

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rescission of Compliance Policy Guide (CPG), section 460.200 (formerly CPG 7132.16) entitled "Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies." CPG 7132.16 no longer reflects current agency enforcement policy consistent with the provisions of section 127 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**FOR FURTHER INFORMATION CONTACT:** Fred Richman, Center for Drug Evaluation and Research (HFD-332), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855-2737, 301-872-7292.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the rescission of CPG, section 460.200 (formerly CPG 7132.16) entitled "Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies." CPG 7132.16 no longer reflects current agency enforcement policy consistent with the provisions of section 127 of FDAMA.

FDAMA adds section 503A to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a) to describe circumstances under which compounded drugs are exempt from certain adulteration, misbranding, and new drug requirements of the act. To gain these exemptions, compounded drug products are generally prepared by a licensed pharmacist or licensed physician for individual patients because the products are not available commercially. FDA is developing regulations and guidance on this subject.

Dated: January 4, 1999.

**William K. Hubbard,**  
Associate Commissioner for Policy  
Coordination.

[FR Doc. 99-382 Filed 1-7-99; 8:45 am]

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meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. The agenda will include a presentation by Dr. Jane E. Henney, Commissioner of Food and Drugs, sharing her priorities for FDA and the relationship between the agency and the health professional community. Other topics on the agenda are the sale of prescription drugs on the internet and direct-to-consumer advertising of prescription drugs.

**DATES:** The meeting will be held on Monday, February 8, 1999, from 1:30 p.m. to 3:30 p.m.

**ADDRESSES:** The meeting will be held at the Hyatt Regency Hotel, One Metro Center, Bethesda, MD.

**FOR FURTHER INFORMATION CONTACT:** Peter H. Rheinstein, Office of Health Affairs (HFY-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6630.

Those persons interested in attending this meeting should call Betty Palsgrove at 301-827-6618 to register. Registration also may be transmitted by fax to 1-800-344-3332 or 301-443-2446. Please include the name and title of the person attending, the name of the organization, address, and telephone number. There is no registration fee for this meeting, however, early registration is suggested because space is limited. Persons will be registered in the order in which calls are received.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff. It will also provide an opportunity for informal discussion on these topics of particular interest to health professional organizations.

Dated: January 4, 1999.

**William K. Hubbard,**  
Associate Commissioner for Policy  
Coordination.

[FR Doc. 99-381 Filed 1-7-99; 8:45 am]

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening until February 13, 1999, the comment period on the draft guidance for industry entitled "Labeling Guidance for Non-Contraceptive Estrogen Drug Products—Physician and Patient Labeling." FDA published a notice of availability of the draft guidance in the **Federal Register** of October 15, 1998. FDA is taking this action in response to a request to extend the comment period.

**DATES:** Written comments may be submitted by February 13, 1999. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of the draft guidance are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm". Submit written requests for single copies of the draft guidance 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. Comments are to be identified with the docket number found in brackets in the heading of this document.

**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:** In the **Federal Register** of October 15, 1998 (63 FR 55399), FDA announced the availability of a draft guidance for industry entitled "Labeling Guidance for Non-Contraceptive Estrogen Drug Products—Physician 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 physician and patient labeling information.

On November 11, 1998, FDA received a letter from Regulatory Affairs, Wyeth-Ayerst Research requesting that the agency extend the comment period on the draft guidance 60 days. The agency has decided to reopen and extend the comment period to February 13, 1999.

Interested persons may, on or before February 13, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Open Meeting for Representatives of Health Professional Organizations

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting with representatives of health professional organizations. The

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0834]

#### Draft Guidance for Industry on Non-Contraceptive Estrogen Class Labeling; Availability; Reopening of Comment Period

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

**ACTION:** Notice; reopening of comment period.