study will be made available to the public at the conclusion of the evaluation.

Construction and mining companies who participate in the study will be randomly assigned to receive eight weekly toolbox safety training sessions that use either a case-study narrative or conventional instructional approach. The training sessions are designed to last fifteen minutes. The impact of these materials will be evaluated through the examination of changes in employee knowledge gains, attitudes toward safety practices, and the use of safety behaviors prior to and following their participation in the safety training program. Trainers will complete brief response cards each week. A sample of trainers will participate in structured interviews. Findings of the study will be reported to participants and in the literature. The total annual burden for this data collection is 233 hours.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
Worker Pre-training Survey (attitude survey)	412	1	15/60
Worker Post-training Survey (attitude survey)	412	1	15/60
Instructor Feedback Cards	41	8	5/60

Dated: January 27, 2003.

Thomas Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–2277 Filed 1–30–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifiers: CMS–R–242, CMS–10069, CMS–10078, CMS–R–52, and CMS–R–30]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Refinement of RHC Certification and QAPI and Supporting Regulations in 42 CFR 491.8 and 491.11; *Form No.:* CMS–R–242 (OMB# 0938–0792); *Use:* This collection contains information collection requirements concerning requests for additional waivers of staffing requirements and documentation of quality assessment and performance improvement programs; *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 3,528; *Total Annual Responses:* 3,573; *Total Annual Hours:* 3,663.

(2) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Waiver Demonstration Application; *Form No.:* CMS–10069 (OMB# 0938–0880); *Use:* The Medicare Waiver Demonstration Application will be used to collect standard information needed to implement Congressionally mandated and administration high priority demonstrations. The application will be used to gather information about the characteristics of the applicant's organization, benefits, and services they propose to offer, success in operating the model, and evidence that the model is likely to be successful in the Medicare program. The standard application will be used for all waiver demonstrations and will reduce the burden on applicants, provide for consistent and timely information collections across demonstration, and provide a user-friendly format for respondents; *Frequency:* On occasion; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 1600.

(3) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Matching Grants to States for the Operation of High Risk Pools; *Form No.:* CMS–10078 (OMB# 0938–0887); *Use:* HHS/CMS is requiring this information as a condition of eligibility for grants that were authorized in the Trade Act of 2002 (Pub. L. 107–210). The information is necessary to determine if a state applicant meets the necessary eligibility criteria for a grant as required by the law. The respondents will be states that have a high risk pool as defined in section 2744(c)(2) of the Public Health Service Act. The grants will provide matching funds to states that incur losses in the operation of high risk pools. High risk pools are set up by states to provide heatlh insurance to individuals that cannot obtain health insurance in the private market because of a history of illness; *Frequency:* On occasion; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 800.

(4) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Coverage of Suppliers of End Stage Renal Disease (ESRD); *Form No.:* CMS–R–52 (OMB# 0938–0386); *Use:* This package is needed to encourage proper distribution and effective utilization of ESRD treatment sources while maintaining and improving the efficient delivery of care by physicians and dialysis facilities; *Frequency:* Annually; *Affected Public:* Business or other for-profit and Federal Government; *Number of Respondents:* 4,297; *Total Annual Responses:* 4,297; *Total Annual Hours:* 148,785.

(5) *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in the Hospice Conditions Coverage. The following

regulations are affected: 42 CFR 418.22; 418.24; 418.28; 418.56(b), (e)(1), (e)(3); 418.58; 418.70(e); 418.83; 418.96(b); and 418.100(b); *Form No.:* CMS–R–30 (OMB# 0938–0302); *Use:* Establishes standards for hospices that wish to participate in the Medicare program. The regulations establish standards for eligibility, reimbursement standards and procedure, and delineate conditions that hospices must meet to be approved for participation in Medicare; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 2,316; *Total Annual Responses:* 2,316; *Total Annual Hours:* 5,981,427.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room: C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 23, 2003.

John P. Burke III,

CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–2239 Filed 1–30–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2002.

ADDRESSES: Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Advisory Committee and Oversight Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app.2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2001 through September 30, 2002:

Center for Biologics Evaluation and Research:

Allergenic Products Advisory Committee,

Biological Response Modifiers Advisory Committee,

Blood Products Advisory Committee,

Transmissible Spongiform Encephalopathies Advisory Committee, and

Vaccines and Related Biological Products Advisory Committee.

Center for Drug Evaluation and Research:

Arthritis Drugs Advisory Committee,

Nonprescription Drugs Advisory Committee, and

Pulmonary-Allergy Drugs Advisory Committee.

Center for Food Safety and Applied Nutrition:

Food Advisory Committee.

Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of reports for the Circulatory System Devices Panel, Dental Products Panel, Ear Nose and Throat Devices Panel, Microbiology Devices Panel, Obstetrics Devices Panel, Ophthalmic Devices Panel, General and Plastic Surgery Devices Panel, Orthopedic and Rehabilitation Devices Panel).

National Center for Toxicological Research:

Science Advisory Board to the National Center for Toxicological Research.

Annual Reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

(1) The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and

(2) The Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: January 16, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–2294 Filed 1–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0007]

Draft Guidance for Industry on Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommendations for Clinical Evaluation; 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 ''Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommendations for Clinical Evaluation.'' The agency is revising its guidance for industry entitled ''Guidance for Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women,'' which was issued in March 1995 (the 1995 guidance). Once finalized, this guidance will replace the 1995 guidance.

DATES: Submit written or electronic comments on the draft guidance by April 1, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send on self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://