have provided fraudulent representation and are subject to § 636.13.

PART 1415—GRASSLANDS RESERVE PROGRAM

5. The authority citation for part 1415 continues to read as follows:

6. Section 1415.6 is amended by revising paragraphs (c) and (d) and removing paragraph (e).

The revisions read as follows:

§ 1415.6 Participant eligibility.
   * * * * *
   (c) Meet the Adjusted Gross Income requirements in part 1440 of this chapter, unless exempted under part 1440 of this chapter; and
   (d) Meet the conservation compliance requirements found in part 12 of this title.
   * * * * *

PART 1465—AGRICULTURAL MANAGEMENT ASSISTANCE

7. The authority citation for part 1465 continues to read as follows:
   Authority: 7 U.S.C. 1524(b).

8. Section 1465.5 is amended by revising paragraphs (c)(10) and (11) and removing paragraph (c)(12).

The revisions read as follows:

§ 1465.5 Program requirements.
   * * * * *
   (c) * * *
   (10) Be in compliance with the terms of all other USDA-administered conservation program agreements to which the participant is a party; and
   (11) Develop and agree to comply with an APO and O&K agreement, as described in § 1465.3.
   * * * * *

PART 1466—ENVIRONMENTAL QUALITY INCENTIVES PROGRAM

9. The authority citation for part 1466 continues to read as follows:

10. Section 1466.6 is amended by:

The revisions read as follows:

§ 1466.6 Program requirements.
   * * * * *
   (b) * * *
   (6) Supply information, as required by NRCS, to determine eligibility for the program, including but not limited to, information to verify the applicant’s status as a limited resource, beginning farmer or rancher, and payment eligibility as established by 7 CFR part 1400; and
   (7) Provide a list of all members of the legal entity and embedded entities along with members’ tax identification numbers and percentage interest in the entity.
   * * * * *

PART 1468—AGRICULTURAL CONSERVATION EASEMENT PROGRAM

11. The authority citation for part 1468 continues to read as follows:

§ 1468.30 [Amended]
12. Section 1468.30 is amended by:
   a. Removing paragraph (c)(3);
   b. Redesignating the second paragraph (c)(4) as paragraph (c)(5); and
   c. Redesigning paragraphs (c)(4) and newly redesignated (c)(5) as paragraphs (c)(3) and (4), respectively.

The revisions read as follows:

§ 1468.30 Eligibility requirements.
   * * * * *
   (5) Supply information, as required by NRCS, to determine eligibility for the program, including but not limited to, information related to eligibility requirements and ranking factors; conservation activity and production system records; information to verify the applicant’s status as a historically underserved producer or a veteran farmer or rancher, if applicable; and payment eligibility as established by 7 CFR part 1400; and
   (6) Provide a list of all members of the legal entity or joint operation, as applicable, and embedded entities along with members’ tax identification numbers and percentage interest in the legal entity or joint operation. Where applicable; American Indians, Alaska Natives, and Pacific Islanders may use another unique identification number for each individual eligible for payments.
   * * * * *

Signed in Washington, DC, on May 14, 2018.

Leonard Jordan,
Vice President, Commodity Credit Corporation, Acting Chief, Natural Resources Conservation Service.

[FR Doc. 2018–10641 Filed 5–17–18; 8:45 am]
BILLING CODE 3410–16–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2017–0636; Special Conditions No. 25–726–SC]

Special Conditions: The Boeing Company Model 777–8 and 777–9 Airplanes; Folding Wingtips

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for The Boeing Company (Boeing) Model 777–8 and 777–9 airplanes. These airplanes 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 folding wingtips. 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 June 18, 2018.


SUPPLEMENTARY INFORMATION:

Background

On April 19, 2017 (for the Model 777–8 airplane), and May 12, 2015 (for the Model 777–9 airplane), Boeing applied for an amendment to Type Certificate (TC) No. T00001SE to include the new Model 777–8 and 777–9 airplanes. These airplanes are constructed with new carbon-fiber-reinforced plastic (CFRP) wings with folding wingtips.

