found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2011–0213R1, dated November 8, 2011; and Glasfaser Flugzeug-Service GmbH Technical Note TN 201–40, TN 205–27, TN 206–26, TN 303–25, TN 304–12, TN 401–30, TN 501–10, and TN 604–11, Revision 1, dated July 14, 2011 (EASA translation approval dated September 9, 2011), for related information. For service information related to this AD, contact Glasfaser Flugzeug-Service Hansjörg Streifeneder GmbH, D–72582 Grabenstetten, Germany; phone: +49(0)73821032, fax: +49(0)73821629; email: *info@streifly.de;* Internet: *www.streifly.de/.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(i) Material Incorporated by Reference

(1) The Director of the **Federal Register** approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following information was approved for IBR on September 11, 2012.

(i) Glasfaser Flugzeug Service GmbH Technical Note TN 201–40, TN 205–27, TN 206–26, TN 303–25, TN 304–12, TN 401–30, TN 501–10, and TN 604–11, Revision 1, dated July 14, 2011.

(ii) Reserved.

(4) For Glasflugel service information identified in this AD, contact Glasfaser Flugzeug-Service Hansjörg Streifeneder GmbH, D–72582 Grabenstetten, Germany; phone: +49(0)73821032, fax: +49(0)73821629; email: *info@streifly.de;* Internet: *www.streifly.de/.*

(5) You may view this service information at FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/index.html.*

Issued in Kansas City, Missouri, on August 31, 2012.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–22039 Filed 9–7–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA–2012–N–0902]

New Animal Drugs; Chorionic Gonadotropin; Naloxone; Oxymorphone; Oxytocin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of four new animal drug applications (NADAs) at the sponsor's request because the products are no longer manufactured or marketed.

DATES: This rule is effective September 20, 2012.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240–453–6843; email: *david.alterman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The sponsors of the four approved NADAs listed in table 1 of this document have requested that FDA withdraw approval because the products are no longer manufactured or marketed:

TABLE 1—WITHDRAWAL OF APPROVAL REQUESTS

NADA No.	Trade name (drug)	Applicant	Citation in 21 CFR
030–525	NUMORPHAN (oxymorphone hydrochloride) Injection.	Endo Pharmaceuticals Inc., 100 Painters Dr., Chadds Ford, PA 19317.	522.1642
035–825	NARCAN (naloxone hydrochloride) Injection.	Endo Pharmaceuticals Inc., 100 Painters Dr., Chadds Ford, PA 19317.	522.1462
046–822	VETOCIN (oxytocin) Injection	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711.	522.1680
103–090	CHORTROPIN (chorionic gonadotropin) Injection.	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711.	522.1081

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 030–525, 035–825, 046–822, and 103–090, and all supplements and amendments thereto, is withdrawn, effective September 20, 2012. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Endo Pharmaceuticals Inc. and United Vaccines, A Harlan Sprague Dawley, Inc., Co., will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

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 the 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.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for ''Endo Pharmaceuticals Inc.'' and ''United Vaccines, A Harlan Sprague Dawley, Inc., Co.''; and in the table in paragraph (c)(2), remove the entries for ''058639'' and ''060951''.

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.

§ 522.1081 [Amended]

■ 4. In § 522.1081, remove and reserve paragraph (b)(2).

§ 522.1462 [Removed]

■ 5. Remove § 522.1462.

§ 522.1642 [Removed]

■ 6. Remove § 522.1642.

§ 522.1680 [Amended]

■ 7. In § 522.1680, in paragraph (b), remove ''058639,''.

Dated: September 5, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–22196 Filed 9–7–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 556

[Docket No. FDA–2012–N–0002]

New Animal Drugs; Enrofloxacin; Tylvalosin

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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective September 10, 2012.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect original and supplemental approval actions during July 2012, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY 2012

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141–336	ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131.	AIVLOSIN (tylvalosin tartrate) Water Soluble Granules.	Original approval for control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.	520.2645 556.748	yes	CE [1]
141–068	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	BAYTRIL 100 (enrofloxacin) Injectable Solution.	Supplement adding control of bovine respiratory disease (BRD) in beef and non-lactating dairy cattle at high risk of developing BRD associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis;* and revising a food safety warning statement.	522.812	yes	CE [1]