

decisionmaker, nor an order compromising a civil penalty action, may be appealed under these sections.

(n) *Compromise*. The FAA may compromise the amount of any civil penalty imposed under this section, under 49 U.S.C. 5123(e), 46031(f), 46303(b), or 46318 at any time before referring the action to the United States Attorney General, or the Delegate of the Attorney General, for collection.

(1) An agency attorney may compromise any civil penalty action where a person charged with a violation agrees to pay a civil penalty and the FAA agrees not to make a finding of violation. Under such agreement, a compromise order is issued following the payment of the agreed-on amount or the signing of a promissory note. The compromise order states the following:

(i) The person has paid a civil penalty or has signed a promissory note providing for installment payments.

(ii) The FAA makes no finding of a violation.

(iii) The compromise order shall not be used as evidence of a prior violation in any subsequent civil penalty proceeding or certificate action proceeding.

(2) An agency attorney may compromise the amount of a civil penalty proposed in a notice, assessed in an order, or imposed in a compromise order.

Issued in Washington, DC, on December 23, 2004.

Rebecca MacPherson,

Assistant Chief Counsel for Regulations.

[FR Doc. 05-528 Filed 1-10-05; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002-NE-33-AD; Amendment 39-13939; AD 2005-01-14]

RIN 2120-AA64

Airworthiness Directives; Bombardier-Rotax GmbH Type 912 F, 912 S, and 914 F Series Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD) for Bombardier-Rotax GmbH Type 912 F, 912 S, and 914 F series reciprocating engines. That AD currently requires venting of the lubrication system and inspection of the valve train on all

engines. That AD also requires venting of the lubrication system of all engines on which the lubrication system has been opened, and any engine on which the propeller has been rotated one full turn in the wrong direction. This AD requires similar actions, and also requires removing the existing part number oil dipstick from service and installing a new oil dipstick. This AD results from the need to clarify the mandated procedures for inspections and venting. This AD also results from the manufacturer discovering that under certain circumstances, the oil level in the oil tank can fall below the minimum level required to sustain proper engine lubrication. We are issuing this AD to prevent damage to the engine valve train due to inadequate venting of the lubrication system, which can result in an in-flight engine failure and forced landing.

DATES: This AD becomes effective February 15, 2005. The Director of the **Federal Register** previously approved the incorporation by reference of certain publications as listed in the regulations as of October 28, 2002 (67 FR 65033, October 23, 2002).

ADDRESSES: You can get the service information identified in this AD from Bombardier-Rotax GmbH, Gunskirchen, Austria; telephone 7246-601-423; fax 7246-601-760.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA. You may examine the service information, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or 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/code_of_federal_regulations/ibr_locations.html.

FOR FURTHER INFORMATION CONTACT:

Richard Woldan, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park; telephone (781) 238-7136; fax (781) 238-7199.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with a proposed airworthiness directive (AD) to supersede AD 2002-21-16. The proposed AD applies to Bombardier-Rotax GmbH Type 912 F, 912 S, and 914 F series reciprocating engines. We published the proposed AD in the **Federal Register** on August 12, 2004 (69 FR 49829). That action proposed to do the following:

- At the next oil change, or within 100 hours TIS after the effective date of the AD, whichever is later, remove the oil dipstick, part number (P/N) 956150, from service, and install a serviceable dipstick that has a different P/N.

- Before the next engine start for engines with 50 hours or less time-in-service (TIS) on the effective date of the AD, since the engine had the oil system opened, or the oil was changed using other than specified procedures, or the propeller was rotated more than one turn in the wrong direction of rotation, inspect for valve train damage, proper venting of the lubrication system and inspect for the correct venting of the hydraulic valve tappets.

- Thereafter, for all engines, properly vent the lubrication system before starting the engine, after any of the following:

- Initial installation of a new or overhauled engine;
- Opening the oil system;
- Changing the oil using improper procedures;

- The propeller was rotated more than one turn in the wrong direction of rotation, allowing air to be ingested into the valve train components.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Comments

We provided the public the opportunity to participate in the development of this AD. We received no comments on the proposal or on the determination of the cost to the public.

Conclusion

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

Costs of Compliance

There are about 624 Bombardier-Rotax GmbH Type 912 F, 912 S, and 914 F series reciprocating engines of the affected design in the worldwide fleet. We estimate that 282 engines installed on aircraft of U.S. registry will be affected by this AD. We also estimate that it will take about one work hour per engine to perform one oil system inspection and venting, and that the average labor rate is \$65 per work hour. Required parts will cost about \$0.85 per engine. Based on these figures, we estimate the total cost of the AD to U.S. operators to be \$18,570.

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 summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "AD Docket No. 2002-NE-33-AD" in your request.

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 Federal Aviation Administration 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 removing Amendment 39-12923 (67 FR 65033, October 23, 2002) and by adding a new airworthiness directive, Amendment 39-13939, to read as follows:

2005-01-14 Bombardier-Rotax GmbH:
Amendment 39-13939. Docket No. 2002-NE-33-AD. Supersedes AD 2002-21-16 (Amendment 39-12923).

Effective Date

(a) This airworthiness directive (AD) becomes effective February 15, 2005.

Affected ADs

(b) This AD supersedes AD 2002-21-16.

Applicability

(c) This AD applies to Bombardier-Rotax GmbH 912 F, 912 S, and 914 F series reciprocating engines. These engines are installed on, but not limited to, Diamond Aircraft Industries, DA20-A1, Diamond Aircraft Industries GmbH Model HK 36 TTS, Model HK 36TTC, and Model HK 36 TTC-ECO, Iniziative Industriali Italiane S.p.A. Sky Arrow 650 TC and Sky Arrow 650 TCN, Aeromot-Industria Mecanico Metalurgica Ltda., Models AMT-300 and AMT-200S, and Stemme S10-VT aircraft.

