14 CFR Part 39

[Docket No. 96–CE–38–AD]

RIN 2120–AA64

Airworthiness Directives; Glasflugel Models H301 ''Libelle,'' H301B ''Libelle,'' Standard ''Libelle,'' Standard Libelle 201B, Club Libelle 205, and Kestrel Sailplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to Glasflugel Models H301 ''Libelle,'' H301B ''Libelle,'' Standard ''Libelle,'' Standard Libelle 201B, Club Libelle 205, and Kestrel sailplanes. The proposed action would require measuring and adjusting the control surface weight and static moment, and inserting amendments into the maintenance manual. The proposed action results from considerable variation of the weight and static moment of the control surface on the affected sailplanes found during repair or repainting of the control surface. The actions specified by the proposed AD are intended to prevent sailplane flutter because the weight and static moment of the control surface are not within certain limits, which could result in flutter and subsequent loss of control of the sailplane.

DATES: Comments must be received on or before December 13, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–38–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Glasflugel, c/o Hr. H. Streifeneder, Glasfaser-Flugzeug-Service GmbH, Hofener Weg, D–72582 Grabenstetten, Germany. This information also may be examined at the Rules Docket at the address below. Send comments on the proposal in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–38–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

FOR FURTHER INFORMATION CONTACT: Mr. J. Mike Kiesov, Project Officer, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone (816) 426–6932; facsimile (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 96–CE–38–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–CE–38–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, recently notified the FAA that an unsafe condition may exist on Glasflugel Models H301 ''Libelle'', H301B ''Libelle'', Standard ''Libelle'', Standard Libelle 201B, Club Libelle 205, and Kestrel sailplanes. The LBA reports that considerable variation in the weight and static moment of the control surfaces on 10 of the affected sailplanes was found during repair or repainting. Glasflugel did not define the required weight or static moment of the control surfaces at the time of manufacture of these sailplanes. If the control surface weight and static moment of these sailplanes are not within certain limits, flutter could result with subsequent loss of control of the sailplane.

Applicable Service Information

Glasflugel has issued amendments to the maintenance manual that include procedures for measuring and adjusting the weight and static moment of the control surfaces. The following specifies the maintenance manual amendments for each specific sailplane model:

Sailplane models	Maintenance manual amendment page numbers
H301 Libelle and H301B Libelle.	Pages 14a and 14b.
Standard Libelle	Pages E14a and E14b.
Standard Libelle 201B.	Pages E15a and E15b.
Club Libelle 205	Pages 42a and 42b.
Kestrel	Pages 27a and 27b.

The FAA's Determination

The LBA issued LTA AD 96–137, LTA AD 96–138, and LTA AD 96–139, all dated April 9, 1996, in order to assure the continued airworthiness of these sailplanes in Germany.

This sailplane model is manufactured in Germany and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA; reviewed all available information, including the maintenance manual amendments referenced above; and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Glasflugel Models H301 ''Libelle'', H301B ''Libelle'', Standard ''Libelle'', Standard Libelle 201B, Club Libelle 205, and Kestrel sailplanes of the same type design registered in the United States, the FAA is proposing AD action. The proposed AD would require measuring and adjusting the control surface weight and static moment, and inserting the

following amendments into the maintenance manual, as applicable:

Sailplane models	Maintenance manual amendment page numbers
H301 Libelle and H301B Libelle.	Pages 14a and 14b.
Standard Libelle	Pages E14a and E14b.
Standard Libelle 201B.	Pages E15a and E15b.
Club Libelle 205	Pages 42a and 42b.
Kestrel	pages 27a and 27b.

Compliance Time of the Proposed AD

The compliance time for the proposed AD is presented in calendar time and whenever the control surface is repaired or repainted (the prevalent one being that which occurs first). The FAA has determined that a calendar time for compliance would be desirable because the unsafe condition described by the proposed AD is not directly related to sailplane operation. The control surface weight and static moment could become outside the specified limits after repair or repainting instead of occurring during normal operation of the sailplane. Also, if the sailplane control surface is already scheduled for repair or repainting, then accomplishing the proposed action at the time of repair or repainting would not force the owner/operator to schedule this action at a later time and would allow the action to be accomplished during already-scheduled maintenance.

