

Drug labeler code	Firm name and address
* * * * *	* * * * *
047015 .....	Rhone Merieux Canada, Inc., 345 Boul. Labbe Blvd., North, Victoriaville, QC G6P 1B1 Canada.
* * * * *	* * * * *

**PART 520—ORAL DOSAGE FORM  
NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

**§ 520.1660d [Amended]**

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (b)(2) by adding the phrase “and 047015” after “017144,” and by removing and reserving paragraph (c).

Dated: July 31, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-19634 Filed 8-8-95; 8:45 am]

BILLING CODE 4160-01-F

**21 CFR Parts 510 and 529**

**Animal Drugs, Feeds, and Related Products; Isoflurane**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Halocarbon Laboratories, Division of Halocarbon Products Corp. The ANADA provides for use of isoflurane as an inhalant for induction and maintenance of general anesthesia in horses and dogs.

**EFFECTIVE DATE:** August 9, 1995.

**FOR FURTHER INFORMATION CONTACT:**

Sandra K. Woods, Center For Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1616.

**SUPPLEMENTARY INFORMATION:**

Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661, filed ANADA 200-129 which provides for inhalant use of isoflurane for induction and maintenance of general anesthesia in horses and dogs. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200-129 for Halocarbon Laboratories’ isoflurane is as a generic copy of Anaquest’s NADA 135-773 for AErrane® (isoflurane). The ANADA is approved as of June 29, 1995, and the regulations are amended by revising 21 CFR 529.1186(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary. In addition, Halocarbon Laboratories has not been previously listed in 21 CFR 510.600(c) as sponsor of an approved application. That section is amended to add entries for the firm.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency’s finding of no significant impact and the evidence

supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects**

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 529*

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 529 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for “Halocarbon Laboratories” and in the table in paragraph (c)(2) by numerically adding a new entry for “012164” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * * * *	* * * * *
Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661.	012164
* * * * *	* * * * *

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	* * * * *
012164 .....	Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661.
* * * * *	* * * * *

**PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 529 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 529.1186 is amended by revising paragraph (b) to read as follows:

**§ 529.1186 Isoflurane.**

\* \* \* \* \*

(b) *Sponsors.* See Nos. 000074, 010019, and 012164 in § 510.600(c) of this chapter.

\* \* \* \* \*

Dated: July 31, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-19684 Filed 8-8-95; 8:45 am]

BILLING CODE 4160-01-F

**AGENCY FOR INTERNATIONAL DEVELOPMENT**

**22 CFR Part 213**

RIN 0422-AA25

**Collection of Debts by Tax Refund Offset**

**AGENCY:** Agency for International Development.

**ACTION:** Final rule.

**SUMMARY:** The Agency for International Development is amending its debt collection regulations to implement the tax refund offset provisions of 31 U.S.C. 3720A.

**DATES:** Effective August 9, 1995.

**FOR FURTHER INFORMATION CONTACT:** Jan W. Miller, Office of the General Counsel, Room 6881, N.S., Agency for International Development, Washington, DC 20523; (202) 647-6380.

**SUPPLEMENTARY INFORMATION:** A proposal to amend 22 CFR part 213 to allow the agency to recover delinquent debts owed the United States Government through the offset of tax refunds was published in the **Federal Register** on January 12, 1995, (60 FR 2911). No comments were received.

**Regulatory Impact**

This rule is not a “significant regulatory action” under Executive Order No. 12866.

**Environmental Impact**

This action does not constitute a major Federal action significantly affecting the quality of the human environment.

**List of Subjects in 22 CFR Part 213**

Claims, salary offset.

Accordingly, 22 CFR part 213 is amended as follows:

1. The authority citation for part 213 is revised to read as follows:

**Authority:** Sec. 621 of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2381; subpart B also issued under 5 U.S.C. 5514; 5 CFR 550, subpart K. Subpart C also issued under 31 U.S.C. 3720A.

2. Part 213 is amended to add a new subpart C as follows:

**PART 213—COLLECTION OF CLAIMS**

\* \* \* \* \*

**Subpart C—Collection of Debts by Tax Refund Offset**

- 213.21 Purpose.
- 213.22 Applicability and scope.
- 213.23 Administrative charges.
- 213.24 Pre-offset notice.
- 213.25 Reasonable attempt to notify and clear and concise notification.
- 213.26 Consideration of evidence and notification of decision.
- 213.27 Change in conditions after submission to IRS.

**Subpart C—Collection of Debts by Tax Refund Offset**

**§ 213.21 Purpose.**

This subpart establishes procedures for AID to refer past due debts to the Internal Revenue Service (IRS) for offset against income tax refunds of taxpayers owing debts to AID.

**§ 213.22 Applicability and scope.**

(a) This subpart implements 31 U.S.C. 3720A which authorizes the IRS to reduce a tax refund by the amount of a past due and legally enforceable debt owed to the United States.

(b) A past due legally enforceable debt referable to the IRS is a debt which is owed to the United States and:

(1) Except for judgement debt or other debts specifically exempt from this requirement, is referred within 10 years after AID’s right of action accrues;

(2) In the case of individuals, is at least \$25.00.

(3) In the case of business debtors is at least \$100.00;

(4) In the case of individual debtors, cannot be currently collected pursuant to the salary offset provisions of 5 U.S.C. 5514(a).

(5) Is ineligible for or cannot be currently collected pursuant to the administrative offset provisions of 31 U.S.C. 3716;

(6) Is the debt of a debtor (or in the case of an individual debtor, his or her spouse) for whom AID records do not show debtor has filed for bankruptcy under title 11 of the United States Code or for whom AID can clearly establish at the time of the referral that an automatic stay under 11 U.S.C. 362 has been lifted or is no longer in effect;

(7) Has been disclosed by AID to a consumer reporting agency as authorized by 31 U.S.C. 3711(f); and

(8) For which AID has given notice, considered any evidence, and determined that the debt is past-due and legally enforceable under the provisions of this subpart.

**§ 213.23 Administrative charges.**

All administrative charges incurred in connection with the referral of debts to the IRS will be added to the debt, thus increasing the amount of the offset.

**§ 213.24 Pre-Offset Notice.**

(a) Before AID refers a debt to the IRS, it will notify or make a reasonable attempt to notify the debtor that:

(1) The debt is past due;

(2) Unless repaid within 60 calendar days thereafter, the debt will be referred to the IRS for offset against any overpayment of tax;

(3) The debtor has at least 60 days from the date of the notice to present evidence that all or part of such debt is