

this section is void and coverage is reinstated retroactively.

(6) If, at any time after the disenrollment has occurred, the employing office or OPM determines that another section of this part applies to the individual's enrollment or the carrier discovers or receives appropriate documentation showing that another section of this part applies to the individual's enrollment, the disenrollment under paragraph (a)(2) of this section is void and coverage is reinstated retroactively.

(b) When a carrier receives, from any reliable source, information of the death of an enrollee with a self only enrollment, the carrier may take action to disenroll the individual on the date set forth in § 890.304(a)(1)(iv) or § 890.304(b)(4), as appropriate. When the date of death is unknown, the carrier may take action to disenroll the individual on the date which is the last day of the pay period in which information of the death is received. Reliable sources include, but are not limited to, claims for hospital or physician costs incurred at time of death and correspondence returned from the Postal Service noting that the addressee is deceased. If, at any time after the disenrollment has occurred, the employing office or OPM determines that another section of this part applies to the individual's enrollment or the carrier discovers or receives appropriate documentation showing that another section of this part applies to the individual's enrollment, the disenrollment under this paragraph (b) is void and coverage is reinstated retroactively.

(c)(1) When a child survivor annuitant covered under a self only enrollment reaches age 22, the carrier may take action to disenroll the individual effective with the date set forth in § 890.304(c)(1) unless records with the carrier indicate that the child is incapable of self support due to a physical or mental disability. The carrier must provide the enrollee with a written notice of disenrollment prescribed or approved by OPM prior to the date set forth in § 890.304(c)(1).

(2) The child survivor annuitant may request the retirement system to reconsider the carrier's decision to disenroll the individual. The request for reconsideration must be made in writing and include the enrollee's name, address, Social Security Number or other identifier, name of carrier, reason(s) for the request, and the survivor annuity claim number. The retirement system must notify the carrier when a request for

reconsideration of the carrier's decision to disenroll the individual is made.

(3) A request for reconsideration of the carrier's decision must be filed with the retirement system within 60 calendar days from the date of the carrier's disenrollment notice. The time limit on filing may be extended when the individual shows that he or she was not notified of the time limit and was not otherwise aware of it, or that he or she was prevented by circumstances beyond his or her control from making the request within the time limit.

(4) After reconsideration, the retirement system must issue a written notice of its final decision to the child survivor annuitant and notify the carrier of the decision. The notice must fully set forth the findings and conclusions on which the decision was based. If upon reconsideration the retirement system determines that he or she is entitled to continued enrollment in the plan, the disenrollment under paragraph (c)(1) of this section is void and coverage is reinstated retroactively.

(5) If, at any time after the disenrollment has occurred, the employing office or OPM determines that another provision of this part applies to the individual's enrollment or the carrier discovers or receives appropriate documentation showing that another section of this part applies to the individual's enrollment, the disenrollment under paragraph (c)(1) of this section is void and coverage is reinstated retroactively.

(d) When an enrollee notifies the carrier that he or she has separated from Federal employment and is no longer eligible for enrollment, the carrier must disenroll the individual on the last day of the pay period in which the separation occurred, if known, otherwise the carrier must disenroll the employee on the date the employee provides as the date of separation. The carrier must provide the enrollee with a written notice of disenrollment prescribed or approved by OPM.

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 97-CE-138-AD; Amendment 39-10865; AD 98-23-02]

RIN 2120-AA64

#### Airworthiness Directives; Cessna Aircraft Company 180 and 185 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

**SUMMARY:** This amendment supersedes Airworthiness Directive (AD) 80-10-01, which applies to certain Cessna Aircraft Company (Cessna) 180 and 185 series airplanes that have either Airglas Engineering Company, Inc., (AECI) Model LW3600-180 (single position) or Model LW3600-180A (two position) fixed penetration wheel skis installed in accordance with Supplemental Type Certificate (STC) SA213AL. AD 80-10-01 requires modifying the ski bungee assemblies, safety cables, and check cables, and their attachments to the airplane and the skis; limiting the maximum airspeed to 160 knots with skis installed; and installing an airspeed limitation placard. This AD is the result of field reports of incidents occurring on the affected airplanes that were in compliance with AD 80-10-01, and the fact that Cessna Model 180K airplanes were inadvertently left out of the existing AD. This AD retains the actions required by AD 80-10-01; requires re-marking the airspeed indicator to display the reduced airspeed limits and placing a certain airplane flight manual (AFM) supplement in the cockpit; and adds Cessna Model 180K airplanes to the Applicability section of the AD. The actions specified by this AD are intended to prevent one or both wheel skis from rotating into a nose-down position during flight, which could result in loss of control of the airplane and/or possible airplane damage during flight or landing operations.

