeling; therefore, FDA is committed to fostering ongoing improvements in the design and conduct of pregnancy registries. In 2002, FDA issued a guidance document entitled "Establishing Pregnancy Exposure Registries" (see *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071639.pdf*). This guidance provides an overview of pregnancy exposure registries, describing when and how to conduct a pregnancy registry about treatment of a disease in pregnancy or use of a specific medication or group of medications during pregnancy. FDA's Office of Women's Health maintains a list of current pregnancy registries on its Web site, see *http://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm134844.htm*. FDA regulations (21 CFR 201.57) describe the content of required product labeling for prescription drugs. In the **Federal Register** of May 29, 2008 (73 FR 30831), FDA published a proposed rule to amend the agency's regulations for required labeling for drugs and biologics when they are used during pregnancy or breastfeeding. When finalized, these revised regulations will improve labeling information about the effects of medicines used during pregnancy and breastfeeding. Enactment of the Food and Drug Administration Amendments Act of 2007 gave FDA new legal authority to require postapproval studies to assess certain safety concerns, including, in certain situations, establishment of a pregnancy registry. Through this data collection and analysis, FDA will identify and address the perceptions and communication needs of pregnant women and health care providers to support their participation in pregnancy registries.

The project will use "mental modeling," a qualitative research method that compares a model of the priorities, perceptions, communication needs, and decisionmaking processes of a group or groups to a model of the same priorities, perceptions, communication needs, and decisionmaking processes developed from expert knowledge and experience. In this study, the decision models of women who are current or potential participants in a pregnancy registry and of health care providers who have participated or might participate in a pregnancy registry will be derived through qualitative structured interviews. The project focuses on an asthma disease-based pregnancy registry; the three cohorts to be interviewed are described in detail in the following paragraphs.

Using information gathered from the interviews, the decision model about pregnancy registry involvement for pregnant women and health care providers will be developed. Once developed, that decision model will be compared to decision models about pregnancy registry involvement that were derived from experts in the fields of obstetrical and asthma treatment during pregnancy, design and conduct of pregnancy registries, FDA medication regulation, and biomedical ethics. FDA will use telephone interviews with the three cohorts to determine the priorities, perceptions, communication needs, and other factors that influence decisions about participation in a pregnancy registry by pregnant women and health care providers. A comparison between an expert model and models based on the information collected directly from women and health care providers may identify consequential perception, priority, and communication gaps. These critical areas can then be redressed through strategic efforts to foster involvement in pregnancy registries designed by FDA or others.

Using a protocol derived from the research that resulted in the "expert model," trained interviewers will conduct 1-on-1 telephone discussions with a total of 60 individuals (20 individuals per cohort) from the 3 cohorts described here:

(1) Potential Pregnancy Registry Participants: Women older than 18 years who are currently being treated for asthma and are pregnant or have been pregnant within the past 18 months, and who may or may not currently be participating in a pregnancy registry;

(2) Current Pregnancy Registry Participants: Pregnant women older than 18 years who are current participants in any pregnancy registry for a chronic condition; and

(3) Health Care Providers: To include a mix of health care providers (including specialists, obstetrician-gynecologists, and primary care providers) some who have participated in a pregnancy registry and some who have not participated in a pregnancy registry.

In the **Federal Register** of August 25, 2009 (74 FR 42901), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received stating that the stakeholder agreed that the proposed study was valid and could provide information to support development of a clinically useful pregnancy registry. The stakeholder requested information about how physicians would be chosen for study participation and which subspecialties would be represented in the cohort. Noting that diversity would be beneficial, the comment suggested inclusion of physicians practicing in the following areas: Allergy/immunology, pulmonology, obstetrics and gynecology, and primary care.

FDA's response is, the Health Care Providers (HCPs) cohort for this mental models study will include a mix of targeted or known HCPs who have participated in pregnancy registries, a variety of specialists who may or may not have participated in pregnancy registries, and Ob/Gyn and primary care providers who may or may not have participated in pregnancy registries. Various resources may be used to identify a diverse sample of prospective primary care and subspecialty HCPs who practice in a variety of clinical settings. Examples might include physicians with privileges at or who refer/transfer patient care to tertiary care hospitals and HCPs who have contacted the Organization for Teratology Information Specialists regarding drug exposures during pregnancy or about pregnancy registry enrollment. The cohort of 20 HCPs will be interviewed by trained interviewers in 1-on-1 in-depth telephone interviews. The telephone interactions will take approximately 60 minutes and will include approximately 45 minutes of structured interview.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|
| 60 | 1 | 60 | 1.0 | 60.0 |
| Total | | | | 60.0 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The study will involve about 60 respondents and take approximately 1 hour each to complete. These estimates are based on the contractor's extensive experience with mental models research.

Dated: February 22, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–3912 Filed 2–25–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0083]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

**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 the recordkeeping requirements for this collection of information concerning substances prohibited from use in animal food or feed and animal proteins prohibited in ruminant feed.

**DATES:** Submit written or electronic comments on the collection of information by April 27, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–827–1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR 589.2000(e)(1)(iv) (OMB Control Number 0910–0339)—Extension**

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Records | Total Hours |
|---|---|---|---|---|---|
| 589.2000(e)(1)(iv) | 400 | 1 | 400 | 14 | 5,600 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.