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Issued in Kansas City, Missouri, on January 30, 2007.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2006-25192; Directorate Identifier 2006-NM-004-AD; Amendment 39-14930; AD 2007-03-19]

RIN 2120-AA64

Airworthiness Directives; Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD), which applies to certain Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes. That AD currently requires repetitive detailed and eddy current inspections of the main fittings of the main landing gears (MLG) to detect discrepancies, and related investigative/corrective actions if necessary. The AD also currently requires servicing the shock strut of the MLGs; inspecting the shock strut of the MLGs for nitrogen pressure, visible chrome dimension, and oil leakage; and servicing any discrepant strut. This new AD requires installing a new, improved MLG main fitting, which terminates the repetitive inspection and servicing requirements of the existing AD. This AD results from stress analyses that showed certain main fittings of the MLGs are susceptible to premature cracking, starting in the radius of the upper lug. We are issuing this AD to detect and correct premature cracking of the main fittings of the MLGs, which could result in failure of the fittings and consequent collapse of the MLGs during landing.

DATES: This AD becomes effective March 15, 2007.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of March 15, 2007.

On August 13, 2004 (69 FR 41421, July 9, 2004), the Director of the Federal

Register approved the incorporation by reference of Bombardier Alert Service Bulletin A601R-32-088, including Appendices A, B, and C, dated February 20, 2003.

ADDRESSES: You may examine the AD docket on the Internet at <http://dms.dot.gov> or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC.

Contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT:

Richard Beckwith, Aerospace Engineer, Airframe and Propulsion Branch, ANE-171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, suite 410, Westbury, New York 11590; telephone (516) 228-7302; fax (516) 794-5531.

SUPPLEMENTARY INFORMATION:

Examining the Docket

You may examine the airworthiness directive (AD) docket on the Internet at <http://dms.dot.gov> or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647-5227) is located on the plaza level of the Nassif Building at the street address stated in the **ADDRESSES** section.

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that supersedes AD 2004-14-16, amendment 39-13725 (69 FR 41421, July 9, 2004). The existing AD applies to certain Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes. That NPRM was published in the **Federal Register** on June 27, 2006 (71 FR 36495). That NPRM proposed to continue to require installing a new, improved main landing gear (MLG) main fitting, which would terminate the repetitive inspection and servicing requirements of the existing AD.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been received on the NPRM.

Request To Change Compliance Time to Cite Dates

Bombardier notes that the proposed compliance time for the corrective

action is quite different from that of the parallel Canadian airworthiness directive. The parallel Canadian airworthiness directive specifies a fixed compliance date of December 31, 2008, for MLG main fittings that have part numbers 601R85001-81 and -82. Bombardier calculates that operators of U.S.-registered airplanes would have 12 months beyond that date to accomplish the proposed actions. Bombardier requests that we harmonize the compliance time in the NPRM with the compliance date in Canadian airworthiness directive CF-2003-09R1, dated September 21, 2005, which is the parallel Canadian airworthiness directive referred to in the NPRM. Bombardier points out that it worked with Messier-Dowty and Transport Canada Civil Aviation (TCCA) to consider carefully that date as it relates to fleet safety, MLG supplier capability/logistics, and the capacity of operators and overhaul facilities. Bombardier considers that the different compliance time will create confusion among U.S. operators and cause an unnecessary burden for all parties involved.

We partially agree. We agree that we should harmonize the compliance times in the NPRM with the compliance dates in the Canadian airworthiness directive. To that end, we developed the compliance time of "within 39 months after the effective date of this AD." This 39-month compliance time will give U.S. operators until May 2009 to comply with the AD. This amount of elapsed time is equivalent to that allowed by the Canadian airworthiness directive's compliance date of December 31, 2008. However, we find that this longer compliance time will not adversely affect the level of safety of the affected U.S.-registered airplanes. This issue has been coordinated with TCCA. No change has been made to the AD in this regard.