Cost Impact

The FAA estimates that 174 sailplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 1 workhour per sailplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. Material to accomplish the surface control weight and static moment balance costs approximately $10 per sailplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $12,180. This figure only takes into account the one-time measurement and adjustment of the control surface weight and static moment; it does not reflect the time it would take an owner/operator of an affected sailplane to insert the amendments into the maintenance manual.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (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) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

Glasflugel: Docket No. 96–CE–38–AD.

Applicability: Models H301 ''Libelle'', H301B ''Libelle'', Standard ''Libelle'', Standard Libelle 201B, Club Libelle 205, and Kestrel sailplanes (all serial numbers), certificated in any category.

Note 1: This AD applies to each sailplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For sailplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next three calendar months after the effective date of this AD or at the time of any repair to or repainting of the control surface, whichever occurs first, unless already accomplished.

To prevent sailplane flutter because the weight and static moment of the control surface are not within certain limits, which could result loss of control of the sailplane, accomplish the following:

(a) Measure and adjust the control surface weight and static moment in accordance with the maintenance manual amendments referenced in paragraph (b) of this AD.

(b) Insert the following amendments into the sailplane maintenance manual, as applicable:

Sailplane models	Amendment page numbers
H301 Libelle and H301B Libelle.	Pages 14a and 14b.
Standard Libelle	Pages E14a and E14b.
Standard Libelle 201B.	Pages E15a and E15b.
Club Libelle 205	Pages 42a and 42b.
Kestrel	Pages 27a and 27b.

(c) Inserting the amendments into the maintenance manual as required by paragraph (b) of this AD may be performed by the owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7), and must be entered into the aircraft records showing compliance with this AD in accordance with section 43.11 of the Federal Aviation Regulations (14 CFR 43.11).

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the sailplane to a location where the requirements of this AD can be accomplished.

(e) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(f) All persons affected by this directive may obtain copies of the maintenance manual amendments referred to herein upon request to Glasflugel, c/o Hr. H. Streifeneder, Glasfaser-Flugzeug-Service GmbH, Hofener Weg, D–72582 Grabenstetten, Germany; or may examine these amendments at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on October 7, 1996.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–26253 Filed 10–11–96; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 96N–0144]

Over-the-Counter Drug Products Containing Colloidal Silver Ingredients or Silver Salts

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish that all over-the-counter (OTC) drug products containing colloidal silver ingredients or silver salts for internal or external use are not generally recognized as safe and effective and are misbranded. FDA is issuing this proposal because many products containing colloidal silver ingredients or silver salts are being marketed for numerous serious disease conditions and FDA is not aware of any substantial scientific evidence that supports the use of OTC colloidal silver ingredients or silver salts for these disease conditions.

DATES: Written comments by January 13, 1997; written comments on the agency's economic impact determination by January 13, 1997. FDA is proposing that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the Federal Register.

ADDRESSEES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Bradford W. Williams, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0063.

SUPPLEMENTARY INFORMATION:

I. Background

Colloidal silver is a suspension of silver particles in a colloidal base. Historically, a number of colloidal silver/silver colloidal salts have been marketed in the United States. Some of these colloidal silver products were recognized as official articles in the United States Pharmacopeia (U.S.P.) and the National Formulary (N.F.). Colloidal silver iodide (Ref. 1) contained not less than 18 percent and not more than 22 percent silver, with the product diluted for local use to concentrations from 0.05 to 10 percent. Strong silver protein (Ref. 1) contained not less than 7.5 percent and not more than 8.5 percent silver, with the product diluted for local use to concentrations from 0.5 to 10 percent. The 10th edition of the N.F. had a cautionary note for these products that stated: ''Caution: Solutions of Colloidal Silver Iodide should be freshly prepared and should be dispensed in amber-colored bottles,'' and ''Caution: Strong Silver Protein Solutions should be freshly prepared and should be dispensed in amber-colored bottles.''

