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

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notice that approval of NADAs 030–525, 035–825, 046–822, and 103–090, and all supplements and amendments thereto, is withdrawn, effective September 20, 2012.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:


§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:


§522.1081 [Amended]

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

§522.1462 [Removed]

5. Remove §522.1462.

§522.1642 [Removed]


§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>
<thead>
<tr>
<th>NADA/ANADA</th>
<th>Sponsor</th>
<th>New animal</th>
<th>Action</th>
<th>21 CFR section</th>
<th>FOIA summary</th>
<th>NEPA review</th>
</tr>
</thead>
<tbody>
<tr>
<td>141–336</td>
<td>ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131.</td>
<td>AVILOSIN (tlyvalosin tartrate) Water Soluble Granules.</td>
<td>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.</td>
<td>520.2645 556.748</td>
<td>yes</td>
<td>CE 1</td>
</tr>
<tr>
<td>141–068</td>
<td>Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.</td>
<td>BAYTRIL 100 (enrofloxacin) Injectable Solution.</td>
<td>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.</td>
<td>522.812</td>
<td>yes</td>
<td>CE 1</td>
</tr>
</tbody>
</table>