

economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs" describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and
- (4) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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 airworthiness directive (AD):

2013-02-02 CFM International, S.A.:

Amendment 39-17323; Docket No. FAA-2012-1289; Directorate Identifier 2012-NE-43-AD.

(a) Effective Date

This AD is effective January 28, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to CFM International, S.A. CFM56-3, CFM56-3B, and CFM56-3C turbofan engines, modified by Supplemental Type Certificate SE00034EN, with a high-pressure turbine (HPT) disk, part number (P/N) 880026, serial number (S/N) GLKBA9307, GLKBA9335, GLKBA9404, GLKBA9407, or GLKBA9409, installed.

(d) Unsafe Condition

This AD was prompted by a report of a forging process error during manufacture of these HPT disks. We are issuing this AD to prevent uncontained release of multiple turbine blades, damage to the engine, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) For CFM56-3, CFM56-3B, and CFM56-3C turbofan engines operating to 20,100 lbs maximum takeoff (MTO) thrust, remove the HPT disk from service on or before accumulating 8,000 cycles-since-new (CSN).

(2) For CFM56-3B and CFM56-3C turbofan engines operating to 22,100 lbs MTO thrust, remove the HPT disk from service on or before accumulating 8,000 CSN.

(3) For CFM56-3C turbofan engines operating to 23,500 lbs MTO thrust, remove the HPT disk from service on or before accumulating 4,000 CSN.

(4) For HPT disks that have been used in multiple models or thrust installations, the formula in the ADDED DATA section of Pratt & Whitney Special Instruction 6F-12 dated December 21, 2012 must be used to calculate the remaining life on the disk.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(g) Related Information

For more information about this AD, contact Kenneth Steeves, Aerospace Engineer, Engine Certification Office, FAA, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7765; fax: 781-238-7199; email: kenneth.steeves@faa.gov.

(h) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Pratt & Whitney Corp. Special Instruction No. 6F-12, dated December 21, 2012.

(ii) Reserved.

(3) For service information identified in this AD, contact Pratt & Whitney, 400 Main St., East Hartford, CT 06108; phone: 860-565-7700; fax: 860-565-1605.

(4) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.

(5) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on January 14, 2013.

Thomas Boudreau,

Acting Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013-01360 Filed 1-25-13; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 522

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Cefpodoxime; Meloxicam

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 December 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 January 28, 2013.

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 approval actions for several original ANADAs during December 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/CVMFOIA/ElectronicReadingRoom/default.htm>.

TABLE 1—ORIGINAL ANADAS APPROVED DURING DECEMBER 2012

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
200-485	Accord Healthcare, Inc., 1009 Slater Rd., suite 210-B, Durham, NC 27703.	Meloxicam Injection	Original approval as a generic copy of NADA 141-219.	522.1367	yes	CE ¹
200-491	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	LOXICOM (meloxicam) Solution for Injection.	Original approval as a generic copy of NADA 141-219.	522.1367	yes	CE ¹
200-543	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101.	Cefpodoxime Proxetil Tablets	Original approval as a generic copy of NADA 141-232.	520.370	yes	CE ¹

¹ The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

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 Parts 520 and 522

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, 520, 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), alphabetically add an entry for “Accord Healthcare, Inc.” and revise the entry for “Jurox Pty. Ltd.”; and in the table in paragraph (c)(2), numerically add an entry for “016729” and revise the entry for “049480” to read as follows:

(1) * * *

Firm name and address	Drug labeler code
* * * * * Accord Healthcare, Inc., 1009 Slater Rd., suite 210-B, Durham, NC 27703	016729
* * * * * Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia	049480

(2) * * *

Drug labeler code	Firm name and address
* * * * *	Accord Healthcare, Inc., 1009 Slater Rd., suite 210-B, Durham, NC 27703
* * * * *	Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia

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.

§ 520.370 [Amended]

- 4. In paragraph (b) of § 520.370, remove “No. 000009” and in its place add “Nos. 000009 and 026637”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 5. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1367 [Amended]

- 6. In paragraph (b) of § 522.1367, remove “No. 000010” and in its place add “Nos. 000010, 016729, and 055529”.

Dated: January 22, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013-01647 Filed 1-25-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 635

[FHWA Docket No. FHWA-2012-0098]

RIN 2125-AF47

Construction and Maintenance— Culvert Pipe Selection

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: Section 1525 of the Moving Ahead for Progress in the 21st Century Act (MAP-21) requires the Secretary of Transportation to modify FHWA regulations to ensure that States shall have the autonomy to determine culvert and storm sewer material types to be included in the construction of a project on a Federal-aid highway. This final rule is intended to implement this legislative requirement.

