Section 4.3 also issued under 19 U.S.C. 288, 1441;

* * * * *

Section 4.9 also issued under 42 U.S.C. 269;

* * * * *

§ 4.2 [Amended]

■ 2. In § 4.2:

■ a. Paragraph (a) is amended: by removing the word "Customs" each time that it appears and adding in its place the term "CBP"; in the first sentence, by removing the words "bonded merchandise or", and by removing the word "shall" and adding in its place the word "must", and; in the second sentence, by removing the word "shall" and adding in its place the word "may";

■ b. Paragraph (b) is amended by removing the word "Customs" and adding in its place the word "customs";

■ c. Paragraph (c) is amended, in the first sentence, by removing the word "may" and adding in its place the word "must", and by removing the word "shall" and adding in its place the word "must"; and; in the last sentence, by removing the word "shall" and adding in its place the word "will", and by removing the word "may" and adding in its place the word "must"; and

■ d. Paragraph (d) is amended by removing the word "shall" and adding in its place the word "must".

§ 4.3 [Amended]

■ 3. In § 4.3:

■ a. Paragraph (a)(3) is amended by removing the words "merchandise on board which is being transported in-bond (not including bonded ship's stores or supplies), or", and adding the words "on board" after the words "foreign merchandise"; and

■ b. Paragraph (b)(2) is amended by removing the word "Customs" each time that it appears and adding in its place the term "CBP".

§ 4.9 [Amended]

■ 4. In § 4.9:

■ a. Paragraph (a) is amended by removing the word "Customs" each time that it appears and adding in its place the term "CBP"; and

■ b. Paragraph (b) is amended in the second sentence by removing the words "when they have merchandise aboard which is being transported in-bond, or", by removing the third and fourth sentences, and by removing the word "Customs" in the last sentence and adding in its place the term "CBP".

§ 4.60 [Amended]

■ 5. In § 4.60:

■ a. Paragraph (a) is amended by removing the words "the Customs Service" and adding in their place the term "CBP";

■ b. Paragraph (a)(3) is amended by removing the words "merchandise on board that is being transported in-bond (not including bonded ship's stores or supplies), or";

■ c. Paragraph (b)(1) is amended by removing the word "Customs" and adding in its place the word "customs";

■ d. Paragraph (c) is amended by removing the word "shall" and adding in its place the word "will";

■ e. Paragraph (d) is amended, in the first sentence, by removing the words "shall be reported" and adding in their place the words "must be reported", and by removing the words "shall note" and adding in their place the words "will note", and; in the last sentence, by removing the word "shall" each time that it appears and adding in its place the word "must"; and

■ f. Paragraph (e) is amended by removing the word "shall" and adding in its place the word "will".

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

■ 6. The general authority citation for part 10 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314.

* * * * *

■ 7. § 10.121 is revised to read as follows:

§ 10.121 Visual or auditory materials of an educational, scientific, or cultural character.

(a) Where photographic film and other articles described in subheading 9817.00.40, Harmonized Tariff Schedule of the United States (HTSUS), are claimed to be free of duty under subheading 9817.00.40, HTSUS, there must be filed, in connection with the entry covering such articles, a document issued by the U.S. Department of State certifying that it has determined that the articles are visual or auditory materials of an educational, scientific, or cultural character within the meaning of the Agreement for Facilitating the International Circulation of Visual and Auditory Materials of an Educational, Scientific, and Cultural Character as required by U.S. note 1(a)(i), Subchapter XVII, chapter 98, HTSUS.

(b) Articles entered under subheading 9817.00.40, HTSUS, will be released from CBP custody prior to submission of the document required in paragraph (a) of this section only upon the deposit of estimated duties with the port director. Liquidation of an entry covering merchandise which has been released under this procedure will be suspended for a period of 90 days from the date of entry or until the required document is submitted, whichever occurs first. In the event that the director of the port of entry does not receive the required document within the 90-day period, the merchandise will be classified and liquidated in the ordinary course, without regard to subheading 9817.00.40, HTSUS.

Dated: November 9, 2010.

David V. Aguilar,

Acting Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2010–28709 Filed 11–12–10; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

[Docket No. FDA–2010–N–0002]

New Animal Drugs; Change of Sponsor; Sulfadiazine and Pyrimethamine Suspension

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 sulfadiazine and pyrimethamine oral suspension from Animal Health Pharmaceuticals, LLC, to Pegasus Laboratories, Inc.

DATES: This rule is effective November 15, 2010.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300, *e-mail: steven.vaughn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–240 for REBALANCE (sulfadiazine and pyrimethamine) Antiprotozoal Oral Suspension to Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514. Accordingly, the regulations are amended in 21 CFR 520.2215 to reflect this change of sponsorship.

Following this change of sponsorship, Animal Health Pharmaceuticals, LLC, is no longer the sponsor of an approved application. Accordingly, § 510.600 (21

CFR 510.600) is being amended to remove the entries for this firm.

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 520

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 520 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 entry for "Animal Health Pharmaceuticals, LLC"; and in the table in paragraph (c)(2) remove the entry for "068718".

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.2215 [Amended]

■ 4. In paragraph (b) of § 520.2215, remove "068718" and add in its place "055246".

Dated: November 8, 2010.

Steven D. Vaughn,

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

[FR Doc. 2010–28549 Filed 11–12–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA–2010–N–0534]

New Animal Drugs for Minor Use and Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding new animal drugs for minor use and minor species to update language and to clarify the regulations consistent with the explanations in the preambles to the proposed and final rules establishing them. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the Agency receives any significant adverse comments and withdraws this direct final rule. The companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective March 30, 2011. Submit either electronic or written comments by January 31, 2011. If FDA receives no significant adverse comments within the specified comment period, the Agency will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0534, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *FAX:* 301–827–6870.

• *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Meg Oeller, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9005.

SUPPLEMENTARY INFORMATION:

I. Background

The Minor Use and Minor Species Animal Health Act of 2004 amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish new regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species. FDA published the final rule to implement these regulations (part 516 (21 CFR part 516)) in the **Federal Register** of July 26, 2007 (72 FR 41010).

FDA is issuing this direct final rule to amend its regulations regarding new animal drugs for minor use and minor species (MUMS) in part 516 to update language and clarify the intent of the regulations consistent with the preambles to the proposed and final rules.

In § 516.3(b), FDA is amending the definition of "*Same dosage form*" to make it clearer that the six dosage form categories listed in the regulations under § 516.3(b)(i) through (b)(vi) are the "categories" of dosage forms that the preamble to the proposed rule referenced as follows: "The second test of sameness which the statute establishes to determine eligibility of an animal drug for designation is 'same dosage form.' The agency proposes to