**DATES:** Effective December 22, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 22, 1998.

**ADDRESSES:** Service information that applies to this AD may be obtained from Airglas Engineering Company, Inc., P.O. Box 190107, Anchorage, Alaska 99519-0107; telephone: (907) 344-1450; facsimile: (907) 349-4938. This information may also be examined at

the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 97-CE-138-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gordon K. Mandell, Aerospace Engineer, FAA, Anchorage Aircraft Certification Office, 222 West 7th Avenue, #14, Room 128, Anchorage, Alaska 99513-7587; telephone: (907) 271-2670; facsimile: (907) 271-6365.

**SUPPLEMENTARY INFORMATION:**

**Events Leading to the Issuance of This AD**

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that applies to certain Cessna 180 and 185 series airplanes that have either Airglas Engineering Company, Inc., (AECI) Model LW3600-180 (single position) or Model LW3600-180A (two position) fixed penetration wheel skis installed in accordance with STC SA213AL was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on June 26, 1998 (63 FR 34833). The NPRM proposed to supersede AD 80-10-01, Amendment 39-3762, which currently requires modifying the ski bungee assemblies, safety cables, and check cables, and their attachments to the airplane and the skis; limiting the maximum airspeed to 160 knots with skis installed; and installing an airspeed limitation placard. The NPRM proposed to require the following:

- Modifying the ski bungee assemblies, safety cables, and check cables, and their attachments to the airplane and the skis;
- Installing a placard adjacent to the airspeed indicator limiting the never exceed speed to 160 knots with the skis installed;
- Re-marking the airspeed indicator to display the reduced never exceed speed (160 KIAS) and the reduced maximum structural cruising speed (139 KIAS) with the skis installed; and
- Placing AECI Document No. AE97-13FM, "Supplemental Airplane Flight Manual and Airplane Flight Manual Supplement", dated October 10, 1997, in the airplane cockpit.

Accomplishment of the proposed actions as specified in the NPRM would be required in accordance with AECI Service Bulletin (SB) No. LW3600-3, originally issued: September 21, 1979; Amended: October 10, 1997; AECI Drawing No. LW3600-180A-1 and -2, Revision "B", dated September 21,

1979; AECI Drawing No. LW3600-180A-3, Revision "A", dated April 30, 1979; AECI Drawing No. LW3600-180, Revision "F", dated September 21, 1979 (for single position wheel ski installations) or AECI Drawing No. LW3600-180A, Revision "E", dated September 21, 1979 (for two position wheel ski installations); AECI Drawing No. LW3600-180A-11, originally issued: September 21, 1979; and AECI Document AE97-13FM, "Supplemental Airplane Flight Manual and Airplane Flight Manual Supplement", dated October 10, 1997.

The NPRM was the result of field reports of incidents occurring on the affected airplanes that were in compliance with AD 80-10-01, and the fact that Cessna Model 180K airplanes were inadvertently left out of the existing AD.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the following comments received.

**Comment Disposition**

The one commenter states that requiring re-marking of the airspeed indicator to display the reduced airspeed limits will not fix the problem because airplane operators that ignore placard requirements will also ignore the airspeed indicator requirements. This commenter operates one of the affected airplanes with skis for 6 months out of each year.

The commenter states that, if the proposed AD is adopted, he will have to accomplish pitot and static pressure checks required by current regulation every 6 months when he changes the airspeed indicator during ski installation and removal.

The commenter also states that skis are similar to other devices, such as landing gear, flaps, ramps, and doors that are affixed to or incorporated into aircraft. The commenter states that the maximum speed at which the other devices can be extended or opened in flight are specified only by placards and not by markings on the airspeed indicator.

