4160-01-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 [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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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notice that approval of NADAs 030-525, 035-825, 046-822, and 103-090, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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.

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