Federal Register / Vol. 83, No. 97 / Friday, May 18, 2018 / Rules and Regulations 23209
The Model 777–9 airplane, a derivative of the Model 777–300ER airplane currently approved under TC No. T00001SE, is a stretched-fuselage, large, twin-engine airplane with seating for 408 passengers and a maximum takeoff weight of 775,000 pounds. The Model 777–8 airplane, a shortened-body derivative of the Model 777–9 airplane, is a large, twin-engine airplane with seating for 359 passengers and a maximum takeoff weight of 775,000 pounds.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Boeing must show that the Model 777–8 and 777–9 airplanes meet the applicable provisions of the regulations listed in TC No. T00001SE, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA. 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 777–8 and 777–9 airplanes 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 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 777–8 and 777–9 airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR 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 Boeing Model 777–8 and 777–9 airplanes will incorporate the following novel or unusual design features: CFRP wings with folding wingtips. Boeing will incorporate this on-ground wingtip-fold capability to reduce the wingspan from 235 to 212 feet when folded. These folding wingtips comply with Code E gate compatibility when folded during ground operations.

Discussion

Boeing will add folding wingtips to their Model 777–8 and 777–9 airplane wings to maintain Code E gate compatibility when folded during ground operations. This wing-folding feature will be operable on the ground only. Boeing has no plan to carry fuel in the folding sections of the wings. Boeing has determined that a catastrophic event could occur if the Model 777–8 and 777–9 airplane wingtips are not properly positioned and secured for takeoff and during flight. In service, numerous takeoff operations with improper airplane configurations have occurred due to failures of the takeoff warning systems, or inadvertent crew actions. For these special conditions, a parallel is drawn between taking off with gust locks engaged and taking off with the wingtips folded, as either condition could result in a catastrophic event. Consequently, the FAA has determined that the level of safety in protecting a misconfigured airplane from takeoff with wingtips folded should be the same as taking off with the gust locks engaged. Therefore, condition 2 of these special conditions has the same intent as § 25.679(a)(2). Per § 25.1309, the applicant must show that such an event is extremely improbable, must not result from a single failure, and that appropriate alerting must be provided for the crew to manage unsafe system-operating conditions. In addition, the applicant must ensure that the wingtips are properly secured during ground operations to protect ground personnel against bodily injury.

Factors to be considered when showing compliance to these special conditions include, but are not limited to:

- With wingtips in the folded position, the conventional airplane-wingtip-position lights may have reduced visibility due to the upward position of the wingtips, possibly impacting ground-operation safety. Light placement may require special consideration to retain the current ground-operation safety, and mitigate any adverse impact this light position may have on pilot visibility during night-lighting conditions.
- Due to upward wingtip positioning on the ground, significant loads may be imposed by wind gusts combined with taxi speed during the transition from the unfolded to the folded position.
- The FAA issued Policy Statement No. PS–ANM–25–12, “Certification of Structural Elements in Flight Control Systems,” to address structural elements in systems that act as both structure and as part of a system. This policy provides additional guidance on the appropriate application of the fatigue and damage-tolerance requirements of § 25.571, and the system-safety requirements of §§ 25.671 and 25.1309.

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.

Discussion of Comments

Notice of Proposed Special Conditions No. 25–17–02–SC for the Boeing Model 777–8 and 777–9 airplanes was published in the Federal Register on November 1, 2017 (82 FR 50581). The FAA received responses from four commenters.

Commenter 1: Air Line Pilots Association (ALPA)

ALPA stated that the special conditions should require demonstration of ground-handling effects due to the folding wingtips, and implementing a robust flight-test procedure to evaluate the effects of the folding wingtips during landing rollout and taxi under high crosswind and gust conditions, to ensure no exceptional piloting skill is required during these operations. ALPA also suggests including, within the Boeing Model 777 series airplane flight manual, the crosswind conditions under which the folding wingtips were studied.

The FAA notes that demonstration of acceptable handling qualities is required by special condition 5 as written. The method of compliance demonstration, and associated documentation, is outside the scope of these special conditions, and the special conditions remain adopted as proposed.

Commenter 2

One commenter suggested various means for the applicant to address the special conditions, for example, the need for additional power cut outs that are separate circuits. The FAA partially agrees with the commenter, noting that special conditions are performance standards that may be satisfied by various means, including those the commenter proposed. However, the method of compliance demonstration is outside the scope of these special
conditions. Therefore, the special conditions remain adopted as proposed.

**Commenter 3**

One commenter expressed concern that the special conditions may be confusing to the United States Congress. The FAA responds that special conditions are part of the Executive Branch rulemaking process, which is independent of the United States Congress lawmaking process. Special conditions are unique to aircraft certification and, therefore, are written with the aerospace-industry audience in mind. The special conditions remain adopted as proposed.

