

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

use the long-established dosage form categories listed in Title 21 of the Code of Federal Regulations to implement this statutory requirement” (70 FR 56394 at 56398, September 27, 2005). To accomplish this clarification, the amendment will add the word “categories” after the phrase “dosage forms” and remove the “s” from “forms” in the first sentence of the definition.

Section 516.20(b)(2) requires that requests for MUMS designation include “* * * the generic and trade name, if any, of the drug * * *” intended to be designated and FDA is amending this language to replace the terms “generic” and “trade” with the terms “established” and “proprietary”, respectively, because the latter are the terms used in the FD&C Act (see section 502(e) (21 U.S.C. 352(e)). FDA is also revising this language to clarify that “drug” in the context of § 516.20(b)(2) refers to the “active pharmaceutical ingredient (API)” name rather than to a formulated drug product name. The purpose of the information required in this provision of the regulation is to permit the Agency to determine whether a drug is eligible for designation on the basis that it is not the “same drug” as a drug that is already designated, conditionally approved, or approved (see section 573(a)(2)(B) of the FD&C Act (21 U.S.C. 360ccc-2)) and, because the definition of “same drug” in § 516.3(b) requires a knowledge of the drug’s “active moiety” in order to make this determination, a request for MUMS designation needs to include the API name. This is because the API name includes the active moiety and the drug product name normally does not. FDA is also clarifying the relationship between established and proprietary names in this context with the use of parentheses.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. FDA is revising part 516 by updating language and clarifying its intent. This rule is intended to make noncontroversial changes to existing regulations. The Agency does not anticipate receiving any significant adverse comment on this rule.

Consistent with FDA’s procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule. The companion proposed rule provides the procedural framework within which the rule may be finalized in the event the direct final is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period

of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct rule.

FDA is providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If FDA receives any significant adverse comment, we intend to withdraw this direct final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule’s underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment also states why this rule would be ineffective without the additional change.

If FDA does not receive significant adverse comment, the Agency will publish a document in the **Federal Register** confirming the effective date of the final rule. The Agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**.

A full description of FDA’s policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance document may be accessed at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm>.

III. Legal Authority

FDA’s authority to issue this direct final rule is provided by section 512(b)(1) of the FD&C Act (21 U.S.C. 360b(b)(1)). This section states that any person may file with the Secretary of Health and Human Services an application with respect to any intended use or uses of a new animal drug and sets forth the specific information that must be included in such an application. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient

enforcement of the FD&C Act. FDA is issuing this direct final rule under these authorities.

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(h) 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this direct final rule would not impose any compliance costs on the sponsors of animal drug products that are currently marketed or in development, the Agency certifies that the direct final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the direct final rule

does not contain policies that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This direct final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the direct final rule have been approved by OMB in accordance with the PRA under the regulations governing designation of new animal drugs for MUMS (part 516, OMB control number 0910–0605). Thus, § 516.20 as amended, does not constitute a new or additional paperwork burden requiring OMB approval.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

■ Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 516 is amended as follows:

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 1. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 2. Amend § 516.3(b) by revising the introductory text of the definition of “*Same dosage form*” to read as follows:

§ 516.3 Definitions.

* * * * *

(b) * * *

Same dosage form means the same as one of the dosage form categories specified in the following parts of this chapter:

* * * * *

■ 3. Amend § 516.20 by revising paragraph (b)(2) to read as follows:

§ 516.20 Content and format of a request for MUMS-drug designation.

* * * * *

(b) * * *

(2) The name and address of the sponsor; the name of the sponsor’s primary contact person and/or permanent-resident U.S. agent including title, address, and telephone number; the established name (and proprietary name, if any) of the active pharmaceutical ingredient of the drug; and the name and address of the source of the active pharmaceutical ingredient of the drug.

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Dated: November 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28550 Filed 11–12–10; 8:45 am]

BILLING CODE 4160–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends Pension Benefit Guaranty Corporation’s regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in December 2010. Interest assumptions are also published on PBGC’s Web site (<http://www.pbgc.gov>).

DATES: Effective December 1, 2010.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC’s regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC’s historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for December 2010.¹

The December 2010 interest assumptions under the benefit payments regulation will be 2.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit’s placement in pay status. In comparison with the interest assumptions in effect for November 2010, these interest assumptions represent an increase of 0.50 percent in the immediate annuity rate and are otherwise unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during December 2010, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a “significant regulatory action”

¹ Appendix B to PBGC’s regulation on Allocation of Assets in Single-Employer Plans (29 CFR Part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.