The Rule also requires specific disclosures in advertisements or other promotional materials to ensure that the claims are fair and not deceptive. This burden is extremely small because retailers typically use advertising copy provided by the insulation manufacturer, and even when retailers prepare their own advertising copy, the Rule provides some of the language to be used. Accordingly, approximately one hour per year per retailer is sufficient for compliance with this requirement, for a total annual burden of approximately 25,000 hours.

Retailers who make energy savings claims in advertisements or other promotional materials must keep records that indicate the substantiation they are relying upon. Because few retailers make these types of promotional claims and because the Rule permits retailers to rely on the insulation manufacturer's substantiation data for any claims that are made, the additional recordkeeping burden is *de minimis.* The time calculated for disclosures, above, would be more than adequate to cover any burden imposed by this recordkeeping requirement.

To summarize, staff estimates that the Rule impose a total of 366,331 burden hours, as follows: 150 recordkeeping and 3,390 testing and disclosure hours for manufacturers; 125 recordkeeping and 29,333 disclosure hours for installers; 283,333 disclosure hours for new home sellers; and 50,000 disclosure hours for retailers. This figure has been rounded to 366,400 burden hours.

Estimated Annual Labor Costs: The total annual labor costs for the Rule's information collection requirements is $7,290,030, derived as follows: $600 for testing, based on 30 hours for manufacturers (30 hours × $20 per hour for skilled technical personnel); $2,750 for complying with the recordkeeping requirements of the Rule, based on 275 (275 hours × $10 per hour for clerical personnel); $33,360 for manufacturers' compliance with third-party disclosure requirements, based on 3,360 hours (3,360 hours × $10 per hour for clerical personnel); and $7,253,350 for compliance by installers, new home sellers, and retailers with third-party disclosure requirements, based on 362,666 hours (362,666 hours × $20 per hour for sales persons).

Estimate of Capital and Other Non-Labor Costs: There are no significant current capital or other non-labor costs associated with this Rule. Because the Rule has been in effect since 1980, members of the industry are familiar with its requirements and already have in place the equipment for conducting tests and storing records. New products are introduced infrequently. Because the required disclosures are placed on packaging or on the product itself, the Rule's additional disclosure requirements do not cause industry members to incur any significant additional non-labor associated costs.

6. Title: FTC Administrative Activities (OMB Control Number 3084–0047)—Extension

Currently, the FTC has OMB clearance for certain administrative and/or procedural activities relating to: (1) FTC procurement activities; (2) the document order form used by the FTC public reference branch; (3) applications to the Commission, including applications and notices contained in the Commission's Rules of Practice (primarily Parts I, II, and IV); and (4) rules governing claims against the FTC under the Equal Access to Justice Act.

The FTC seeks to delete items (1), (2), and (4). With respect to item (1), OMB has advised the FTC that it must seek clearance only for any agency-unique information collections that have been published as a supplement to the Federal Acquisition Regulations. The FTC has no such supplement and accordingly, there is no requirements to obtain OMB approval. Deleting this item eliminates 1,000 of 2,300 hours estimated in the FTC's 1995 submission for OMB Control No. 3084–0047.

With respect to item (2), FTC Form 14 is excluded from the PRA's definition of ''information'' because the form asks only for the respondent's name, address, a description of the records and the number of copies requested. *See* 5 CFR 1320.3(h)(1) (the definition of ''information'' excludes an ''affidavit'' or ''certification'' that asks the respondent for identifying information such as his or her name, address, the date, and the nature of the instrument); OMB Implementing Guidance to the Paperwork Reduction Act of 1995 (Preliminary Draft), February 3, 1997 (certain other information, such as quantity, quality, or location, may also be excluded). Deleting this item eliminates another 1,000 or 2,300 hours.

With respect to item (4), the ''law enforcement'' exception of the PRA excludes this category, because it involves collecting information during the conduct of a Federal investigation, civil action, administrative action, investigation, or audit with respect to a specific party, or subsequent adjudicative or judicial proceeding designed to determine fines or other penalties. *See* 5 CFR 1320.4(a)(1)–(3). Deleting this item eliminates another 200 hours of the 2,300 hours previously estimated for this submission.

With respect to item (3), the FTC is requesting an extension for those provisions covered by that category. Several of the Commission's rules contain provisions that allow certain modifications to, or exemptions from, a rule. For example, part 901 of the Commission's rules, 16 CFR part 901, implementing the Fair Debt Collection Practices Act, 15 U.S.C. 1692, sets forth the procedures and standards for approving petitions received from a state that is requesting permission to apply state law in lieu of federal standards.

Estimated Annual Burden Hours: Most applications to the Commission generally fall within the ''law enforcement exception'' discussed above, and those that are not rare and burden associated with them is *de minimis.* For example, over the last decade, the Commission has received only one application for an exemption under the Fair Debt Collection Practices Act provisions. Staff has estimated that such a submission can be completed well within 50 hours. Applications and notices to the Commission contained in other rules (generally in Parts I, II, and IV of the Commission's Rules of Practice) are also infrequent and difficult to quantify. An example is a request for a waiver of costs for obtaining Commission records. *See* 16 CFR 4.8(e). Nonetheless, in order to cover any potential ''collections of information'' for which we have not otherwise requested clearance, we are requesting a total of 100 burden hours as an estimate of the time needed to submit any relevant responses.

Estimated Annual Labor Costs: Based on 100 burden hours, and an hourly rate of $250 for attorney time, we estimate the annual cost burden to be no more than $25,000.

Estimated Capital and Start-Up Costs/Operation and Maintenance: Not applicable.

Debra A. Valentine,

General Counsel.

[FR Doc. 99–384 Filed 1–7–99; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92D–0077]

Compliance Policy Guide, Section 460.200 (CPG 7132.16); Rescinded

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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]

BILLING CODE 4160–01–F

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 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]

BILLING CODE 4160–01–F

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.

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