

FDC date	State	City	Airport	FDC No.	SIAP
08/13/96	NH	Lebanon	Lebanon Muni	FDC 6/5998	NDB or GPS-B, AMDT 3...THIS REPLACES NOTAM 6/5252 LEB
08/19/96	MS	Jackson	Jackson Intl	FDC 6/6274	LOC BC RWY 15R AMDT 4...THIS CORRECTS TL96-19
08/22/96	MN	Moose Lake	Moose Lake-Carlton County	FDC 6/6428	NDB or GPS RWY 4, ORIG-A...
08/22/96	SD	Aberdeen	Aberdeen Regional	FDC 6/6416	ILS RWY 31, AMDT 12...
08/22/96	SD	Aberdeen	Aberdeen Regional	FDC 6/6417	LOC/DME BC RWY 13, AMDT 9...
08/22/96	SD	Aberdeen	Aberdeen Regional	FDC 6/6418	NDB RWY 31, AMDT 9...
08/22/96	SD	Aberdeen	Aberdeen Regional	FDC 6/6419	VOR/DME or GPS RWY 13, AMDT 11...
08/22/96	SD	Aberdeen	Aberdeen Regional	FDC 6/6420	VOR or GPS RWY 31 AMDT 19...
08/23/96	MN	Appleton	Appleton Muni	FDC 6/6454	NDB RWY 13 ORIG...
08/23/96	MN	Owatonna	Owatonna Muni	FDC 6/6458	VOR/DME RWY 30 AMDT 2A...
08/26/96	IA	Davenport	Davenport Muni	FDC 6/6486	VOR or GPS RWY 21, AMDT 7...
08/26/96	IA	Davenport	Davenport Muni	FDC 6/6488	ILS RWY 15, ORIG...
08/26/96	IA	Davenport	Davenport Muni	FDC 6/6490	VOR or GPS RWY 3, AMDT 8...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6469	NDB RWY 13, AMDT 15A...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6472	ILS RWY 13, AMDT 1A...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6474	ILS RWY 31, AMDT 24B...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6476	VOR/DME or TACAN or GPS RWY 13, AMDT 17A...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6478	VOR or TACAN or GPS RWY 31, AMDT 25A...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6479	NDB RWY 31, AMDT 23A...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6480	NDB RWY 35, ORIG...
08/26/96	IA	Sioux City	Sioux Gateway	FDC 6/6481	GPS RWY 17, ORIG...
08/26/96	OK	Oklahoma City	Will Rogers World	FDC 6/6468	ILS RWY 4R AMDT 9...
08/28/96	IL	Chicago	Chicago O'Hare Intl	FDC 6/6638	ILS RWY 4R AMDT 6...
08/28/96	MN	Faribault	Faribault Muni	FDC 6/6632	VOR or GPS-A AMDT 3A...
08/28/96	MN	Owatonna	Owatonna Muni	FDC 6/6636	VOR or GPS RWY 12 AMDT 8A...
08/28/96	MN	WaSECA	WaSECA Muni	FDC 6/6634	VOR or GPS-A AMDT 3A...
08/28/96	OH	Hillsboro	Highland County	FDC 6/6635	VOR/DME or GPS-A AMDT 1A...
09/03/96	FL	Jacksonville	Craig Muni	FDC 6/6770	ILS RWY 32, AMDT 3...
09/03/96	GA	Jefferson	Jackson County	FDC 6/6760	VOR/DME or GPS RWY 34 Orig...
09/03/96	MN	Waseca	Waseca Muni	FDC 6/6703	NDB or GPS RWY 15 AMT 3A...
09/03/96	MN	Waseca	Wasec Muni	FDC 6/6703	NDB or GPS RWY 15 AMT 3A...
09/03/96	OH	Wilmington	Clinton Field	FDC 6/6706	VOR or GPS-A ORIG...
09/03/96	OH	Wilmington	Clinton Field	FDC 6/6706	VOR or GPS-A ORIG

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Atipamezole

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 Pfizer, Inc. The NADA provides for intramuscular

use of atipamezole hydrochloride sterile injectable solution in dogs as a medetomidine reversing agent.

EFFECTIVE DATE: September 17, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0614.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, has filed NADA 141-033, which provides for intramuscular use of Antisedan® (atipamezole hydrochloride) sterile injectable solution in dogs as a reversing agent for Domitor® (medetomidine).

