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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 Nutrion.

[FR Doc. 99–33094 Filed 12–21–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–2534]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of di(*n*-octyl)phosphite as an extreme pressure-antiwear adjuvant for lubricants intended for incidental contact with food. This action responds to a petition filed by Ciba Specialty Chemicals Corp.

DATES: Effective December 22, 1999. Submit written objections and requests for a hearing by January 21, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 9, 1999 (64 FR 43190), FDA announced that a food additive petition (FAP 9B4683) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., P.O. Box 2005, Tarrytown, NY 10591–9005. The petition proposed to amend the food additive regulations in § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) to provide for the safe use of di(*n*-octyl)phosphite as an extreme pressure-antiwear adjuvant for lubricants intended for incidental contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 178.3570 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4683 (64 FR 43190). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before January 21, 2000, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS.

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3570 is amended in the table in paragraph (a)(3) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3570 Lubricants with incidental food contact.

* * * * *

(a) * * *

(3) * * *

Substances	Limitations
* * * * * * *	
Di (*n*-octyl) phosphite (CAS Reg. No. 1809–14–9).	For use only as an extreme pressure-antiwear adjuvant at a level not to exceed 0.5 percent by weight of the lubricant.
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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]

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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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