Request To Incorporate by Reference (IBR) the Service Information

The Modification and Replacement Parts Association (MARPA) requests that we either publish the relevant service information with the AD in the Docket Management System (DMS), or IBR it with the NPRM. MARPA states that the purpose of the IBR system is brevity, to keep from expanding the **Federal Register** needlessly by publishing documents already in the hands of the affected individuals. Traditionally, "affected individuals" have been aircraft owners and operators who are generally provided service information by the manufacturer. MARPA states that the group of affected individuals has expanded because

aircraft maintenance is now performed by specialty shops instead of aircraft owners and operators. This new class includes maintenance and repair organizations, component servicing and repair shops, parts purveyors and distributors, and organizations that manufacture or service alternatively certified parts under 14 CFR 21.303 (parts manufacturer approval (PMA)), which do not possess the proprietary service information referenced in the NPRM. MARPA states that the concept of brevity is now nearly archaic as documents exist more frequently in electronic format than on paper.

MARPA also comments on our practice of IBR and referencing propriety service information. MARPA asserts that if we IBR proprietary service information with a public document, such as an AD, then that service information loses its protected status and becomes a public document. MARPA further states that "If a service document is used as a mandatory element of compliance it should not simply be referenced, but should be incorporated into the regulatory document. Public laws by definition must be public, which means they cannot rely upon private writings."

We do not agree that documents should be incorporated by reference during the NPRM phase of rulemaking. The Office of the Federal Register (OFR) requires that documents that are necessary to accomplish the requirements of the AD be incorporated by reference during the final rule phase of rulemaking. This final rule incorporates by reference the document necessary for the accomplishment of the requirements mandated by this AD. Further, we point out that while documents that are incorporated by reference do become public information, they do not lose their copyright protection. For that reason, we advise the public to contact the manufacturer to obtain copies of the referenced service information.

In regard to the commenter's request that service documents be made available to the public by publication in the **Federal Register**, we agree that incorporation by reference was authorized to reduce the volume of material published in the **Federal Register** and the Code of Federal Regulations. However, as specified in the **Federal Register** Document Drafting Handbook, the Director of the OFR decides when an agency may incorporate material by reference. As the commenter is aware, the OFR files documents for public inspection on the workday before the date of publication of the rule at its office in Washington,

DC. As stated in the **Federal Register** Document Drafting Handbook, when documents are filed for public inspection, anyone may inspect or copy file documents during the OFR's hours of business. Further questions regarding publication of documents in the **Federal Register** or incorporation by reference should be directed to the OFR.

In regard to the commenter's request to post service bulletins on the Department of Transportation's DMS, we are currently in the process of reviewing issues surrounding the posting of service bulletins on the DMS as part of an AD docket. Once we have thoroughly examined all aspects of this issue and have made a final determination, we will consider whether our current practice needs to be revised. No change to the final rule is necessary in response to this comment.

Request To Reference PMA Parts

MARPA also states that type certificate holders in their service documents universally ignore the possible existence of PMA parts. According to MARPA, this is especially true with foreign manufacturers where the concept may not exist or be implemented in the country of origin. MARPA states that frequently the service bulletin upon which an AD is based will require the removal of a certain part number and the installation of a different part number as a corrective action. MARPA states that this practice runs afoul of 14 CFR 21.303, which permits the development, certification, and installation of alternatively certified parts (PMA). MARPA states that mandating the installation of a certain part number to the exclusion of all other parts is not a favored general practice. According to MARPA, such action has the dual effect of preventing, in some cases, the installation of perfectly good parts, while at the same time prohibiting the development of new parts permitted under 14 CFR 21.303. MARPA states that such a prohibition runs the risk of taking the AD out of the realm of safety and into the world of economics since prohibiting the development, sale, and use of a perfectly airworthy part has nothing to do with safety.

We infer that the commenter would like the AD to permit installation of any equivalent PMA parts so that it is not necessary for an operator to request approval of an alternative method of compliance (AMOC) in order to install an "equivalent" PMA part. Whether an alternative part is "equivalent" in adequately resolving the unsafe condition can only be determined on a case-by-case basis based on a complete understanding of the unsafe condition.

We are not currently aware of any such parts. Our policy is that, in order for operators to replace a part with one that is not specified in the AD, they must request an AMOC. This is necessary so that we can make a specific determination that an alternative part is or is not susceptible to the same unsafe condition.

