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Certifier	<u>M. Bell</u>

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98D-0834]

**Draft Guidance for Industry on Noncontraceptive Estrogen Class Labeling;  
Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling." The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform health care provider and patient labeling information. FDA published a notice of availability of an earlier version of this draft guidance in the **Federal Register** of October 15, 1998 (63 FR 55399). The agency received numerous comments. As a result, the original draft guidance was revised substantially and is being issued in draft for a second time.

**DATES:** Written comments on the draft guidance document may be submitted by (*insert date 60 days after date of publication in the Federal Register*). General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of the draft guidance for industry can be obtained on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of "Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling" to the Drug Information Branch (HFD-210), 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written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Lana L. Pauls, Reproductive and Urologic Drug Products, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4260.

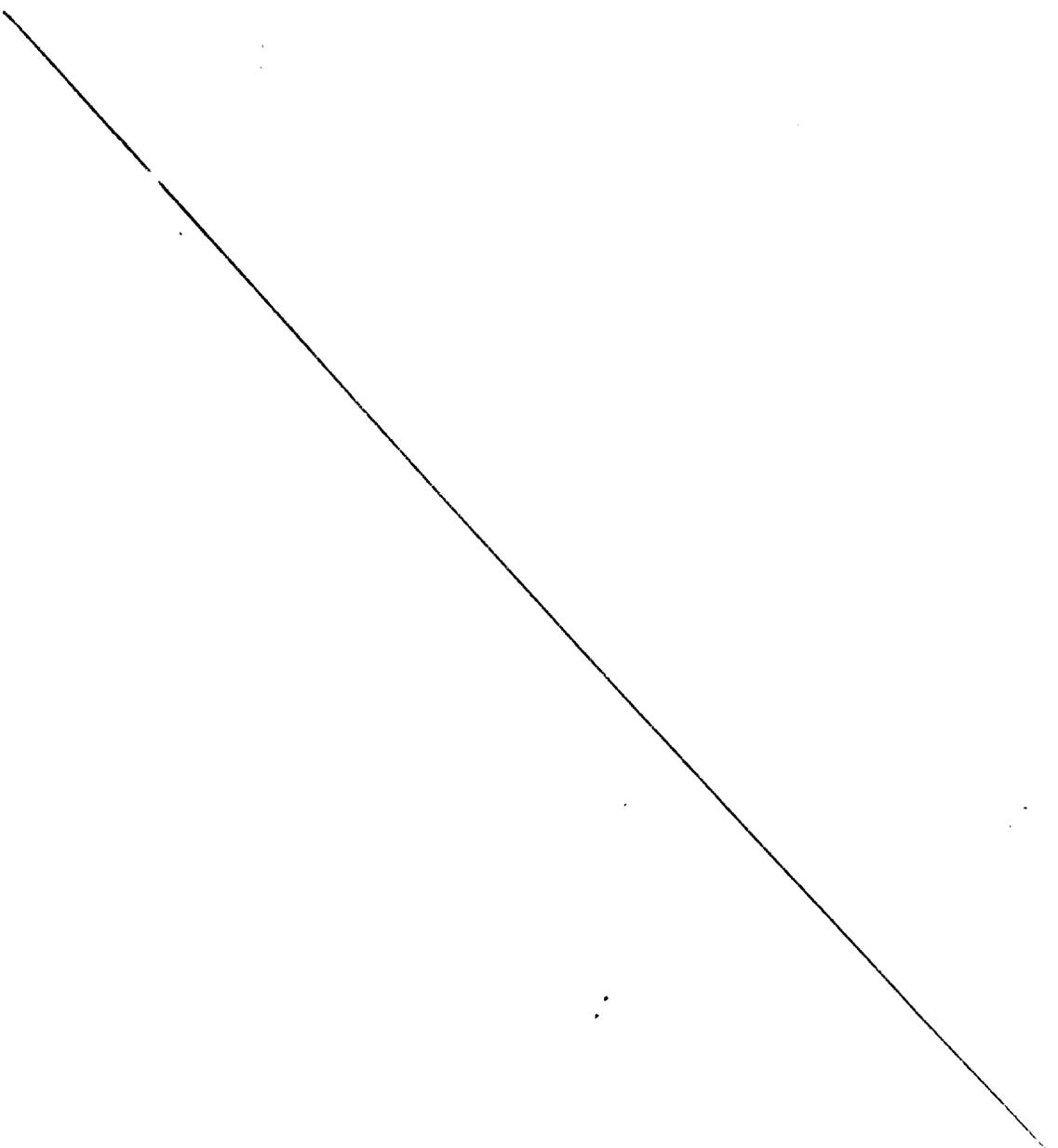
**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled “Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling.” The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform health care provider and patient labeling information. Once finalized, this draft guidance will replace the “Labeling Guidance for Estrogen Drug Products, Physician Labeling” and “Labeling Guidance for Estrogen Drug Products, Patient Package Insert,” both of which were revised and published in August 1992.

The draft guidance outlines recommended language for the prescribing information for the health care provider and the patient package inserts. Included are black box warnings explaining the increased risk of cancer of the uterus associated with the use of estrogens. Once finalized, the recommendations in this draft guidance should be followed for all approved, pending, and future applications.

In the **Federal Register** of October 15, 1998 (63 FR 55399), FDA announced the availability of an earlier version of this draft guidance. The agency received numerous comments. As a result, the original draft guidance was revised substantially and is being issued in draft for a second time.

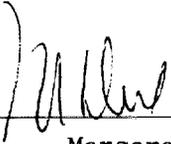
This Level 1 draft guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). It represents the agency’s current thinking on estrogen class labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number



found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/17/99  
September 17, 1999



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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