DATES: This rule is effective February 27, 2013.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Yakowenko, Office of Program Administration, (202) 366-1562, or Mr. Michael Harkins, Office of the Chief Counsel, (202) 366-4928, Federal Highway Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document may be viewed online through the Federal eRulemaking portal at <http://www.regulations.gov>. Retrieval help and guidelines are available on the Web site. It is available 24 hours each day, 365 days a year. An electronic copy of this document may also be downloaded from the Office of the Federal Register’s home page at: <http://www.archives.gov/federal-register> and the Government Printing Office’s Web page at: <http://www.gpo.gov/fdsys>.

Background

Under the “Administrative Procedure Act” (5 U.S.C. 553(b)), an agency may waive the normal notice and comment procedure if it finds, for good cause, that it would be impracticable, unnecessary, or contrary to the public interest. The FHWA finds that notice and comment for this rule is unnecessary because it implements a congressional mandate to amend 23 CFR 635.411 to allow States to choose culvert and storm sewer material type. The regulatory amendments in this final rule are based upon the statutory language and FHWA does not anticipate receiving meaningful comments to alter the regulation given the explicit mandate. Accordingly, FHWA finds good cause under 5 U.S.C. 553(b)(3)(B) to waive notice and opportunity for comment.

Regulatory History

The “General Material Requirements,” found in 23 CFR part 635 subpart D, supports competitive bidding principles in 23 U.S.C. 112 with certain requirements and procedures relating to product and material selection and use on Federal-aid highway projects.

Securing competition in the area of culvert pipe material selection has been a concern of FHWA since the 1960s. In an internal Bureau of Public Roads (now FHWA) Memorandum issued October 7, 1963, the Bureau of Public Roads addressed the issue of culvert selection and in general product selection in writing:

* * * a State’s desire to select only one type of pipe for bidding purposes on the basis that such selection will favor State and local public interests cannot be accepted by Public Roads.

This Memorandum further states,

Except where otherwise dictated by engineering evaluations of individual site conditions, there is no basic disadvantage in specifying all acceptable alternate types and either calling for competitive bids on them or permitting the successful bidder to name the type he will furnish. Even when it is indicated that one type might receive lower bid prices, competitive bidding of the one type with other acceptable types could result in lower contract prices.

Through a revision to Policy & Procedure Memorandum 21-6.3 dated October 3, 1972, the FHWA included a table entitled “Summary of Acceptable Criteria for Specifying Types of Culvert Pipes.” On September 30, 1974, the table was included in the CFR as an appendix to 23 CFR 635.117 (39 FR 35152). According to § 635.117(d), as in effect in 1974, Appendix A

* * * sets forth the FHWA requirements regarding the specification of alternate types of culvert pipes, and the number and types of such alternatives which must be set forth in the specifications for various types of drainage installations.

On September 10, 1976, this section was redesignated as 23 CFR 635.411 (41 FR 36204) and remained unchanged until 2006, though the market had changed to the extent that Appendix A no longer adequately encompassed the universe of available alternatives.

Section 5514 of the *Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users* (SAFETEA-LU, Pub. L. 109-59; August 10, 2005), titled “Competition for Specification of Alternative Types of Culvert Pipes,” required the Secretary of Transportation to ensure that States provide for competition with respect to the specification of alternative types of culvert pipes through requirements that are commensurate with competition for other construction materials. To implement this provision, the FHWA issued a final rule on November 15, 2006 (71 FR 66450), that deleted Appendix A from the CFR.

MAP-21 Legislative Provision

On July 6, 2012, President Obama signed the *Moving Ahead for Progress in the 21st Century Act* (MAP-21), Public Law 112-141, 126 Stat. 405. Section 1525 of MAP-21, “State Autonomy for Culvert Pipe Selection,” requires the Secretary of Transportation, within 180 days of the date of enactment of MAP-21 (October 1, 2012) to modify section 635.411 of title 23 CFR, to ensure that States shall have the autonomy to determine culvert and storm sewer material types to be included in the construction of a project on a Federal-aid highway. The use of the word “autonomy” in this section gives the State transportation departments (State DOTs) and other direct recipients the sole authority and discretion to make a decision regarding culvert and storm sewer material types without any input or approval from the FHWA. As a result, a State DOT may choose to exercise its autonomy regarding culvert and storm sewer type selection to either:

(a) Include all material types deemed acceptable as a result of engineering and economic analysis, or

(b) Restrict the pool of available culvert and storm sewer material types to those which the State DOT would select.

Although section 1525 gives the States the autonomy to determine culvert and storm sewer material types, section 1525 does not relieve the States of compliance with other applicable