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Dated: December 8, 1999.

L. Robert Lake,

Director, Office of Policy, Planning, and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–33095 Filed 12–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Atipamezole; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect that Orion Corp. is the correct sponsor of a new animal drug application (NADA) for Atipamezole Injection. When FDA issued the regulation reflecting the NADA approval, Pfizer, Inc., the U.S. agent for Orion Corp., was incorrectly listed as the sponsor of the application. This document corrects that error.

EFFECTIVE DATE: December 22, 1999.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1739.

SUPPLEMENTARY INFORMATION: FDA has discovered an error in the agency's regulations for animal drugs, feeds, and related products. A final rule published in the **Federal Register** of September 17, 1996 (61 FR 48829), added § 522.147 (21 CFR 522.147) and incorrectly stated that Pfizer, Inc., was the sponsor of the NADA. FDA is amending § 522.147 to correctly identify Orion Corp. as the sponsor.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.147 [Amended]

2. Section 522.147 *Atipamezole hydrochloride* is amended in paragraph (b) by removing ''000069'' and adding in its place ''052483''.

Dated: December 14, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–33123 Filed 12–21–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Sevoflurane

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 a new animal drug application (NADA) filed by Abbott Laboratories. The NADA provides for use of sevoflurane as an inhalant for induction and maintenance of general anesthesia in dogs.

EFFECTIVE DATE: December 22, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064–4000, filed NADA 141–103 that provides for use of SevoFlo™ (sevoflurane) as an inhalant for induction and maintenance of general anesthesia in dogs. The NADA is approved as of November 17, 1999, and the regulations are amended by adding § 529.2150 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for nonfood producing animals qualifies for 5 years of market exclusivity beginning November 17, 1999, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 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 part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

2. Section 529.2150 is added to read as follows:

§ 529.2150 Sevoflurane.

(a) *Specifications.* The drug is a clear, colorless, stable liquid containing no additives or chemical stabilizers.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For induction of surgical anesthesia: 5 to 7 percent sevoflurane with oxygen. For maintenance of surgical anesthesia: 3.7 to 4 percent sevoflurane with oxygen in the absence of premedication and 3.3 to 3.6 percent in the presence of premedication.

(2) *Indications for use.* For induction and maintenance of general anesthesia in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 13, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–33121 Filed 12–21–99; 8:45 am]

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