Dated: November 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0427]

Agency Information Collection Activities; Proposed Collection; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 requirements for filing objections and requests for a hearing on a regulation or order.

DATES: Submit written or electronic comments on the collection of information by January 17, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12 (OMB Control Number 0910–0184)—Extension

Under part 12 (21 CFR part 12), § 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), sets forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection for which a hearing has been requested must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	10	1	10	20	200

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

The burden estimate for this collection of information is based on past filings. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order estimate approximately 10 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: November 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0834 (formerly Docket No. 98D–0834]

Draft Guidance for Industry on Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommended Prescribing Information for Health Care Providers and Patient Labeling; 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 ''Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommended Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance is intended to assist applicants in developing labeling for new drug applications (NDAs) for such drug products. This is the fifth draft of the guidance, which FDA initially published for comment in October 1998.

DATES: Submit written or electronic comments on the draft guidance by January 17, 2006. 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 one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Kober, Center for Drug Evaluation and Research (5359), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 22, rm. 5376, Silver Spring, MD 20993, 301–796–0934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommended Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance describes the recommended labeling for health care providers and patient instructions for inclusion in NDAs.

A draft of this guidance was first issued on October 15, 1998 (63 FR 55399). After public review and comment, a second version of this draft guidance was issued on September 27, 1999 (64 FR 52100). On May 31, 2002, the National Institutes of Health Women's Health Initiative (WHI) study of oral conjugated estrogens (CE 0.625 milligram (mg)) plus medroxyprogesterone acetate (MPA 2.5 mg)/day in postmenopausal women was stopped after a mean of 5.2 years of followup because test statistics for invasive breast cancer exceeded the stopping boundary for this adverse effect and the global index statistic supported risks exceeding benefits. Data on the major clinical outcomes regarding increased risks for invasive breast cancer, heart attacks, strokes, and venous thromboembolism rates, including pulmonary embolism, became available July 17, 2002. Consequently, the agency withdrew the draft guidance on September 10, 2002 (67 FR 57432), pending consideration of the results from the WHI study. In the **Federal Register** of February 3, 2003 (68 FR 5300), the agency issued a third draft reflecting the agency's thinking after consideration of the results from the WHI study concerning overall risks and benefits of hormone therapy for postmenopausal symptoms.

A fourth draft of this guidance was issued on February 17, 2004 (69 FR 7492), to address comments received, incorporate new study results from the Women's Health Initiative Memory Study (WHIMS), a substudy of the WHI study, and better inform prescribers and patients regarding the availability of the lowest effective dose for these drug products. (The results of the WHIMS substudy were published on May 28, 2003. Postmenopausal women, 65 to 79 years of age, during 4 years of treatment with CE 0.625 mg plus MPA 2.5 mg/day had a greater risk of developing probable dementia than those on placebo.)

The agency is issuing this fifth draft of the guidance to incorporate new study results from the WHI and WHIMS studies. This fifth draft supersedes the fourth draft, and retains and updates the labeling recommendations regarding the results of the WHI study and the WHIMS substudy for postmenopausal women treated with CE 0.625 mg plus MPA 2.5 mg/day. It also reflects the agency's thinking after consideration of the results published on April 14, 2004, of the WHI study, and the results published on June 23/30, 2004, of the WHIMS substudy for postmenopausal women with prior hysterectomy treated with CE 0.625 mg/day alone. The WHI study of CE 0.625 mg/day alone in postmenopausal women with prior hysterectomy was stopped after a mean followup of 6.8 years because of an increased risk of stroke. The WHIMS substudy of CE 0.625 mg/day alone was stopped after a mean followup of 5.2 years. Estrogen-alone therapy did not reduce probable dementia or cognitive decline incidence and increased the risk for both endpoints combined. This fifth draft of the guidance recommends adding risk information related to the results of the WHI and WHIMS estrogen-alone studies to appropriate sections of labeling including the boxed warning. Further revisions to the guidance may be necessary as additional information becomes available.

This level 1 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 labeling for noncontraceptive estrogen drug products for the treatment of moderate to severe vasomotor symptoms and moderate to severe vulvar and vaginal atrophy symptoms. 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 statutes and regulations.