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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2012-0046; Directorate Identifier 2011-CE-040-AD; Amendment 39-17186; AD 2012-15-07 R1]

RIN 2120-AA64

Airworthiness Directives; Glasflugel Gliders

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

ACTION: Final rule; request for comments.

SUMMARY: We are revising an existing airworthiness directive (AD) for Glasflugel Models Standard Libelle-201B, Club Libelle 205, Mosquito, and Kestrel gliders. That AD currently requires actions to address the unsafe condition on these products. This new AD includes clarification that the replacement control rod has an additional drain hole at the rod bottom between the forks and is the acceptable configuration for compliance. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as corrosion damage to the elevator control rod that could lead to failure of the elevator control rod, possibly resulting in loss of control of the glider. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective September 25, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of September 11, 2012.

We must receive any comments on this AD by October 25, 2012.

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

For service information identified in this AD, contact Glasfaser Flugzeug-Service Hansjörg Streifeneder GmbH, D-72582 Grabenstetten, Germany; phone: +49(0)73821032, fax: +49(0)73821629; email: info@streifly.de; Internet: www.streifly.de/. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4165; fax: (816) 329-4090; email: jim.rutherford@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

On July 18, 2012, we issued AD 2012-15-07, amendment 39-17136 (77 FR 46940, August 7, 2012) for Glasflugel Models Standard Libelle-201B, Club Libelle 205, Mosquito, and Kestrel gliders. That AD resulted from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. We issued that AD to require actions to address the unsafe condition on these products.

Actions Since AD Was Issued

Since we issued AD 2012-15-07, amendment 39-17136 (77 FR 46940, August 7, 2012), compliance with the existing AD required operators to not install an elevator control rod with a control bore hole. An operator reported that the improved replacement rods, as expected, have no control bore hole on the side at the top of the rod where there had previously been a hole. However, the improved replacement rods do have a new drain hole at the bottom of the rod between the forks. The operator

expressed confusion as to whether this drain hole would cause the new rod to not be in compliance since there was no clarification of “on the side.”

Relevant Service Information

Glasfaser Flugzeug-Service GmbH has issued Technical Note TN 201-40, TN 205-27, TN 206-26, TN 303-25, TN 304-12, TN 401-30, TN 501-10, and TN 604-11, Revision 1, dated July 14, 2011 (EASA translation approval dated September 9, 2011). The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD retains the actions from AD 2012-15-07 but adds the language of “on the side” to assure that the replacement control rod, which has an additional drain hole at the rod bottom between the forks, is an acceptable configuration for compliance.

FAA's Justification and Determination of the Effective Date

This action incorporates clarification that the additional drain hole at the rod bottom between the forks on the replacement control rods is the acceptable configuration for compliance and does not require any additional work for those airplanes. Therefore, we find that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA-2012-0046 and directorate identifier 2011-CE-040-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.

Costs of Compliance

We estimate that this AD will affect 54 products of U.S. registry. We also estimate that it would take about 6 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$333 per product.

Based on these figures, we estimate the cost of the AD on U.S. operators to be \$45,522, or \$843 per product.

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 this AD:

- (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),

(3) Will not affect intrastate aviation in Alaska, 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.

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 the NPRM, 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.

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 AD:

2012-15-07 R1 Glasflugel: Amendment 39-17186; Docket No. FAA-2012-0046; Directorate Identifier 2011-CE-040-AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective September 25, 2012.

(b) Affected ADs

This AD revises AD 2012-15-07, amendment 39-17136 (77 FR 46940, August 7, 2012).

(c) Applicability

This AD applies to the following Glasflugel models and serial number (S/N) gliders, certificated in any category:

- (1) Club Libelle 205, all S/Ns.
- (2) Kestrel, all S/Ns, except S/N 85, 110, and 125.
- (3) Mosquito, all S/Ns.
- (4) Standard Libelle-201B, S/N 169.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as corrosion damage to the elevator control rod that could lead to failure of the elevator control rod, possibly resulting in loss of control of the glider. We are issuing this AD to require actions to address the unsafe condition on these products.

(f) Actions and Compliance

Unless already done, do the following actions:

(1) Within 30 days after September 11, 2012 (the effective date of AD 2012-15-07), inspect the elevator control rod in the vertical fin following Glasfaser Flugzeug-Service GmbH Technical Note TN 201-40, TN 205-27, TN 206-26, TN 303-25, TN 304-12, TN 401-30, TN 501-10, and TN 604-11, Revision 1, dated July 14, 2011 (EASA translation approval dated September 9, 2011), as applicable to glider model.

