F2511012920095 with titanium-reinforced brackets having P/N F2511305220096; and perform any related investigative and corrective actions (which may include detailed inspections for cracking of the bracket or damage to surrounding structure caused by a broken bracket, and applicable corrective actions for any damage that is found); in accordance with the Accomplishment Instructions of Airbus Service Bulletins A330–25–3249 and A340–25–4245, excluding Appendix 01, both dated May 3, 2005, as applicable. If any crack is found, before further flight, repair in accordance with the applicable service bulletin. Replacement of the affected bracket with a titanium-reinforced bracket having P/N F2511305220096 ends the repetitive inspections required by paragraph (h) or (i) of this AD. Although the service bulletins specify to submit certain information to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, International Branch, ANM–116, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(m) EASA airworthiness directives 2006–0045 and 2006–0047, both dated February 16, 2006, also address the subject of this AD.

Material Incorporated by Reference

(n) You must use the applicable service bulletin specified in Table 1 of this AD to perform the actions that are required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of the service bulletins specified in Table 2 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) On April 25, 2005 (70 FR 13345, March 21, 2005), the Director of the Federal Register approved the incorporation by reference of Airbus Service Bulletin A330–25–3227, including Appendix 01, dated June 17, 2004; and Airbus Service Bulletin A340–25–4230, including Appendix 01, dated June 17, 2004.

(3) Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov;* or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

TABLE 1.—ALL MATERIAL INCORPORATED BY REFERENCE

Airbus service bulletin	Revision level	Date
A330–25–3227, including Appendix 01	Original	June 17, 2004.
A330–25–3227, excluding Appendix 01	01	May 3, 2005.
A330–25–3249	Original	May 3, 2005.
A340–25–4230, including Appendix 01	Original	June 17, 2004.
A340–25–4230, excluding Appendix 01	01	May 3, 2005.
A340–25–4245	Original	May 3, 2005.

TABLE 2.—NEW MATERIAL INCORPORATED BY REFERENCE

Airbus service bulletin	Revision level	Date
A330–25–3227, excluding Appendix 01	01	May 3, 2005.
A330–25–3249	Original	May 3, 2005.
A340–25–4230, excluding Appendix 01	01	May 3, 2005.
A340–25–4245	Original	May 3, 2005.

Issued in Renton, Washington, on December 21, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–22473 Filed 1–3–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Implantation or Injectable Dosage Form New Animal Drugs; Doxapram

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 Modern Veterinary Therapeutics, LLC. The ANADA provides for the use of doxapram hydrochloride injectable solution in dogs, cats, and horses to stimulate respiration during and after general anesthesia.

DATES: This rule is effective January 4, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Modern Veterinary Therapeutics, LLC, 18301 SW. 86th Ave., Miami, FL 33157, filed ANADA 200–435 that provides for use of RESPIRAM (doxapram hydrochloride), an injectable solution, in dogs, cats, and horses to stimulate respiration during and after general anesthesia. Modern Veterinary Therapeutics, LLC's RESPIRAM is approved as a generic copy of DOPRAM-V Injectable, sponsored by Fort Dodge Animal Health, Division of Wyeth, under NADA 034 879. The ANADA is approved as of November 21, 2006, and the regulations are amended in 21 CFR 522.775 to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In addition, Modern Veterinary Therapeutics, LLC, has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 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.

The agency has determined under 21 CFR 25.33(a)(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.

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

21 CFR Part 510

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

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add a new entry for ''Modern Veterinary Therapeutics, LLC''; and in the table in paragraph (c)(2) numerically add a new entry for ''015914'' 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
* * * * *	
Modern Veterinary Therapeutics, LLC, 18301 SW. 86th Ave., Miami, FL 33157.	015914
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
015914	Modern Veterinary Therapeutics, LLC, 18301 SW. 86th Ave., Miami, FL 33157
* *	* * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Revise § 522.775 to read as follows:

§ 522.775 Doxapram.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) doxapram hydrochloride.

(b) *Sponsor.* See Nos. 000856 and 015914 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For intravenous use in dogs and cats at a dose of 2½ to 5 mg per pound (/lb) body weight in barbiturate anesthesia, 0.5 mg/lb in inhalation anesthesia; for intravenous use in horses at 0.25 mg/lb body weight in barbiturate anesthesia, 0.2 mg/lb in inhalation anesthesia, 0.25 mg/lb with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(2) *Indications for use.* Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; or to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; or to stimulate respiration following dystocia or caesarean section.

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

Dated: December 19, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–22510 Filed 12–29–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clomipramine Tablets

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 Novartis Animal Health US, Inc. The supplemental NADA adds a 5-milligram tablet size of clomipramine hydrochloride, used in dogs for treatment of separation anxiety.

DATES: This rule is effective January 4, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 141–120 that provides for the veterinary prescription use of CLOMICALM (clomipramine hydrochloride) Tablets for treatment of separation anxiety in dogs. The supplement provides for a 5-milligram tablet size of clomipramine hydrochloride. The supplemental NADA is approved as of November 22, 2006, and 21 CFR 520.455 is amended 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 21 CFR part 20 and 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 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.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type