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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA-2015-0177; Special Conditions No. 25-579-SC]

Special Conditions: Cessna Aircraft Company Model 680A Airplane, Pilot-Compartment View Through Hydrophobic Windshield Coatings in Lieu of Windshield Wipers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions, request for comment.

SUMMARY: These special conditions are issued for the Cessna Model 680A airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is hydrophobic windshield coatings in lieu of windshield wipers. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: *Effective date:* This action is effective on Cessna Aircraft Company on April 6, 2015. We must receive your comments by May 21, 2015.

ADDRESSES: Send comments identified by docket number FAA-2015-0177 using any of the following methods:

- *Federal eRegulations Portal:* Go to <http://www.regulations.gov/> and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M-30, U.S. Department of

Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

Privacy: The FAA will post all comments it receives, without change, to <http://www.regulations.gov/>, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477-19478), as well as at <http://DocketsInfo.dot.gov/>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov/> at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Bob Hettman, ANM-112, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone (425) 227-2683; facsimile (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Background

On January 25, 2012, Cessna Aircraft Company applied for an amended type certificate for a new Model 680A airplane.

The Model 680A, a derivative of the Cessna Model 680 airplane currently approved under type-certificate number T00012WI, is intended to be a nine-passenger executive airplane with a maximum takeoff weight of 30,300 pounds and a maximum operating altitude of 45,000 feet. The Model 680A

airplane uses a hydrophobic windshield coating, in lieu of windshield wipers, for an unobstructed outside view from the pilot compartment.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Cessna Aircraft Company must show that the Model 680A airplane meets the applicable provisions of the regulations listed in type-certificate no. T00012WI, or the applicable regulations in effect on the date of application for the change except for earlier amendments as agreed upon by the FAA. The regulations listed in the type certificate are commonly referred to as the "original type-certification basis."

The certification basis includes certain special conditions, exemptions, or later amended sections of the applicable part that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model 680A airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same or similar novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model 680A airplane must comply with the fuel-vent and exhaust-emission requirements of part 34, and the noise-certification requirements of part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Features

The Cessna Model 680A airplane will incorporate the following novel or unusual design features:

The airplane flight-deck design incorporates a hydrophobic windshield coating that, during precipitation, provides an adequate outside view from the pilot compartment. Sole reliance on such a coating, without windshield wipers, constitutes a novel or unusual design feature for which the applicable airworthiness regulations do not contain adequate or appropriate safety standards. Therefore, special conditions are required to provide a level of safety equivalent to that established by the regulations.

Discussion

Section 25.773(b)(1) requires a means to maintain a clear portion of the windshield for both pilots of a transport-category airplane to have a sufficiently extensive view along the flight path during precipitation conditions. The regulations require this means to maintain such an area clear vision during heavy-rain precipitation at airplane speeds up to 1.5 V_{SR1} .

This requirement has existed in principle since 1953 in part 4b of the "Civil Air Regulations" (CAR). Section 4b.351(b)(1) of CAR 4b required that "Means shall be provided for maintaining a sufficient portion of the windshield clear so that both pilots are afforded a sufficiently extensive view along the flight path in all normal flight attitudes of the airplane. Such means shall be designed to function under the following conditions without continuous attention on the part of the crew: (i) In heavy rain at speeds up to 1.6 V_{S1} , flaps retracted."

Effective December 26, 2002, Amendment 25-108 changed the speed for effectiveness of the means to maintain an area of clear vision from up to 1.6 V_{S1} to 1.5 V_{SR1} to accommodate the redefinition of the reference stall speed from the minimum speed in the stall, V_{S1} , to greater than or equal to the 1g stall speed, V_{SR1} . As noted in the preamble to the final rule for that amendment, the reduced factor of 1.5 on V_{SR1} is to maintain approximately the same speed as the 1.6 factor on V_{S1} .

The requirement that the means to maintain a clear area of forward vision must function at high speeds and high precipitation rates is based on the use of windshield wipers as the means to maintain an adequate area of clear vision in precipitation conditions. The requirement in 14 CFR 121.313(b) and 125.213(b) to provide "a windshield wiper or equivalent for each pilot station" has remained unchanged since at least 1953.

