that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by April 27, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

National Tobacco Retailer Tracking Survey

On February 28, 1997, new Federal regulations in 21 CFR part 897 went into effect that prohibit retailers from selling cigarettes and smokeless tobacco to persons younger than 18 years of age, and require retailers to verify, by means of photographic identification, the age of purchaser younger than 27 years old. To enforce these requirements, FDA is commissioning State officials to conduct compliance checks during which an adolescent, accompanied by a commissioned official, will attempt to purchase cigarettes and smokeless tobacco at retail establishments.

FDA is planning to conduct a national advertising campaign aimed at raising retailers' awareness of the new regulations and motivating retailers to comply. The campaign will target persons who sell cigarettes or smokeless tobacco to consumers for their personal use, including clerks and cashiers in grocery and convenience stores, pharmacies and drug stores, gas stations, liquor stores, taverns and bars, and tobacco stores. As a part of the campaign, FDA is proposing to conduct a three-part telephone survey of tobacco retailers to measure their awareness of, and compliance with, the new regulations before and after exposure to the advertising campaign.

The initial overall media campaign would focus on the 10 States with which FDA has already contracted to conduct compliance checks, and would be expanded as additional States contract with FDA. The media campaign would be conducted over a 12-month period in each State that receives it. States that have contracted with FDA and are exposed to the media campaign (test States) will be compared with States that have not contracted with FDA (control States). Although some of the control States may contract with FDA during the course of the data collection, at the start of the data collection there would be 10 test States and 10 control States.

A total of 6,000 tobacco retailers would be randomly selected to participate in a telephone interview over three phases of data collection. Data would be collected in three phases over a 12-month period. The first phase would occur immediately before the 10 test States that have contracted with FDA are exposed to the media campaign. The second phase would occur approximately 6 months later and would allow for an assessment of retailer awareness of and compliance with the new regulations after recent exposure to the advertising campaign in the original 10 test States. A third phase of data collection would be conducted approximately 6 months after the second phase. This phase would address retailer awareness of and compliance with the new regulations after extended exposure to the media campaign in the original 10 test States, and would address retailer awareness of and compliance with the new regulations after recent exposure to the advertising campaign in those former control States that contracted with FDA after the first phase of data collection. All interviewing would be conducted by a single-market research firm that would employ computer-aided telephone interviewing technology to expedite the fieldwork and improve accuracy. FDA plans to use the results of the survey to assess the effectiveness of the advertising campaign. Under section 903(b)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393 (b)(2)(C)), FDA is authorized to conduct surveys and other research relating to its responsibilities.

In the **Federal Register** of December 30, 1997 (62 FR 67876), the agency requested comments on the proposed collection of information. No comments were received.

Respondents to this collection of information would be tobacco retailers and salesclerks.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
6,000	1	6,000	0.2	1,200

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

Dated: March 20, 1998.

William K. Hubbard,

Associate Commisioner for Policy Coordination.

[FR Doc. 98–7832 Filed 3–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0489]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by April 26, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collections of information to OMB for review and clearance.

Petition For Administrative Reconsideration of Action—21 CFR 10.33—(OMB Control Number 0910–0192—Reinstatement)

Section 10.33 (21 CFR 10.33), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may petition the Commissioner of Food and Drugs (the Commissioner) for reconsideration of an agency's action. A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. Each petition must be submitted no later than 30 days after the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions.

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
10.33(b)	7	1	7	10	70

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

Due to a typographical error, the total burden hours were reported as 700 in FDA's December 16, 1997 (62 FR 65812), notice providing 60 days for public comment on this collection of information. The total has been corrected to 70. The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative reconsideration of an action estimate approximately seven requests being received by the agency annually, each requiring an average of 10 hours preparation time.

Dated: March 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7893 Filed 3–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on May 13, 14, and 15, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 13, 1998, the committee will discuss the science of corticosteroid induced osteoporosis. On May 14, 1998, the committee will discuss new drug application (NDA) 20–866, Ergoset™, (bromocryptine mesylate, Ergoscience) as monotherapy as an adjunct to diet to improve glycemic control in patients with non-insulin-dependent diabetes mellitus, whose hyperglycemia cannot be satisfactorily managed with diet alone; or concomitantly with a sulfonylurea when diet and Ergoset™ alone do not result in glycemic control. On May 15, 1998, the committee will discuss NDA 20–898, Thyrogen™, (thyrotropin alpha, rTSH, Genzyme) as an adjunct for the detection of thyroid cancer.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 8, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on May 13, 14, and 15, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 8, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 19, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–7897 Filed 3–25–98; 8:45 am]

BILLING CODE 4160–01–F