Medetomidine is a sedative and analgesic agent approved for use in dogs. The NADA is approved as of August 6, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.147 to reflect the

approval. The basis of approval is discussed in the freedom of information summary.

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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, 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 (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning August 6, 1996, because no active ingredient (including any ester or salt of the drug)

has been previously approved in any other application filed under section 512(b)(1) of the act.

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

2. New § 522.147 is added to read as follows:

§ 522.147 Atipamezole hydrochloride.

(a) *Specifications.* Each milliliter of sterile injectable solution contains 5.0 milligrams of atipamezole hydrochloride.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Inject intramuscularly the same volume as that of medetomidine used.

(2) *Indications for use.* To reverse clinical effects of the sedative and analgesic agent medetomidine hydrochloride.

(3) *Limitations.* For intramuscular use only. Not recommended for use in pregnant or lactating animals, or animals intended for breeding. Atipamezole has not been evaluated in breeding animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 4, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-23758 Filed 9-16-96; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR parts 1309, 1310 and 1313

[DEA No. 138F]

Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act); Correction

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to the final regulations which were published on Wednesday, August 7, 1996 (61 FR 40981). The regulations related to the removal of the exemption for certain pseudoephedrine products marketed under the Food, Drug, and Cosmetic Act (FD&C Act).

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT:

Frank Sapienza, Acting Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307-7183.

SUPPLEMENTARY INFORMATION: The final regulations that are the subject of these corrections remove the exemption for certain pseudoephedrine products marketed under the Food, Drug, and Cosmetic Act (FD&C Act). The regulations amend Title 21, Code of Federal Regulations, to revise certain sections in Parts 1309, 1310 and 1313.

The final rule (61 FR 40981) added a new section designated as "Section 1309.28". This new section should have been designated as "Section 1309.29". Therefore, in each instance where the final rule refers to the wording "Section 1309.28", the reader should substitute the wording "Section 1309.29".

Accordingly, the publication on August 7, 1996 of the final regulation (61 FR 40981) is corrected as follows:

PART 1309—[CORRECTED]

§ 1309.02 [Corrected]

1. On page 40989 in the second column § 1309.02(f) is corrected by removing "§ 1309.28" and adding "§ 1309.29" in its place.

§ 1309.29 [Corrected]

2. On page 40989, in the third column, amendatory instruction 3 is corrected to read as follows: "Section 1309.29 is added to read as follows:"

3. On page 40989, in the third column, the number and heading under amendatory instruction 3 are corrected to read as follows:

"§ 1309.29 Exemption of retail distributors of certain pseudoephedrine products."

PART 1310—[CORRECTED]

§ 1310.04 [Corrected]

4. On page 40990, § 1310.04, is corrected by removing § 1309.28" and adding "§ 1309.29" in its place.

Dated: September 9, 1996.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 96-23556 Filed 9-16-96; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 120, 123, and 128

[Public Notice 2408]

Bureau of Political-Military Affairs; Amendments to the International Traffic in Arms Regulations

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic in Arms Regulations (ITAR) to correct a typographical error in the definition of "technical data;" eliminate the requirement of reporting subsequent exports of unclassified technical data; and clarify authority and use the current names of any office, bureau, or titles of officers that have changed since 1990.

EFFECTIVE DATE: September 17, 1996.

FOR FURTHER INFORMATION CONTACT:

Philips S. Rhoads, Chief, Compliance and Enforcement Branch, Office of Defense Controls, Bureau of Political-Military Affairs, Department of State (703 875-6650).

SUPPLEMENTARY INFORMATION: Federal Register Public Notice No. 1179, dated March 29, 1990, announced that the Office of Munitions Control had changed its name to the Office of Defense Trade Controls. (55 FR 11714.) Part 128 of the International Traffic in Arms Regulations (ITAR) is being amended to reflect the current name of the Office of Defense Trade Controls. Other amendments reflect the name change of the Bureau of Politico-Military Affairs to its current name, the Bureau of Political-Military Affairs.

Additionally, references to the "Under Secretary of State for Security Assistance, Science and Technology" are being amended to the current title of the "Under Secretary of State for Arms Control and International Security Affairs." Furthermore, cross references to other sections in the ITAR are being