Commerce Control List remains unchanged.

DATES: This correction is effective February 17, 1998.

FOR FURTHER INFORMATION CONTACT: Patricia Muldonian, Office of Exporter Services, Regulatory Policy Division, Bureau of Export Administration, telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION: On January 15, 1998, the Bureau of Export Administration published in the **Federal Register** an interim rule that made changes to the Commerce Control List necessary to implement the Wassenaar Arrangement List of Dual-Use Items. The rule also removed License Exception availability for certain items controlled for missile technology reasons and for certain other items controlled for national security reasons for which the U.S. has agreed to license with extreme vigilance.

BXA has received many industry comments on the date of February 17, 1998, for submission of license applications for items removed from eligibility for export or reexport under a particular License Exception authorization or the designator NLR, stating that more time is required to determine how the rule affected their products and to develop and revise export compliance software necessary to implement the provisions of the Export Administration Regulations. To ensure that industry has adequate time to review and implement the changes to the EAR published on January 15, BXA is conforming the saving clause dates identified in the January 15 interim rule implementing the Wassenaar Arrangement. Shipments of items removed from eligibility for export or reexport under a particular License Exception authorization or NLR as a result of the January 15 rule may now be exported or reexported under that License Exception authorization or NLR until (and including) April 15, 1998. Note that this rule does not affect the reporting requirements of Section 743.1 of the Export Administration Regulations, and any item removed from License Exception or NLR eligibility as a result of the January 15 rule may be subject to reporting requirements. The April 15, 1998 date concerning submission of license applications identifying the new Export Control Classification Numbers (ECCNs) as a result of revisions to the numbering and structure of certain entries on the Commerce Control List is not changed by this rule.

Therefore, in rule FR Doc. 98–1, published on January 15, 1998 (63 FR 2452), on page 2454, in the third column, in the Saving Clause paragraph, last line, ''February 17, 1998'' is revised to read ''April 15, 1998''.

Dated: February 11, 1998.

William V. Skidmore,

Acting Deputy Assistant Secretary for Export Administration.

[FR Doc. 98–3905 Filed 2–13–98; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADA's) from DuPont Merck Pharmaceutical Co. to Endo Pharmaceuticals, Inc.

EFFECTIVE DATE: February 17, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: DuPont Merck Pharmaceutical Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805, has informed FDA that it has transferred ownership of, and all rights and interests in NADA 30–525 (Oxymorphone hydrochloride) and NADA 35–825 (Naloxone hydrochloride), to Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317. Accordingly, the agency is amending the regulations in 21 CFR 522.1462 and 522.1642 to reflect the transfer of ownership. The agency is also amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by alphabetically adding a new listing for Endo Pharmaceuticals, Inc.

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, 376e.

2. Section 510.600 is amended in paragraph (c)(1) by alphabetically adding a new entry for ''Endo Pharmaceuticals, Inc.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''060951'' 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
* * * *	* * *
Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317	060951
* * * *	* * *

(2) * * *

Drug labeler code	Firm Name and address
* * *	* * * *
060951	Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317.
* * *	* * * *

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.

§ 522.1462 [Amended]

4. Section 522.1462 *Naloxone hydrochloride injection* is amended in paragraph (b) by removing ''000056'' and adding in its place ''060951''.

§ 522.1642 [Amended]

5. Section 522.1642 *Oxymorphone hydrochloride injection* is amended in paragraph (b) by removing ''000056'' and adding in its place ''060951''.

Dated: January 28, 1998.

Andrew J. Beaulieau,

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

[FR Doc. 98–3902 Filed 2–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Tilmicosin Phosphate Injection

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 Elanco Animal Health, A Division of Eli Lilly and Co. The supplemental NADA provides for removal of the label warnings concerning subcutaneous use of tilmicosin phosphate injection in preruminating (veal) calves. Removal of the warning is based on a tissue residue depletion study in calves less than 1 month of age.

EFFECTIVE DATE: February 17, 1998.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is sponsor of NADA 140–929 that provides for the subcutaneous use of Micotil® 300 (tilmicosin phosphate) Injection for the treatment of cattle with bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*. The drug is limited to use by or on the order of a licensed veterinarian. The firm filed a supplemental NADA providing for removal of the warning statements regarding use of the product in preruminating (veal) calves. The supplemental NADA is approved as of December 23, 1997, and the regulations are amended in 21 CFR 522.2471(d)(1)(iii) 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 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.

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.

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.

§ 522.2471 [Amended]

2. Section 522.2471 *Tilmicosin phosphate injection* is amended in paragraph (d)(1)(iii) by removing the 13th and 14th sentences.

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3897 Filed 2–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

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 Merial Ltd. The supplemental NADA provides for use of 1 percent ivermectin injection for treatment and control of grubs in American bison and a tolerance for residues of ivermectin and its metabolites in edible tissues.

EFFECTIVE DATE: February 17, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Ilesin, NJ 08830–3077, is sponsor of NADA 128–409, which provides for the use of Ivomec® Injection (1 percent ivermectin) for cattle, swine, and reindeer. The firm filed a supplement that provides for use