

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
21-Oct-10	CA	HALF MOON BAY	HALF MOON BAY	0/0656	9/7/10	RNAV (GPS) Y RWY 30, ORIG.
21-Oct-10	CA	HALF MOON BAY	HALF MOON BAY	0/0657	9/7/10	RNAV (GPS) Y RWY 12, ORIG.
21-Oct-10	CA	HALF MOON BAY	HALF MOON BAY	0/0658	9/7/10	RNAV (GPS) Z RWY 12, ORIG.
21-Oct-10	CA	HALF MOON BAY	HALF MOON BAY	0/0659	9/7/10	RNAV (GPS) Z RWY 30, ORIG.
21-Oct-10	RI	BLOCK ISLAND	BLOCK ISLAND STATE	0/0748	9/7/10	RNAV (GPS) RWY 10, ORIG-A.
21-Oct-10	RI	BLOCK ISLAND	BLOCK ISLAND STATE	0/0752	9/7/10	VOR/DME RWY 10, AMDT 5A.
21-Oct-10	VA	RICHMOND	RICHMOND INTL	0/0805	9/7/10	VOR RWY 25, AMDT 16A.
21-Oct-10	VA	RICHMOND	RICHMOND INTL	0/0806	9/7/10	VOR RWY 20, AMDT 1A.
21-Oct-10	VA	RICHMOND	RICHMOND INTL	0/0807	9/7/10	VOR RWY 16, AMDT 27A.
21-Oct-10	GA	GRIFFIN	GRIFFIN-SPALDING COUNTY	0/2036	9/7/10	GPS RWY 14, ORIG-A.
21-Oct-10	GA	GRIFFIN	GRIFFIN-SPALDING COUNTY	0/2037	9/7/10	GPS RWY 32, ORIG-A.
21-Oct-10	VA	FREDERICKSBURG	SHANNON	0/2537	9/7/10	GPS RWY 24, ORIG-B.
21-Oct-10	VA	FREDERICKSBURG	SHANNON	0/2539	9/7/10	NDB RWY 24, AMDT 2B.
21-Oct-10	AL	TALLADEGA	TALLADEGA MUNI	0/3032	9/7/10	VOR/DME RWY 3, AMDT 5.
21-Oct-10	VA	SALUDA	HUMMEL FIELD	0/4180	9/14/10	GPS RWY 1, ORIG-A.
21-Oct-10	VA	CHASE CITY	CHASE CITY MUNI	0/4228	9/14/10	RNAV (GPS) RWY 18, ORIG.
21-Oct-10	VA	CHASE CITY	CHASE CITY MUNI	0/4229	9/14/10	RNAV (GPS) RWY 36, ORIG-A.
21-Oct-10	MA	BOSTON	GEN EDWARD LAWRENCE LOGAN INTL.	0/5055	9/7/10	VOR/DME RWY 33L, AMDT 2C.
21-Oct-10	MA	BOSTON	GEN EDWARD LAWRENCE LOGAN INTL.	0/5057	9/7/10	VOR/DME RWY 27, AMDT 2B.
21-Oct-10	MA	BOSTON	GEN EDWARD LAWRENCE LOGAN INTL.	0/5058	9/7/10	VOR/DME RWY 15R, AMDT 2A.
21-Oct-10	MA	BOSTON	GEN EDWARD LAWRENCE LOGAN INTL.	0/5088	9/7/10	ILS RWY 22L, AMDT 7.
21-Oct-10	MA	BOSTON	GEN EDWARD LAWRENCE LOGAN INTL.	0/5089	9/7/10	VOR/DME OR GPS A, ORIG-A.
21-Oct-10	MA	BOSTON	GEN EDWARD LAWRENCE LOGAN INTL.	0/5092	9/7/10	ILS RWY 27, AMDT 2.
21-Oct-10	FL	TAMPA	TAMPA INTL	0/8288	9/13/10	RNAV (GPS) RWY 36L, AMDT 1.
21-Oct-10	CA	HAYWARD	HAYWARD EXECUTIVE	0/8839	9/7/10	LOC/DME RWY 28L, AMDT 1B.
21-Oct-10	CA	HAYWARD	HAYWARD EXECUTIVE	0/8843	9/7/10	VOR/DME OR GPS B, AMDT 1C.