In response to the commenter's statement regarding a practice that "runs afoul of 14 CFR 21.303," under which the FAA issues PMAs, this statement appears to reflect a misunderstanding of the relationship between ADs and the certification procedural regulations of part 21 of the Federal Aviation Regulations (14 CFR part 21). Those regulations, including section 21.303 of the Federal Aviation Regulations (14 CFR 21.203), are intended to ensure that aeronautical products comply with the applicable airworthiness standards. But ADs are issued when, notwithstanding those procedures, we become aware of unsafe conditions in these products or parts. Therefore, an AD takes precedence over design approvals when we identify an unsafe condition, and mandating installation of a certain part number in an AD is not at variance with section § 21.303.

The AD provides a means of compliance for operators to ensure that the identified unsafe condition is addressed appropriately. For an unsafe condition attributable to a part, the AD normally identifies the replacement parts necessary to obtain that compliance. As stated in section 39.7 of the Federal Aviation Regulations (14 CFR 39.7), "Anyone who operates a product that does not meet the requirements of an applicable airworthiness directive is in violation of this section." Unless an operator obtains approval for an AMOC, replacing a part with one not specified by the AD would make the operator subject to an enforcement action and result in a civil penalty. We have not changed the final rule in this regard.

Request for Compliance With FAA Order 8040.2/Agreement on Parts Replacement

MARPA points out that this AD, as written, does not comply with proposed Order 8040.2 (AD Process for Mandatory Continuing Airworthiness Information (MCAI)), which states in the PMA section: "MCAI that require replacement or installation of certain parts could have replacement parts approved under 14 CFR 21.303 based on a finding of identity. We have determined that any parts approved under this regulation and installed should be

subject to the actions of our AD and included in the applicability of our AD.” MARPA points out that the Small Airplane Directorate has developed a blanket statement that resolves this issue. The statement includes words similar to those in the proposed Order 8040.2.

We recognize the need for standardization on this issue and currently are in the process of reviewing it at the national level. The Transport Airplane Directorate considers that to delay this particular AD action would be inappropriate, since we have determined that an unsafe condition exists and that replacement of certain parts must be accomplished to ensure continued safety. Therefore, no change has been made to the final rule in this regard.

The NPRM did not address PMA parts, as provided in draft FAA Order 8040.2, because the Order was only a draft that was out for comment at the time. After issuance of the NPRM, the Order was revised and issued as FAA Order 8040.5 with an effective date of September 29, 2006. FAA Order 8040.5 does not address PMA parts in ADs. We acknowledge the need to ensure that unsafe PMA parts are identified and addressed in MCAI-related ADs. We are currently examining all aspects of this issue, including input from industry. Once we have made a final determination, we will consider how our policy regarding PMA parts in ADs needs to be revised. We consider that to delay this AD action would be inappropriate, since we have determined that an unsafe condition

exists and that replacement of certain parts must be accomplished to ensure continued safety. Therefore, no change has been made to the final rule in this regard.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this AD. There are approximately 278 airplanes of U.S. registry that are affected by this AD. The average labor rate is \$80 per work hour.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Fleet cost
Inspections (required by AD 2004–14–16)	4	None	\$320, per inspection cycle	\$88,960, per inspection cycle.
Replacement (new action)	46	\$105,732	\$109,412	\$30,416,536.

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

We have determined that 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); 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

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 Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–13725 (69

FR 41421, July 9, 2004) and by adding the following new airworthiness directive (AD):

2007–03–19 Bombardier, Inc. (Formerly Canadair): Amendment 39–14930. Docket No. FAA–2006–25192; Directorate Identifier 2006–NM–004–AD.

Effective Date

(a) This AD becomes effective March 15, 2007.

Affected ADs

(b) This AD supersedes AD 2004–14–16.

Applicability

(c) This AD applies to Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, serial numbers 7003 and subsequent; certificated in any category; equipped with main landing gear (MLG) main fittings, part numbers (P/N) 601R85001–81 and 601R85001–82 (Messier Dowty Incorporated P/Ns 17064–105 and 17064–106).

Unsafe Condition

(d) This AD results from stress analyses that showed certain main fittings of the MLGs are susceptible to premature cracking, starting in the radius of the upper lug. We are issuing this AD to detect and correct premature cracking of the main fittings of the MLGs, which could result in failure of the fittings and consequent collapse of the MLGs during landing.

