

1. Is not a "significant regulatory action" under Executive Order 12866,
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and
3. Will not have a significant

economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

The Boeing Company: Docket No. FAA-2010-1111; Directorate Identifier 2010-NM-129-AD.

Comments Due Date

(a) We must receive comments by December 30, 2010.

Affected ADs

(b) None.

Applicability

(c) This AD applies to The Boeing Company Model 747-200B, -300, -400, -400D, and -400F series airplanes, certificated in any category; equipped with Pratt and Whitney 4000 or General Electric CF6-80C2 series engines, as identified in Boeing Alert Service Bulletin 747-54A2232, dated April 15, 2010.

Subject

(d) Air Transport Association (ATA) of America Code 54: Nacelles/pylons.

Unsafe Condition

(e) This AD results from a report that the left and right spring beam mid-pivot bolt assembly access doors for the no. 1 strut were inadvertently installed in the incorrect position during strut modification. The Federal Aviation Administration is issuing this AD to detect and correct incorrectly installed mid-pivot bolt assemblies on the spring beam on the outboard struts. Incorrectly installed bolt assemblies could lead to fatigue cracking and consequent fracturing of the mid-pivot bolt assembly,

which could lead to loss of the spring beam load path and the possible separation of a strut and engine from the airplane during flight.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection To Determine if Correct Door Is Installed

(g) Within 24 months after the effective date of this AD, do an inspection to determine if the correct mid-pivot access door is installed, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747-54A2232, dated April 15, 2010.

(h) If, during the inspection required by paragraph (g) of this AD, the correct mid-pivot door is found to be installed, before further flight, install a marker on the mid-pivot access door, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747-54A2232, dated April 15, 2010.

(i) If, during the inspection required by paragraph (g) of this AD, the correct mid-pivot door is not found to be installed, before further flight, do the actions required by paragraphs (i)(1), (i)(2), and (i)(3) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747-54A2232, dated April 15, 2010.

(1) Rotate the mid-pivot bolt assembly to the correct orientation and replace the mid-pivot access door with a new or serviceable mid-pivot access door.

(2) Install a marker on the mid-pivot access door.

(3) Do the actions required by paragraph (i)(3)(i) or (i)(3)(ii) of this AD.

(i) (Option 1) Do an ultrasonic inspection for cracking of the mid-pivot bolt assembly.

(A) If no cracking is found, do the actions required by paragraphs (i)(3)(i)(A)(1) and (i)(3)(i)(A)(2) of this AD.

(1) Repeat the ultrasonic inspection for cracking of the mid-pivot bolt assembly thereafter at intervals not to exceed 24 months until the action required by paragraph (i)(3)(i)(A)(2) of this AD is done.

(2) Within 60 months after the effective date of this AD, replace the mid-pivot bolt assembly with a new mid-pivot bolt assembly. Replacement terminates the repetitive inspections required by paragraph (i)(3)(i)(A)(1) of this AD.

(B) If any cracking is found, replace the mid-pivot bolt assembly with a new mid-pivot bolt assembly, before further flight.

(ii) (Option 2) Replace the mid-pivot bolt assembly with a new mid-pivot bolt assembly.

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to *Attn:* Kenneth Paoletti, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind

Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6434; fax (425) 917-6590. Information may be e-mailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Issued in Renton, Washington, on November 2, 2010.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010-28605 Filed 11-12-10; 8:45 am]

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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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend 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. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit electronic or written comments by January 31, 2011.

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(s), 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 proposing 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 proposing to amend 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 proposing to amend 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 proposing to revise 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 proposing to clarify the relationship between established and proprietary names in this context with the use of parentheses.

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural

framework to proceed with standard notice-and-comment rulemaking if the direct final rule receives significant adverse comment and is withdrawn. FDA is publishing the direct final rule because we believe the rule is non-controversial and we do not anticipate receiving any significant adverse comments.

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 terminating a direct final rulemaking, 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). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a significant adverse comment. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received on this companion proposed rule will also be treated as comments on the direct final rule. We will not provide additional opportunity for comment.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this companion proposed rule. Instead, we will publish a document confirming the effective date within 30 days after the comment period ends, and we intend the direct final rule to become effective 30 days after publication of the confirmation notice.

If we receive any significant adverse comments, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures. The Agency will address the comments in a subsequent final rule.

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 proposed 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 proposed 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 proposed 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 proposed rule is not a significant regulatory action as defined by 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 proposed rule would not impose any compliance costs on the sponsors of animal drug products that are currently marketed or in development, the Agency proposes to certify that the 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 proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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 tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism impact statement is not required.

VII. Paperwork Reduction Act of 1995

This proposed 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 this proposed 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. 2010-28551 Filed 11-12-10; 8:45 am]

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