

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/prd/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto: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 Willingham, 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://>