Compliance

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

Restatement of the Requirements of AD 2004-14-16

Detailed Inspection of Main Fittings of the MLGs

(f) Before the accumulation of 2,500 total flight cycles on the MLGs, or within 250 flight cycles after August 13, 2004 (the effective date of AD 2004-14-16), whichever occurs later: Do a detailed inspection on the main fittings of the MLGs to detect discrepancies (*i.e.*, linear paint cracks or lack of paint (paint peeling), any other paint damage, adhesion, paint bulging, or corrosion), in accordance with Part A of the Accomplishment Instructions of Bombardier Alert Service Bulletin (ASB) A601R-32-088, dated February 20, 2003; or Bombardier ASB 601R-32-088, Revision A, dated June 16, 2005, including Appendices A, B, and C, dated February 20, 2003. Repeat the inspection thereafter at intervals not to exceed 100 flight cycles until paragraph (k) of this AD is accomplished.

Note 1: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Related Investigative/Corrective Actions

(g) If any discrepancy is detected during any inspection required by paragraph (f) of this AD, before further flight: Do the related investigative/corrective actions in accordance with Part B or F of the Accomplishment Instructions of Bombardier ASB A601R-32-088, including Appendices A and C, dated February 20, 2003; or Bombardier ASB A601R-32-088, Revision A, dated June 16, 2005, including Appendices A, B, and C, dated February 20, 2003. If an eddy current inspection (a related investigative action specified in Part B) is used to confirm the detailed inspection findings, the next eddy current required by paragraph (h) of this AD must be conducted within 500 flight cycles after the eddy current inspection specified in this paragraph, and thereafter at intervals not

to exceed 500 flight cycles until paragraph (k) of this AD is accomplished.

Eddy Current Inspection of Main Fittings of the MLGs

(h) At the time specified in paragraph (f) of this AD, do an eddy current inspection on the main fittings of the MLGs to detect cracks, in accordance with Part B of the Accomplishment Instructions of Bombardier ASB A601R-32-088, including Appendix A, dated February 20, 2003; or Bombardier ASB A601R-32-088, Revision A, dated June 16, 2005, including Appendices A, B, and C, dated February 20, 2003. Repeat the eddy current inspection thereafter at intervals not to exceed 500 flight cycles, until paragraph (k) of this AD is accomplished. If any crack is found, before further flight, replace the affected main fittings of the MLGs with new or serviceable fittings in accordance with paragraph E.(5) of Part B of the Accomplishment Instructions of the service bulletin or in accordance with paragraph (k) of this AD. If any crack is found after the effective date of this AD, do the replacement in accordance with paragraph (k) of this AD.

Servicing of Shock Struts

(i) Before the accumulation of 2,500 total flight cycles on the MLGs, or within 500 flight cycles after August 13, 2004, whichever occurs later, service the shock strut of the MLGs in accordance with Part C or D, as applicable, of the Accomplishment Instructions of Bombardier ASB A601R-32-088, including Appendix B, dated February 20, 2003; or Bombardier ASB A601R-32-088, Revision A, dated June 16, 2005, including Appendices A, B, and C, dated February 20, 2003.

Shock Strut Inspection

(j) Within 500 flight cycles after completing the servicing required by paragraph (i) of this AD, inspect the shock strut of the MLGs for nitrogen pressure, visible chrome dimension, and oil leakage, in accordance with Part E of the Accomplishment Instructions of Bombardier ASB A601R-32-088, including Appendix B, dated February 20, 2003; or Bombardier ASB A601R-32-088, Revision A, dated June 16, 2005, including Appendices A, B, and C, dated February 20, 2003. Repeat the inspection thereafter at intervals not to exceed 500 flight cycles, until paragraph (k) of this AD is accomplished. If the nitrogen

pressure and visible chrome dimensions are found outside the limits (the service bulletin refers to the airplane maintenance manual as the source of defined limits) and/or oil leakage is found, before further flight, service the affected shock strut of the MLGs in accordance with Part C or D, as applicable, of the Accomplishment Instructions of the service bulletin.