The commenter goes on to state that, based on the above information, the costs of installing and removing the skis will become extremely high, and the commenter asks the FAA to remove the requirement of re-marking the airspeed indicator to display the reduced airspeed limits.

The FAA does not concur that the requirement in the proposed AD of re-marking the airspeed indicator is not justified.

The FAA's intent of requiring that the airspeed indicator be re-marked is not to provide another airspeed limit indication for certain pilots to ignore, but to provide consistent indications of airspeed limits, i.e., to eliminate the confusion generated by having the information in an airspeed limitation placard contradicting the airspeed indicator.

The proposed AD requires re-marking the airspeed indicator, but does not specifically require removing the existing airspeed indicator and replacing it with one marked differently. If the existing airspeed indicator is left in place and re-marked, no pitot and static pressure checks would be required. Each airplane owner/operator has the choice of changing the markings of the airspeed indicator either by replacing the airspeed indicator or by re-marking the existing airspeed indicator without removing it.

The FAA understands that an owner/operator who decides to replace the airspeed indicator will have to accomplish pitot and static pressure checks each time the airspeed indicator is replaced and that there are costs involved with this. However, the FAA has determined that the safety benefits of eliminating the confusion caused when the airspeed indicator contradicts current placards far outweigh this burden.

In addition, the FAA does not consider skis similar to other devices, such as landing gear, flaps, ramps, and doors that are affixed to or incorporated into aircraft. The compared items are all ones that can be extended or opened and retracted or closed during flight. On the other hand, the installation of skis on aircraft changes the aircraft's configuration until the skis are removed. Fixed penetration wheel skis cannot be extended or opened and then retracted or closed.

The commenter's assertion that the maximum speed at which wing flaps can be extended in flight is not specified by airspeed indicator markings is incorrect. The range of airspeeds over which the flaps of a small airplane can be extended in flight is specified by a white arc on the airspeed indicator. The upper end of the white arc is the maximum speed at which the flaps can be extended.

No changes have been made to the final rule as a result of these comments.

**The FAA's Determination**

After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require the adoption of

the rule as proposed except for minor editorial corrections. The FAA has determined that these minor corrections will not change the meaning of the AD and will not impose any additional burden upon the public than was already proposed.

#### Cost Impact

The FAA estimates that 170 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 4 workhours per airplane to accomplish this action, and that the average labor rate is approximately \$60 an hour. Parts cost approximately \$350 per airplane. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be \$100,300, or \$590 per airplane.

AECI has informed the FAA that approximately 12 of the affected airplanes have the modification required by this AD already incorporated. Based on this, the cost impact of the proposed AD is reduced by \$7,080, from \$100,300 to \$93,220.

None of the above figures take into account the costs involved if operators would have to re-accomplish the work, i.e., ski removal and re-installation.

AD 80-10-01 currently requires most of the same actions on the affected airplanes that are required by this AD. The only differences between this AD and AD 80-10-01 are the addition of Cessna Model 180K airplanes to the applicability and the requirements for re-marking the airspeed indicator and placing an AFM supplement in the cockpit. Fabricating and installing the placard, placing the AFM supplement in the cockpit, and re-marking the airspeed indicator (provided the indicator is re-marked by painting the outside of the glass) can be accomplished by:

—For airplanes operated in accordance with part 91 of the Federal Aviation Regulations (14 CFR part 91): An owner/operator who holds at least a private pilot's certificate; and  
 —For airplanes operated in accordance with part 135 of the Federal Aviation Regulations (14 CFR part 135): An operator who holds an operating certificate issued under part 135 of the Federal Aviation Regulations (14 CFR part 135), as authorized by sections 43.3, 43.7, and 43.9 of the Federal Aviation Regulations (14 CFR 43.3, 43.7, and 43.9).

The only cost impact upon the public for airplanes other than the affected Cessna Model 180K airplanes is the time it will take the affected airplane owners/operators to incorporate these actions. Therefore, this AD has no additional cost impact over that already required by AD 80-10-01, except for the costs

associated with the affected Cessna Model 180K airplanes.