(2) If you find any discrepancy in the inspection required by paragraph (f)(1) of this AD, before further flight, replace the elevator control rod with an elevator control rod that does not have a control bore hole on the side following Glasfaser Flugzeug-Service GmbH Technical Note TN 201-40, TN 205-27, TN 206-26, TN 303-25, TN 304-12, TN 401-30, TN 501-10, and TN 604-11, Revision 1, dated July 14, 2011 (EASA translation approval dated September 9, 2011), as applicable to glider model.

(3) Within 9 months after September 11, 2012 (the effective date of AD 2012-15-07), unless already done as required by paragraph (f)(2) of this AD, replace the elevator control rod in the vertical fin with an elevator control rod that does not have a control bore hole on the side following Glasfaser Flugzeug-Service GmbH Technical Note TN 201-40, TN 205-27, TN 206-26, TN 303-25, TN 304-12, TN 401-30, TN 501-10, and TN 604-11, Revision 1, dated July 14, 2011 (EASA translation approval dated September 9, 2011), as applicable to glider model.

(4) As of September 11, 2012 (the effective date of AD 2012-15-07), do not install an elevator control rod with a control bore hole on the side.

Note to paragraphs (f)(2), (f)(3), and (f)(4) of this AD: The replacement control rod has an additional drain hole at the rod bottom between the forks and is an acceptable configuration for compliance.

(5) The actions mandated by this AD may be accomplished by persons authorized to perform maintenance in accordance with 14 CFR 43.3 and by persons authorized to approve aircraft for return to service after maintenance in accordance with 14 CFR 43.7.

(g) Other FAA AD Provisions

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: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4165; fax: (816) 329-4090; email: jim.rutherford@faa.gov. Before using any approved AMOC on any airplane 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, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2011-0213R1, dated November 8, 2011; and Glasfaser Flugzeug-Service GmbH Technical Note TN 201-40, TN 205-27, TN 206-26, TN 303-25, TN 304-12, TN 401-30, TN 501-10, and TN 604-11, Revision 1, dated July 14, 2011 (EASA translation approval dated September 9,

2011), for related information. For service information related to this AD, contact Glasfaser Flugzeug-Service Hansjörg Streifeneder GmbH, D-72582 Grabenstetten, Germany; phone: +49(0)73821032, fax: +49(0)73821629; email: info@streifly.de; Internet: www.streifly.de/. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(i) 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.

(3) The following information was approved for IBR on September 11, 2012.

(i) Glasfaser Flugzeug Service GmbH Technical Note TN 201-40, TN 205-27, TN 206-26, TN 303-25, TN 304-12, TN 401-30, TN 501-10, and TN 604-11, Revision 1, dated July 14, 2011.

(ii) Reserved.

(4) For Glasflugel service information identified in this AD, contact Glasfaser Flugzeug-Service Hansjörg Streifeneder GmbH, D-72582 Grabenstetten, Germany; phone: +49(0)73821032, fax: +49(0)73821629; email: info@streifly.de; Internet: www.streifly.de/.

(5) You may view this service information at FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(6) You may view this service information that is incorporated by reference 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/index.html>.

Issued in Kansas City, Missouri, on August 31, 2012.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012-22039 Filed 9-7-12; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA-2012-N-0902]

New Animal Drugs; Chorionic Gonadotropin; Naloxone; Oxymorphone; Oxytocin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of four new animal drug applications (NADAs) at the sponsor's request because the products are no longer manufactured or marketed.

DATES: This rule is effective September 20, 2012.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240-453-6843; email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The sponsors of the four approved NADAs listed in table 1 of this document have requested that FDA withdraw approval because the products are no longer manufactured or marketed:

TABLE 1—WITHDRAWAL OF APPROVAL REQUESTS

NADA No.	Trade name (drug)	Applicant	Citation in 21 CFR
030-525	NUMORPHAN (oxymorphone hydrochloride) Injection.	Endo Pharmaceuticals Inc., 100 Painters Dr., Chadds Ford, PA 19317.	522.1642
035-825	NARCAN (naloxone hydrochloride) Injection.	Endo Pharmaceuticals Inc., 100 Painters Dr., Chadds Ford, PA 19317.	522.1462
046-822	VETOCIN (oxytocin) Injection	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711.	522.1680
103-090	CHORTROPIN (chorionic gonadotropin) Injection.	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711.	522.1081

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 030-525, 035-825, 046-822, and 103-090, and all supplements and amendments thereto, is withdrawn, effective September 20, 2012. As

provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Endo Pharmaceuticals Inc.

and United Vaccines, A Harlan Sprague Dawley, Inc., Co., will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.