

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2008-0598; Directorate Identifier 2008-CE-031-AD; Amendment 39-15543; AD 2008-11-20]

RIN 2120-AA64

Airworthiness Directives; Stemme GmbH & Co. KG Model S10-VT Powered Sailplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above that will supersede an existing AD. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

AD 2007-0315-E was issued to address a possible fuel leakage in the gear compartment in front of the engine and mandated inspections and replacement of fuel plastic-made connectors by connectors made of metal. Since its publication, another fuel leakage has been reported on a S10-VT which had implemented the STEMME Service Bulletin (SB) A31-10-082 as required by AD 2007-0315-E.

It has been determined that the fuel leak may have been caused by the deformation that the originally installed clamps created on the fuel hoses and thus preventing the new clamps from being sufficiently pinched to perform a correct tightening.

This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective June 23, 2008.

On June 23, 2008, the Director of the Federal Register approved the incorporation by reference of STEMME F & D Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008, listed in this AD.

As of February 20, 2008 (73 FR 5733, January 31, 2008), the Director of the Federal Register approved the incorporation by reference of STEMME F & D Service Bulletin A31-10-082, AM-Index: 01.a, dated November 30, 2007, listed in this AD.

We must receive comments on this AD by July 2, 2008.

ADDRESSES: You may send comments by any of the following methods:

<bullet> *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>.

Follow the instructions for submitting comments.

<bullet> *Fax:* (202) 493-2251.

<bullet> *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

<bullet> *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4130; fax: (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Discussion

On January 24, 2008, we issued AD 2008-03-06, Amendment 39-15355 (73 FR 5733, January 31, 2008). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2008-03-06, the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued Emergency AD No. 2008-0053-E, dated March 5, 2008 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

AD 2007-0315-E was issued to address a possible fuel leakage in the gear compartment in front of the engine and mandated inspections and replacement of fuel plastic-made connectors by connectors made of metal. Since its publication, another fuel leakage has been reported on a S10-VT which had implemented the STEMME Service Bulletin (SB) A31-10-082 as required by AD 2007-0315-E.

It has been determined that the fuel leak may have been caused by the deformation that the originally installed clamps created on the fuel hoses and thus preventing the

new clamps from being sufficiently pinched to perform a correct tightening.

The present Airworthiness Directive (AD) supersedes AD 2007-0315-E and requires you to check the fuel system according to the STEMME SB A31-10-083 as well as to replace single-ear clamps and plastic connectors.

The actions specified by this AD are intended to reduce the potential for a fire to ignite and which could lead to loss of control of the sailplane.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

STEMME F & D has issued Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all information provided by the State of Design Authority and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

This AD is considered an interim action because we are not including a mandatory requirement to replace STEMME part number (P/N) M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps on all affected sailplanes unless a leak in the fuel system is found. The Administrative Procedure Act does not permit the FAA to "bootstrap" a long-term requirement into an urgent safety of flight action where the rule becomes effective at the same time the public has the opportunity to comment. The short-term action and the long-term action are analyzed separately for justification to bypass prior public notice.

After issuing this AD, we may initiate further AD action (notice of proposed rulemaking followed by a final rule) to require replacing all P/N M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps on all affected sailplanes by a specified time. Credit will be given in any subsequent action for the replacement done under this AD.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might have also required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are described in a separate paragraph of the AD. These requirements take precedence over those copied from the MCAI.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because a leak in the area of the fuel line was found, which could result in the possibility of fuel leaking into the engine compartment. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2008-0598; Directorate Identifier 2008-CE-031-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, 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

We 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.

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 removing Amendment 39-15355 (73 FR 5733, January 31, 2008), and adding the following new AD:

2008-11-20 Stemme GmbH & Co. KG:
Amendment 39-15543; Docket No. FAA-2008-0598; Directorate Identifier 2008-CE-031-AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective June 23, 2008.

Affected ADs

(b) This AD supersedes AD 2008-03-06; Amendment 39-15355.

Applicability

(c) This AD applies to Model S10-VT powered sailplanes, serial numbers 11-001 through 11-112, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 28: Fuel.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states: AD 2007-0315-E was issued to address a possible fuel leakage in the gear compartment in front of the engine and mandated inspections and replacement of fuel plastic-made connectors by connectors made of metal. Since its publication, another fuel leakage has been reported on a S10-VT which had implemented the STEMME Service Bulletin (SB) A31-10-082 as required by AD 2007-0315-E.

