Agency for Health Care Policy and Research (AHCPR), the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA), the National Institutes of Health (NIH), and the Office of Public Health and Science (OPHS), serve on the Board. This public meeting will have two purposes:

1. Members of the Orphan Products Board will discuss their agencies recent orphan product development activities.

2. In keeping with its mandate to foster actions within the Department of Health and Human Services to facilitate the research, development, and approval of orphan products and to coordinate Government activities with the private sector in order to achieve these goals, the board encourages presentations by members of the public on any issues involving the development and availability of orphan products. Those persons wishing to make a presentation at the meeting should submit a written request for a time slot to the Executive Director of the Orphan Products Board. The request for participation should be submitted before February 4, 1998, and should include: (a) Name, address, and telephone number of the person desiring to make a presentation; (b) affiliation, if any; (c) a summary of the presentation; and (d) the approximate amount of time required for the presentation (no more than 10 minutes, unless more time can be justified).

Individuals and organizations with common interests or proposals are urged to coordinate or consolidate their presentations. Joint presentations may be required of persons or organizations with a common interest. The time available will be allocated among the individuals who request an opportunity for a presentation. Formal written statements or extensions of remarks (five copies) should be presented to the Executive Director on the day of the meeting for inclusion in the record of the meeting. At the discretion of the Chairman, and as time permits, any person in attendance may be heard. This time will, most likely, be at the end of the scheduled session. For those unable to attend the meeting, comments may be sent to the listed contact person.

Dated: December 18, 1997.

John M. Eisenberg,

Acting Assistant Secretary for Health.

[FR Doc. 97–33869 Filed 12–29–97; 8:30 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency For Health Care Policy and Research

Notice of Health Care Policy and Research; Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following special emphasis panel scheduled to meet during the month of January 1998:

Name: Health Care Policy and Research Special Emphasis Panel.

Date and Time: January 6–7, 1998, 8:00 a.m.

Place: Doubletree Hotel, 1750 Rockville Pike, Rockville Room, Rockville, MD 20852. Open January 6, 8:00 a.m. to 8:30 a.m. Closed for remainder of meeting.

Purpose: This Panel is charged with conducting the initial review of grant applications proposing health services research training programs under the National Research Service Awards Program.

Agenda: The open session of the meeting on January 6, from 8:00 a.m. to 8:30 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the committee will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, Agency for Health Care Policy and Research, has made a formal determination that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Sheila Simmons, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland, 20852, Telephone (301) 594–1452 x 1627.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: December 22, 1997.

John Eisenberg,

Administrator.

[FR Doc. 97–33870 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0446]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on adverse drug experience reporting and recordkeeping requirements.

DATES: Submit written comments on the collection of information by March 2, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Postmarketing Reporting of Adverse Drug Experiences—21 CFR 310.305 and 314.80—(OMB Control Number 0910–0230—Reinstatement)

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences occasioned by the use of marketed drugs. In order to help ensure this, FDA issued regulations in §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to impose reporting and recordkeeping requirements on the drug industry that would enable FDA to take actions necessary for protection of the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report to FDA serious, unexpected adverse drug experiences, as well as followup reports when needed (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as those obtained in scientific literature and from postmarketing epidemiological/surveillance studies. Under § 314.80(c)(2) applicants must provide periodic reports of adverse drug experiences. Under § 314.80(i) applicants must keep for 10 years records of all adverse drug experience reports known to the applicant.

For marketed prescription drug products without approved new drug applications or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports when needed (§ 310.305(c)(1) and (c)(3)). Under § 310.305(f) each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA's adverse drug experience reporting system is to provide a signal for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provides, for the first time, the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning) and, when necessary, to initiate removal of a drug from the market.

Respondents to this collection of information are manufacturers, packers, distributors and applicants. 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
310.305(c)(5)	1	1	1	1	1
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	683	1.5	1,025	5	5,125
Total					5,131

[1] The reporting burden for §§ 310.305(c)(1)(i), 310.305(c)(3), and 314.80(c)(1)(i) was reported in 0910–0291. There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
310.305(f)	25	1	25	1	25
314.80(i)	683	1	683	1	683
Total					6,547

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

These estimates are based on FDA's knowledge of adverse drug experience reporting, including knowledge about the time needed to prepare the reports and the number of reports submitted to the agency.

Dated: December 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33797 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0529]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a three-part telephone survey of tobacco retailers, to assess the effectiveness of an advertising campaign aimed at increasing retailers' awareness of, and motivating retailers to comply with, new regulations 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 containing the bearer's date of birth, the age of every purchaser who is younger than 27 years old.

DATES: Submit written comments on the collection of information by March 2, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and two copies of any comment are to be submitted except that individuals may submit one copy comments should 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.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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