

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 BURDEN¹

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]

BILLING CODE 4160-01-F

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 Type 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

Waddel, or Pamela Milan at 301-490-5500, e-mail "cbridges@lcn.net" or "cwaddell@lcn.net", or "pmilan@lcn.net". If you need special accommodations due to a disability, please contact Cody Bridges at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-33927 Filed 12-29-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 1998; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of December 9, 1997 (62 FR 64849). The notice announced the rates for prescription drug user fees for Fiscal Year (FY) 1998. The document was published with an inadvertent editorial error. This document corrects that error.

DATES: The new fee rates were effective October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Michael E. Roosevelt, Office of Financial Management (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5088.

In FR Doc. No. 97-32166, beginning on page 64849 in the **Federal Register** of Tuesday, December 9, 1997, the following correction is made:

1. On page 64850, in the last column, in the table at the bottom of the page, and on page 64851, in the first column, in the table at the top of the page, the heading of the second column "Fee rates for FY 1997" is corrected to read "Fee rates for FY 1998".

Dated: December 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-33800 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-0401]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Export of Medical Devices—Foreign Letters of Approval" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 3, 1997 (62 FR 51872), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0264. The approval expires on November 30, 2000.

Dated: December 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-33794 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-0380]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Importer's Entry Notice" has been approved by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 the **Federal Register** of September 22, 1997 (62 FR 49519), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0046. The approval expires on November 30, 2000.

Dated: December 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-33796 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-0022]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Agreement for Shipment of Devices for Sterilization" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 4, 1997 (62 FR 46744), the agency announced