It has been determined that the fuel leak may have been caused by the deformation that the originally installed clamps created on the fuel hoses and thus preventing the new clamps from being sufficiently pinched to perform a correct tightening.

The present Airworthiness Directive (AD) supersedes AD 2007-0315-E and requires you to check the fuel system according to the STEMME SB A31-10-083 as well as to replace single-ear clamps and plastic connectors.

The actions specified by this AD are intended to reduce the potential for a fire to ignite and which could lead to loss of control of the sailplane.

Actions and Compliance

(f) Unless already done, do the following actions:

(1) *For all sailplanes affected by this AD, except for serial numbers 11-036, 11-067, 11-068, and 11-090:* Before further flight after March 21, 2008 (the compliance date retained from AD 2008-03-06), replace all plastic T- and Y-connectors in the fuel system with metal connectors. Do the replacements following STEMME F & D Service Bulletin A31-10-082, AM.—Index: 01.a, dated November 30, 2007.

Note: Serial numbers 11-036, 11-067, 11-068, and 11-090 had the plastic T- and Y-connectors in the fuel system replaced with metal connectors by the manufacturer.

(2) *For all sailplanes affected by this AD:* Before further flight after June 23, 2008 (the effective date of this AD), inspect the fuel system for possible leakage. Do the inspection following STEMME F & D Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008.

(3) For all sailplanes affected by this AD: If any leak is found during the inspection required in paragraph (f)(2) of this AD, before further flight, repair the leak following an FAA-approved repair procedure and replace all STEMME part number (P/N) M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps. Do the replacements following STEMME F & D Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008.

(4) After June 23, 2008 (the effective date of this AD), do not install plastic "T" and "Y" shape connectors and P/N M476 single-ear clamps in the fuel system.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows:

(1) The MCAI and the service information require replacing all P/N M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps within the next 12 months after the effective date.

(2) This AD is considered an interim action because we are not including a mandatory requirement to replace all STEMME P/N M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps on all affected sailplanes unless a leak in the fuel system is found. The Administrative Procedure Act does not permit the FAA to "bootstrap" a long-term requirement into an urgent safety of flight action where the rule becomes effective at the same time the public has the opportunity to comment. The short-term action and the long-term action are analyzed separately for justification to bypass prior public notice.

(3) After issuing this AD, we may initiate further AD action (notice of proposed rulemaking followed by a final rule) to require replacing all P/N M476 single-ear clamps in the fuel system with P/N 10M-181 single-ear clamps on all affected sailplanes by a specified time. Credit will be given in any subsequent action for the replacement done under this AD.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, 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: Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4130; fax: (816) 329-409. Before using any approved AMOC on any sailplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) Emergency AD No. 2008-0053-E, dated March 5, 2008; STEMME F & D Service Bulletin A31-10-082, AM-Index: 01.a, dated November 30, 2007; and STEMME F & D Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008, for related information.

Material Incorporated by Reference

(i) You must use STEMME F & D Service Bulletin A31-10-082, AM-Index: 01.a, dated November 30, 2007, and STEMME F & D Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of STEMME F & D Service Bulletin A31-10-083, Am-Index: 01.a, dated February 26, 2008, under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) On February 20, 2008 (73 FR 5733, January 31, 2008), the Director of the Federal Register previously approved the incorporation by reference of STEMME F & D Service Bulletin A31-10-082, AM-Index: 01.a, dated November 30, 2007.

(3) For service information identified in this AD, contact STEMME GmbH & Co. KG, Flugplatzstraße 2, Nr. 7, 15344 Strausberg, Federal Republic of Germany.

(4) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; 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/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri on May 23, 2008.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-12115 Filed 5-30-08; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Butorphanol

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 of an abbreviated new animal drug application (ANADA) filed by Lloyd, Inc. The ANADA provides for the veterinary prescription use of butorphanol tartrate injectable solution in horses for the relief of pain.

DATES: This rule is effective June 2, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., 604 West Thomas Ave., Shenandoah, IA 51601, filed ANADA 200-332 that provides for the veterinary prescription use of BUTORPHIC (butorphanol tartrate) Injection in horses for the relief of pain associated with colic and postpartum pain. Lloyd, Inc.'s BUTORPHIC Injection is approved as a generic copy of TORBUGESIC, sponsored by Fort Dodge Animal Health, Division of Wyeth, under NADA 135-780. The ANADA is approved as of May 1, 2008, and 21 CFR 522.246 is amended to reflect the approval.

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 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