The effectiveness of windshield wipers to maintain an area of clear vision normally degrades as airspeed

and precipitation rates increase. It is assumed that because high speeds and high precipitation rates represent limiting conditions for windshield wipers, they will also be effective at lower speeds and precipitation levels. Accordingly, § 25.773(b)(1)(i) does not require maintenance of a clear area of forward vision at lower speeds or lower precipitation rates.

A forced airflow blown directly over the windshield has also been used to maintain an area of clear vision in precipitation. The limiting conditions for this technology are comparable to those for windshield wipers. Accordingly, introduction of this technology did not present a need for special conditions to maintain the level of safety embodied in the existing regulations.

Hydrophobic windshield coatings may depend to some degree on airflow to maintain a clear-vision area. The heavy rain and high speed conditions specified in the current rule do not necessarily represent the limiting condition for this new technology. For example, airflow over the windshield, which may be necessary to remove moisture from the windshield, may not be adequate to maintain a sufficiently clear-vision area of the windshield in low-speed flight or during surface operations. Alternatively, airflow over the windshield may be disturbed during such critical times as the approach to land, where the airplane is at a higher-than-normal pitch attitude. In these cases, areas of airflow disturbance or separation on the windshield could cause failure to maintain a clear-vision area on the windshield.

In addition to potentially depending on airflow to function effectively, hydrophobic coatings may also be dependent on water-droplet size for effective precipitation removal. For example, precipitation in the form of a light mist may not be sufficient for the coating's properties to result in maintaining a clear area of vision.

The current regulations identify speed and precipitation rate requirements that represent limiting conditions for windshield wipers and blowers, but not for hydrophobic coatings. Likewise, it is necessary to issue special conditions to maintain the level of safety represented by the current regulations.

These special conditions provide an appropriate safety standard for the hydrophobic coating technology as the means to maintain a clear area of vision by requiring the coating to be effective at low speeds and low precipitation rates, as well as at the higher speeds and precipitation rates identified in the current regulation. These are the only

new or changed requirements relative to those in § 25.773(b)(1) at Amendment 25-108.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Cessna Model 680A airplane. Should Cessna apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Cessna Model 680A airplane. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type-certification basis for Cessna Model 680A airplanes.

The airplane must have a means to maintain a clear portion of the windshield, during precipitation conditions, enough for both pilots to have a sufficiently extensive view along

the ground or flight path in normal taxi and flight attitudes of the airplane. This means must be designed to function, without continuous attention on the part of the flightcrew, in conditions from light misting precipitation to heavy rain, at speeds from fully stopped in still air, to 1.5 V_{SR1} with lift and drag devices retracted.

Issued in Renton, Washington, on March 27, 2015.

Michael Kazyski,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-07713 Filed 4-3-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2009-N-0443]

Advisory Committee; Anti-Infective Drugs Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name of the Anti-Infective Drugs Advisory Committee. This action is being taken to change the name of this committee on the Agency's list of standing advisory committees.

DATES: This rule is effective April 6, 2015. The name change became applicable March 4, 2015.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, FAX: 301-847-8640, or *Michael.Ortwerth@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Anti-Infective Drugs Advisory Committee (the Committee) was established on October 7, 1980 (45 FR 79025). The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

The Committee name has been changed to the following: Antimicrobial Drugs Advisory Committee. The Agency changed the name to better reflect the

products and issues that will be brought to the committee. The change became effective March 4, 2015.

Therefore, the Agency is amending 21 CFR 14.100(c) as set forth in the regulatory text of this document.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely removes the name of the Anti-Infective Drugs Advisory Committee from the list of standing advisory committees in 21 CFR 14.100 and replaces it with the Antimicrobial Drugs Advisory Committee.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451-1461; 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155; Pub. L. 113-54.

■ 2. Amend § 14.100 by revising paragraph (c)(2) introductory text to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(2) *Antimicrobial Drugs Advisory Committee.*

* * * * *

Dated: March 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07789 Filed 4-3-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2015-N-0804]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Urethral Insert With Pump for Bladder Drainage

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the urethral insert with pump for bladder drainage into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the urethral insert with pump for bladder drainage's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective April 6, 2015. The classification was applicable on October 14, 2014.

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G210, Silver Spring, MD 20993-0002, 301-796-6549.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.