[FR Doc. 2010-24109 Filed 9-29-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2010-N-0002]

Implantation or Injectable Dosage Form New Animal Drugs; Dexmedetomidine

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 supplemental new animal drug application (NADA) filed by Orion Corp. The supplemental NADA provides for veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a preanesthetic to general anesthesia in cats.

DATES: This rule is effective September 30, 2010.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl.,

Rockville, MD 20855, 240-276-8337, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Orion Corp., Orionintie 1, 02200 Espoo, Finland, filed a supplement to NADA 141-267 for DEXDOMITOR (dexmedetomidine hydrochloride). The supplemental NADA provides for veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a preanesthetic to general anesthesia in cats. The supplemental application is approved as of August 16, 2010, and the regulations in 21 CFR 522.558 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of the safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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.

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.

■ 2. In § 522.558, revise paragraph (c)(2)(ii) to read as follows:

§ 522.558 Dexmedetomidine.

* * * * *

(c) * * *
(2) * * *

(ii) *Indications for use.* For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures; and as a preanesthetic to general anesthesia.

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Dated: September 24, 2010.

Steven D. Vaughn,

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

[FR Doc. 2010-24494 Filed 9-29-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2010-N-0002]

New Animal Drugs for Use in Animal Feeds; Melengestrol

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 more accurately reflect the recent approval of two supplemental new animal drug applications (NADAs) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADAs provided for increased levels of monensin in two-way Type C medicated feeds containing melengestrol acetate and monensin, and in three-way Type C medicated feeds containing melengestrol acetate, monensin, and tylosin phosphate for heifers fed in confinement for slaughter. These amendments are being made to improve the accuracy of the regulations.

DATES: This rule is effective September 30, 2010.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, email: suzanne.sechen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplements to NADA 125-476 for use of liquid MGA 500 (melengestrol acetate) and RUMENSIN (monensin, USP) single-ingredient Type A

medicated articles to make two-way Type C medicated feeds and to NADA 138-870 for use of liquid MGA 500, RUMENSIN, and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles to make three-way Type C medicated feeds for heifers fed in confinement for slaughter. The supplemental NADAs provided for use of increased levels of monensin, previously approved for single-ingredient monensin Type C medicated feeds under NADA 95-735 (72 FR 653, January 8, 2007). The supplements were approved in October 2009 and the regulations were amended in § 558.342 (21 CFR 558.342) (74 FR 59911, November 19, 2009; 74 FR 61029, November 23, 2009).

Labeling submitted with these supplements also provided for use of a dry MGA 200 Type A medicated article in formulating both the two-way and three-way combination feeds with increased levels of monensin. This was consistent with the February 2009 supplemental approvals under NADA 125-476 and NADA 138-870 of these same two-way and three-way combinations using dry MGA 200 for conditions of use that had been originally approved under Pharmacia & Upjohn Co.'s NADA 124-309 and NADA 138-792. Approval of these supplements in this manner was intended, in part, to simplify administration of the two-way and three-way combinations under a single NADA file for each combination and to treat Pharmacia & Upjohn's applications in a manner consistent with similar applications held by other sponsors. As of February 2009, NADA 124-309 and NADA 138-792 no longer contained the most current approved labeling and were administratively considered part of NADA 125-476 and NADA 138-870, respectively.

FDA has noticed that the regulations in § 558.342 contain entries for use of monensin in these two-way and three-way combinations at the lower use levels. At this time, the regulations are being amended to reflect the conditions of use described in labeling approved in October 2009 under NADA 125-476 and NADA 138-870. These amendments are being made to improve the accuracy of the regulations.

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 558

Animal drugs, Animal feeds.