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

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 21 U.S.C. 393 (b)(2)(C), FDA is authorized to conduct surveys and other research relating to its responsibilities under the Federal, Food, Drug, and Cosmetic Act.

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]

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
897	6,000	1	6,000	.2	1,200

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

Dated: December 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–33925 Filed 12–29–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0509]

Hoffmann-La Roche, Inc.; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Hoffmann-La Roche, Inc. The NADA provides for use of chlortetracycline Type A medicated article to make Type B or Type C medicated feeds. The sponsor requested the withdrawal of approval because the animal drug product is no longer manufactured or marketed.

EFFECTIVE DATE: January 9, 1998.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199, is the sponsor of NADA 100–903 that provides for use of chlortetracycline Type A medicated articles to make Tpye B or Type C medicated feeds. The animal drug product had been subject to review under the National Academy of Sciences/National Research Council, Drug Efficacy Study Implementation Program, and it was currently subject to requirements for finalization under that program. By letter of August 20, 1997, the sponsor requested withdrawal of approval of the NADA because the animal drug product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.48), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 100–903 and all supplements and amendments thereto is hereby withdrawn, effective January 9, 1998.

This product had not been the subject of a regulation published under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Therefore, an amendment to the animal drug regulations to reflect the withdrawal of approval is not required.

Dated: December 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33922 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Developing U.S. Public Health Service Policy on Xenotransplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Developing U.S. Public Health Service Policy on Xenotransplantation. The topic to be discussed is the current and evolving U.S. Public Health Service (U.S. PHS) policy on xenotransplantation. Xenotransplantation refers to any procedure that involves the use of live cells, tissues, and organs from a nonhuman animal source, transplanted or implanted into a human or used for ex vivo perfusion. The meeting is being sponsored by U.S. PHS agencies including FDA, National Institutes of Health, Centers for Disease Control and Prevention, and the Health Resources and Services Administration.

Date and Time: The public workshop will be held on January 21 and 22, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Natcher Auditorium, National Institutes of Health, 9000 Rockville Pike, Bldg. 45, Bethesda, MD.

Contact: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6333, FAX 301–443–3874, or e-mail Beth@a1.cber.fda.gov.

SUPPLEMENTARY INFORMATION: The goals of the meeting include the following: (1) Describing the scope of current clinical trials in xenotransplantation; (2) exploring the potential public health benefits and risks of xenotransplantation; (3) presenting frameworks for the evaluation of ethical issues presented by xenotransplantation; (4) describing current and evolving PHS policy on xenotransplantation and the development of specific public health mechanisms to implement policy; such mechanisms may include, but are not limited to: (a) a revised U.S. PHS guideline on infectious disease issues in xenotransplantation; (b) the evolving regulatory framework for oversight of xenotransplantation; (c) the pilot xenotransplantation registry database; (d) the strategies for archiving biologic specimens for public health investigations; (e) the methods for ensuring public awareness of current issues and discussion of new developments in xenotransplantation; and (5) presenting international perspectives on xenotransplantation policy development. The meeting is open to all interested persons.

Registration: There is no fee to attend this meeting. To register for the meeting please contact Cody Bridges, Chris