#### Regulatory Impact

The regulations adopted herein will 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 final rule does 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) 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 final evaluation prepared for this action is contained 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, Incorporation by reference, Safety.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

2. Section 39.13 is amended by removing Airworthiness Directive (AD) 80-10-01, Amendment 39-3762, and by adding a new AD to read as follows:

#### 98-23-02 Cessna Aircraft Company:

Amendment 39-10865; Docket No. 97-CE-138-AD; Supersedes AD 80-10-01, Amendment 39-3762.

**Applicability:** The following airplane models, all serial numbers; certificated in any category, that have either Airglas Engineering Company, Inc., (AECI) Model LW3600-180 (single position) or Model LW3600-180A (two position) fixed penetration wheel skis installed in accordance with Supplemental Type Certificate (STC) SA213AL:

#### Models

180	180D	180H	185A	185E
180A	180E	180J	185B	A185E
180B	180F	180K	185C	A185F
180C	180G	185	185D	

**Note 1:** This AD applies to each airplane 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 airplanes 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 (g) 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 50 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished.

To prevent one or both wheel skis from rotating into a nose-down position during flight, which could result in loss of control of the airplane and/or possible airplane damage during flight or landing operations, accomplish the following:

(a) Modify the wheel ski bungee assemblies, safety cables, and check cables, and their attachments to the airplane and the skis, in accordance with Airglas Engineering Company, Inc. (AECI) Drawing No. LW3600-180A-1 and -2, Revision "B", dated September 21, 1979; AECI Drawing No. LW3600-180A-3, Revision "A", dated April 30, 1979; and AECI Drawing No. LW3600-180, Revision "F", dated September 21, 1979 (for single position wheel ski installations) or AECI Drawing No. LW3600-180A, Revision "E", dated September 21, 1979 (for two position wheel ski installations).

**Note 2:** AECI Service Bulletin (SB) No. LW3600-3, originally issued: September 21, 1979; Amended: October 10, 1997, specifies following the procedures provided in the drawings referenced in paragraph (a) of this AD.

(b) Fabricate a placard using letters at least 1/8 inch in height and install this placard adjacent to the airspeed indicator, in accordance with AECI Drawing No. LW3600-180A-11, originally issued: September 21, 1979, and AECI SB No. LW3600-3, originally issued: September 21, 1979; Amended: October 10, 1997.

(c) Re-mark the airspeed indicator to display the never exceed airspeed (160 knots indicated airspeed (KIAS)) and the maximum structural cruising speed (139 KIAS) with skis installed, in accordance with AECI SB No. LW3600-3, originally issued: September 21, 1979; Amended: October 10, 1997.

(d) Place AECI Document AE97-13FM, "Supplemental Airplane Flight Manual and Airplane Flight Manual Supplement", dated October 10, 1997, in the airplane cockpit, in accordance with AECI SB No. LW3600-3, originally issued: September 21, 1979; Amended: October 10, 1997.

(e) The placard, airspeed indicator re-marking (provided the indicator is re-marked

by painting the outside of the glass), and AFM supplement placement requirements of paragraphs (b), (c), and (d) of this AD, respectively, can be accomplished by:

(1) *For airplanes operated in accordance with part 91 of the Federal Aviation Regulations (14 CFR part 91):* An owner/operator who holds at least a private pilot's certificate; and

(2) *For airplanes operated in accordance with part 135 of the Federal Aviation Regulations (14 CFR part 135):* An operator who holds an operating certificate issued under part 135 of the Federal Aviation Regulations (14 CFR part 135), as authorized by sections 43.3, 43.7, and 43.9 of the Federal Aviation Regulations (14 CFR 43.3, 43.7, and 43.9).

(f) 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 airplane to a location where the requirements of this AD can be accomplished.

(g) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Anchorage Aircraft Certification Office (ACO), 222 West 7th Avenue, #14, Room 128, Anchorage, Alaska 99513-7587.

(1) The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Anchorage ACO.

(2) Alternative methods of compliance approved for AD 80-10-01 are not considered approved as alternative methods of compliance for this AD.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Anchorage ACO.