Mild silver protein (Ref. 2) contained not less than 19 percent and not more than 23 percent silver, with the product diluted for local use to concentrations from 0.1 to 5 percent. The 12th edition of the N.F. had a cautionary note, which stated: ''Caution: Solutions of Mild Silver Protein should be freshly prepared or contain a suitable stabilizer, and should be dispensed in amber-colored bottles.''

Ammoniacal silver nitrate solution (Ref. 2) contained 28.5 to 30.5 percent silver, was made extemporaneously, and was used locally without dilution. Silver nitrate solution (Ref. 3) was made extemporaneously and was used locally at strengths from 0.1 to 10 percent.

None of these formerly recognized colloidal silver preparations has been official in the U.S.P. or the N.F. since 1975. Moreover, of the silver salts evaluated as part of the agency's OTC drug review thus far, none was found to be generally recognized as safe and effective for its intended use(s). These included silver nitrate as an astringent (58 FR 27636, May 10, 1993) and as a smoking deterrent (58 FR 31236, June 1, 1993) and mild silver protein as an ophthalmic anti-infective (57 FR 60416, December 18, 1992). Silver acetate was also evaluated as a smoking deterrent and found not to be generally recognized as safe and effective (58 FR 31236).

II. Recent Developments

In recent years, colloidal silver preparations of unknown formulation have been appearing in retail outlets. These products are labeled for numerous disease conditions, including human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), cancer, tuberculosis, malaria, lupus, syphilis, scarlet fever, shingles, herpes, pneumonia, typhoid, exanthematic typhus, tetanus, variola, scarlatina, erysipelas, rheumatism, candida, staphylococcus and streptococcus infections, tonsillitis, parasites, fungus, bubonic plague, cholera, chronic fatigue, acne, warts, Meniere's disease (syndrome), whooping cough, enlarged prostate, perineal eczema, hemorrhoids, impetigo, ringworm, recurrent boils, burns, and appendicitis.

Several marketers of these products use a labeling brochure that refers to colloidal silver as a treatment or cure for 650 diseases (Ref. 4). Some colloidal silver products have been promoted using reprints of articles, taken from magazines and newspapers, that make claims of extensive health benefits for colloidal silver, similar to the claims listed above. The articles have also been shipped with colloidal silver products, when the products were ordered through the mail (Ref. 5). The dosage form of these colloidal silver products is usually oral, but product labeling also contains directions for topical and, occasionally, intravenous use.

In October 1994, FDA issued Health Fraud Bulletin #19 (Ref. 6) to address the emerging marketing of colloidal silver products offered for serious disease conditions. In that bulletin, the agency stated that it was ''not aware of any substantial scientific evidence which demonstrates that any OTC colloidal silver solution is useful to prevent or treat any serious disease condition.'' The bulletin explained that FDA has not approved a new drug application (NDA) for a colloidal silver product. In addition, the bulletin stated no data or information has been submitted to FDA to document an exemption from the new drug provisions of the Federal Food, Drug, and Cosmetic Act (the act) under the 1938 or 1962 grandfather provisions. The bulletin referred to 21 CFR 314.200(e)(2), which sets forth the type of evidence necessary to support an exemption under a grandfather provision.

III. The ''Grandfather'' Exemption

Some marketers of various colloidal silver preparations claim their products are exempt from the ''new drug'' provisions of section 201(p) of the act (21 U.S.C. 321(p)) under the ''grandfather'' provisions of the 1938 act and the 1962 amendments to the act. The marketers frequently claim that their products were marketed before 1938, that only insubstantial changes have been made in product formulation and labeling since that time, and that