DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0834]

Withdrawal of Guidances on Estrogen and Estrogen/Progestin-Containing Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of two guidances: A draft entitled‘‘Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescibing Information for Healthcare Providers and Patient Labeling’’ and a final ‘‘Guidance for Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women.’’ These guidances are under agency review for change.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to agency guidance documents.

FOR FURTHER INFORMATION CONTACT: Dan Shames, 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 withdrawal of two guidances on estrogen and estrogen/progestin drug products. The two guidances being withdrawn are the draft guidance ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescibing Information for Healthcare Providers and Patient Labeling'' (labeling guidance) and the final ''Guidance for Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women'' (combination guidance). The draft labeling guidance was made available for comment in the **Federal Register** of September 27, 1999 (64 FR 52100); the final combination guidance was made available in March 1995. Both guidances are undergoing review for change as a result of the results from the National Institutes of Health (NIH) Women's Health Initiative trial.[1]

Interested persons may submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**). 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. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

[1] The results of the NIH Women's Health Initiative trial were reported in the *Journal of the American Medical Association,* 2002;288:321–333.

Persons with access to the Internet may obtain CDER guidance documents at http://www.fda.gov/cder/guidance/index.htm.

Dated: August 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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