Unsafe Condition

(d) This AD results from the manufacturer discovering that under certain circumstances, the oil level in the oil tank can fall below the minimum level required to sustain proper engine lubrication. The actions specified in this AD are intended to prevent damage to the engine valve train due to inadequate venting of the lubrication system, which can result in an in-flight engine failure and forced 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.

Initial Venting and Inspection for Correct Venting

(f) Before the next engine start, for all Bombardier-Rotax GmbH 912 F, 912 S, and 914 F series reciprocating engines that have not been operated since doing any of the actions identified in section 1.5(a) of Rotax Mandatory Service Bulletin (MSB) SB-912-036/SB-914-022, Revision 1, dated August 2002, do the following:

- (1) Perform venting of the lubrication system; and
- (2) Perform inspection for correct venting of the hydraulic valve tappets. Use Section 3.1.1 through section 3.1.4 of the Accomplishment Instructions of Rotax MSB SB-912-036/SB-914-022, Revision 1, dated

August 2002 to do the venting and inspection.

Inspection of Engine Valve Train

(g) Before the next engine start, for all Bombardier-Rotax GmbH 912 F, 912 S, and 914 F series reciprocating engines that have been operated for 50 hours or less on the effective date of this AD since doing any of the actions identified in section 1.5 (b) of Rotax MSB SB-912-036/SB-914-022, Revision 1, dated August 2002, do the following:

- (1) Disassemble and perform inspection of the engine valve train; and
- (2) Reassemble, vent the lubrication system, and inspect for correct venting of the hydraulic valve tappets. Use Section 3.1.5 through Section 3.1.7 of the Accomplishment Instructions of Rotax MSB SB-912-036/SB-914-022, Revision 1, dated August 2002.

Repetitive Venting of the Lubrication System

(h) Thereafter, for all Bombardier-Rotax GmbH 912 F, 912 S, and 914 F series reciprocating engines, after doing any of the actions in the following paragraphs (h)(1) through (h)(4), vent the lubrication system and inspect for correct venting of the hydraulic valve tappets before starting the engine. Use section 3.1.1 through section 3.1.4 of the Accomplishment Instructions of Rotax MSB SB-912-036/SB-914-022, Revision 1, dated August 2002 to do the venting and inspecting.

- (1) The installation of a new or overhauled engine.
- (2) The oil system has been opened allowing air to enter the valve train (e.g. oil pump, oil cooler, oil suction line removed which allows oil to drain from the engine oil galleries).
- (3) The engine oil was changed using procedures other than those included in section 1.2 of Rotax MSB SB-912-036/SB-914-022 Revision 1, dated August 2002.
- (4) The propeller was turned more than one turn in the wrong direction of rotation.

(3) The engine oil was changed using procedures other than those included in section 1.2 of Rotax MSB SB-912-036/SB-914-022 Revision 1, dated August 2002.

(4) The propeller was turned more than one turn in the wrong direction of rotation.

Removal of Existing Oil Dipstick From Service

(i) At the next oil change or within 100 hours time-in-service after the effective date of this AD, whichever is later, remove the oil dipstick, part number (P/N) 956150, from service, and install a dipstick that has a different P/N. Information on removing oil dipstick P/N 956150 from service can be found in Rotax MSB SB-912-040/SB-914-026, Revision 1, dated August 2003.

Prohibition of Oil Dipstick, P/N 956150

(j) After the effective date of this AD, do not use dipstick P/N 956150 after complying with paragraph (i) of this AD.

Alternative Methods of Compliance

(k) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Special Flight Permits

(l) Special flight permits are not allowed.

Material Incorporated by Reference

(m) You must use Bombardier-Rotax GmbH Mandatory Service Bulletin SB-912-036/SB-914-022 Revision 1, dated August 2002, to perform the venting and inspecting required by this AD. The Director of the Federal Register previously approved the incorporation by reference of this Mandatory Service Bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, on October 23, 2002 (67 FR 65033). You can get a copy from Bombardier-Rotax GmbH, Guns kirchen, Austria; telephone 7246-601-423; fax 7246-601-760. You can review a copy at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or 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/code_of_federal_regulations/ibr_locations.html.

Related Information

(n) Austro Control airworthiness directives No. 113R1, dated August 30, 2002, and No. 116, dated September 15, 2003, and Rotax Service Instruction SI-04-1997, Revision 3, dated September 2002 also address the subject of this AD.

Issued in Burlington, Massachusetts, on January 3, 2005.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.
[FR Doc. 05-486 Filed 1-10-05; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 520****Oral Dosage Form New Animal Drugs; Ivermectin Meal**

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 a new animal drug application (NADA) filed by Merial, Ltd. The NADA provides for use of ivermectin meal for the control of various species of internal parasites in horses.

DATES: This rule is effective January 11, 2005.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: melanie.berson@fda.gov.

SUPPLEMENTARY INFORMATION: Merial, Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed NADA 141-241 for ZIMECTERIN-EZ (ivermectin) 0.6% w/w for Horses. The application provides for use of ivermectin meal for the control of various species of internal parasites in horses. The NADA is approved as of December 16, 2004, and part 520 (21 CFR part 520) is amended by adding new § 520.1194 to reflect the approval. 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning December 16, 2004.

The agency has determined under 21 CFR 25.33(d)(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 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. Section 520.1194 is added to read as follows:

§ 520.1194 Ivermectin meal.

(a) *Specifications.* Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses—*(1) *Amount.* Administer 136 micrograms (mcg) ivermectin per pound (lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinum* and *C. pateratum*, *Cylicocylus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large Mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.