New Requirements of This AD

Replacement

(k) Within 39 months after the effective date of this AD: Replace the main fittings of the MLGs, P/Ns 601R85001-81 and 601R85001-82 (Messier Dowty Incorporated P/Ns 17064-105 and 17064-106), with new main fittings, P/Ns 601R85001-83 and 601R85001-84 (Messier Dowty Incorporated P/Ns 17064-107 and 17064-108), in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601R-32-093, Revision B, dated July 14, 2005. Doing this replacement terminates all requirements of paragraphs (f), (g), (h), (i), and (j) of this AD.

Note 2: Bombardier Service Bulletin 601R-32-093, Revision B, refers to Messier-Dowty Service Bulletin M-DT SB17002-32-25, Revision 1, dated October 17, 2003, as an additional source of service information for replacing the main fittings.

Parts Installation

(l) As of the effective date of this AD, no person may install a main fitting of the MLG, P/Ns 601R85001-81 and 601R85001-82 (Messier Dowty Incorporated P/Ns 17064-105 and 17064-106), on any airplane.

No Reporting Required

(m) Although the Accomplishment Instructions of Bombardier ASB A601R-32-088, dated February 20, 2003; and ASB 601R-32-088, Revision A, dated June 16, 2005; specify to report certain information to the manufacturer, this AD does not include that action.

Actions Accomplished in Accordance with Previous Revisions of Service Bulletin

(n) Actions accomplished before the effective date of this AD in accordance with the service bulletins listed in Table 1 of this AD are acceptable for compliance with the actions in paragraph (k) of this AD.

TABLE 1.—PREVIOUS REVISIONS OF SERVICE BULLETIN

Bombardier Service Bulletin	Revision level	Date
601R-32-093	Original	October 17, 2003.
601R-32-093	A	September 21, 2004.

Alternative Methods of Compliance (AMOCs)

(o)(1) The Manager, New York Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to

which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(p) Canadian airworthiness directive CF-2003-09R1, dated September 21, 2005, also addresses the subject of this AD.

Material Incorporated by Reference

(q) You must use the applicable service information in Table 2 of this AD to perform the actions that are required by this AD, unless the AD specifies otherwise.

TABLE 2.—ALL MATERIAL INCORPORATED BY REFERENCE

Service Bulletin	Revision level	Date
Bombardier Alert Service Bulletin A601R-32-088, including Appendices A, B, and C.	Original	February 20, 2003.
Bombardier Alert Service Bulletin A601R-32-088, including Appendices A, B, and C, dated February 20, 2003.	A	June 16, 2005.
Bombardier Service Bulletin 601R-32-093	B	July 14, 2005.

(1) The Director of the Federal Register approved the incorporation by reference of the documents in Table 3 of this AD, in

accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

TABLE 3.—NEW MATERIAL INCORPORATED BY REFERENCE

Service Bulletin	Revision level	Date
Bombardier Alert Service Bulletin A601R-32-088, including Appendices A, B, and C, dated February 20, 2003.	A	June 16, 2005.
Bombardier Service Bulletin 601R-32-093	B	July 14, 2005.

(2) On August 13, 2004 (69 FR 41421, July 9, 2004), the Director of the Federal Register approved the incorporation by reference of Bombardier Alert Service Bulletin A601R-32-088, including Appendices A, B, and C, dated February 20, 2003.

(3) Contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL-401, Nassif Building, Washington, DC; on the Internet at <http://dms.dot.gov>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on January 29, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin and Betamethasone Spray

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 of an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for topical use of a gentamicin sulfate and betamethasone valerate topical spray on dogs for the treatment of infected superficial lesions.

DATES: This rule is effective February 8, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-415 for Gentamicin Sulfate Topical Spray (gentamicin sulfate, USP with betamethasone valerate, USP) for use on dogs for the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin. First Priority's Gentamicin Sulfate Topical Spray is approved as a generic copy of Schering-Plough Animal Health Corp.'s GENTOCIN Topical Spray, approved under NADA 132-338. The ANADA is approved as of January 12, 2006, and 21 CFR 524.1044f is amended to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

The agency has determined under 21 CFR 25.33(a)(1) 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.

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 in 21 CFR Part 524

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 part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. In § 524.1044f, revise the section heading and paragraph (b) to read as follows:

§ 524.1044f Gentamicin and betamethasone spray.

* * * * *

(b) See Nos. 000061, 054925, and 058829 in § 510.600(c) of this chapter.

* * * * *