(h) The modifications, placard installation, airspeed indicator re-marking, and AFM supplement placement required by this AD shall be done in accordance with AECI SB No. LW3600-3, originally issued: September 21, 1979; Amended: October 10, 1997; AECI Drawing No. LW3600-180A-1 and -2, Revision "B", dated September 21, 1979; AECI Drawing No. LW3600-180A-3, Revision "A", dated April 30, 1979; AECI Drawing No. LW3600-180, Revision "F", dated September 21, 1979 (for single position wheel ski installations) or AECI Drawing No. LW3600-180A, Revision "E", dated September 21, 1979 (for two position wheel ski installations); AECI Drawing No. LW3600-180A-11, originally issued: September 21, 1979; and AECI Document AE97-13FM, "Supplemental Airplane Flight Manual and Airplane Flight Manual Supplement", dated October 10, 1997. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airglas Engineering Company, Inc., P.O. Box 190107, Anchorage, Alaska 99519-0107. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) This amendment supersedes AD 80-10-01, Amendment 39-3762.

(j) This amendment becomes effective on December 22, 1998.

Issued in Kansas City, Missouri, on October 27, 1998.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 98-29363 Filed 11-3-98; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 211

[Docket No. 92N-0314]

#### Tamper-Evident Packaging Requirements for Over-the-Counter Human Drug Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations on tamper-resistant packaging to require that all over-the-counter (OTC) human drug products marketed in two-piece, hard gelatin capsules be sealed using a tamper-evident technology; to change the term "tamper-resistant" in the labeling of all OTC drug products to "tamper-evident;" and to specify that the required OTC drug product labeling statement must refer to all packaging features used to comply with the tamper-evident packaging requirements, including those on the secondary package, the immediate container or closure, and any capsule sealing technologies used. FDA is taking this action as a result of its continuing review of the potential public health threat posed by product tampering and to improve consumer protection by addressing specific vulnerabilities in the OTC drug market.

**DATES:** Effective December 4, 1998.

Compliance dates: All two-piece, hard gelatin capsules subject to the final rule that are initially introduced or initially delivered for introduction into interstate commerce by November 4, 1999, must be sealed in compliance with the requirements of the final rule.

OTC drug products that use the term "tamper-resistant" in their labeling must change the term to "tamper-evident" by November 6, 2000.

**FOR FURTHER INFORMATION CONTACT:**

Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-594-5640.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of January 18, 1994 (59 FR 2542), FDA proposed to amend the tamper-evident packaging requirements for OTC drug products in § 211.132 (21 CFR 211.132). This regulation, which is intended to protect consumers from malicious tampering with OTC drug products, was first codified in 1982 and amended in 1989.

The 1982 regulation (47 FR 50442, November 5, 1982) was issued in response to a tampering incident in the Chicago area in which seven people died after ingesting cyanide-laced Extra-Strength Tylenol capsules. The regulation required, among other things, that any OTC drug product (except a dermatologic, dentifrice, insulin, or lozenge product) for retail sale be packaged in a "tamper-resistant" package, so that a breach of the package would provide visible evidence to consumers that tampering had occurred. Although the risk of tampering was reduced significantly by this rule, the two-piece, hard gelatin capsule remained vulnerable to tampering. Three deaths in 1986 were associated with this dosage form. In response to the continued susceptibility of two-piece, hard gelatin capsules, FDA amended § 211.132 (54 FR 5227, February 2, 1989) to require that OTC drug products marketed in two-piece, hard gelatin capsules must be packaged using at least two tamper-resistant packaging features, or with at least one tamper-resistant packaging feature if a tamper-resistant capsule seal was employed.

Despite these regulations, two-piece, hard gelatin capsules have continued to be a target of malicious drug tampering. This dosage form was implicated in a February 1991 tragedy, resulting in two deaths, involving Sudafed capsules contaminated with cyanide. The Sudafed package and dosage form met FDA's tamper-resistant standards, and there were visible signs of tampering that were both numerous and conspicuous. Based on investigations and discussions surrounding the 1991 tampering fatalities, as well as FDA's ongoing review of the public health threat from OTC drug product tampering, the agency initiated this rulemaking to reduce the potential for tampering with vulnerable two-piece, hard gelatin capsules. The agency invited comments from the public not only with respect to the proposed amendments, but also on effective ways to educate consumers about OTC drug product tampering issues and steps