**Commenter 4**

One commenter stated concern over the applicability of these special conditions to future models on the Boeing Model 777 airplane type certificate. Should Boeing apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well. The FAA responds that these special conditions provide requirements for a safe design for folding wingtips on future Model 777 airplane derivatives, as well as on the current Model 777 airplanes. These special conditions will ensure that future models incorporating the same novel or unusual design feature meet the level of safety equivalent to that established in the regulations.

The commenter suggested that the 1.25 factor specified in § 25.415(d) be applied to the portion of the system that is isolated in-flight, and is not critical for safe flight and landing. The FAA disagrees with the comment. The structure the commenter addressed has no impact on safety of flight. Additionally, the special conditions require that the wingtips must have a means by which to safeguard against unlocking from the extended, flight-deployed position in-flight because of failures, including the failure of any single structural element. The special conditions remain adopted as proposed.

The commenter suggested that the airplane must demonstrate acceptable handling qualities under normal and asymmetric operation. The special conditions remain adopted as proposed.

The FAA responded that the FAA repeat the § 25.675 text in special condition 6, in lieu of only referencing § 25.675 in the special condition. The FAA finds that the special condition has the same legal effect either way, and finds no advantage to repeating the text of § 25.675 in special condition 6.

**Applicability**

As discussed above, these special conditions are applicable to Boeing Model 777–8 and 777–9 airplanes. Should Boeing apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

**Conclusion**

This action affects only a certain novel or unusual design feature on one model series of airplanes. It is not a rule of general applicability.

**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 Boeing Model 777–8 and 777–9 airplanes.

**Note:** The term “latch” refers to the mechanism that allows the wingtip to carry flight loads in the down (flight-deployed) position. The term “lock” refers to the mechanism that prevents disconnection of the latch when the wing tip is down.

1. More than one means must be available to alert the flightcrew when a wingtip is in the folded position during taxi. The term “lock” must be used to refer to the mechanism that prevents disconnection of the latch when the wing tip is down.

2. In addition to a takeoff warning in § 25.1529, the latch must be unique in their wingtip-monitoring function. When meeting this condition, the applicant must add a function to the takeoff warning system, as required by § 25.703(a)(1) and (2), to warn of an unlocked or improperly positioned wingtip, including indication to the flightcrew when a wingtip is in the folded position during taxi.

3. The applicant must consider the effects of folding-wingtip freeplay when evaluating compliance to the design load requirements of 14 CFR part 25, subpart C, and the aeroelastic stability (including flutter, divergence, control reversal, and any undue loss of stability and control as a result of structural deformation) requirements of § 25.629. Thus, the effects of normal wear, and other long-term durability conditions (such as corrosion) of the folding-wingtip operating mechanism on freeplay, and its impact on loads and aeroelastic stability, must be considered.

Where freeplay limitations are required to ensure aeroelastic stability, acceptable freeplay limits and freeplay check procedures must be established. If lubrication is required to control excessive wear, lubrication intervals must be established. These procedures and limitations must be documented in accordance with § 25.1529. The freeplay-check and mechanism-lubrication intervals, if required, must be documented as a certification maintenance requirement (CMR). Guidance for CMRs can be found in Advisory Circular 25–19A, “Certification Maintenance Requirements.” The effects of freeplay on wing-joint torsional and bending stiffness, as well as wing frequencies, must be evaluated when showing compliance to loads and aeroelastic stability requirements. Also, the effects of freeplay on fatigue and damage tolerance must be considered when showing compliance with § 25.571.

4. The folding wingtips and their operating mechanism must be designed for 65 knot, horizontal, ground-gust conditions in any direction as specified in § 25.415(a). Relevant design conditions must be defined using combinations of steady wind and taxi speeds determined by rational analysis utilizing airport wind data. The folding wingtip is not a control surface as specified in § 25.415(b). Therefore, in lieu of the equation provided in § 25.415(b), the hinge moment may be calculated from rational wind-tunnel data. The 1.25 factor specified in § 25.415(d) need not be applied to the portion of the system that is isolated in-flight and is not critical for safe flight and landing. The folding-wingtip system must be designed for the conditions specified in § 25.415(e), (f), and (g). Runway roughness, as specified in § 25.491, must be evaluated separately up to the maximum relevant airplane ground speeds. All of the above conditions must be applied to the folding wingtips in the extended (flight-
to position the lock in the locked position if the latches and the latching mechanisms are not in the latched position, and it must not be possible to unlatch the latches with the locks in the locked position.

Issued in Des Moines, Washington, on May 11, 2018.

Victor Wicklund,
Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–10576 Filed 5–17–18; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 864
[Docket No. FDA–2016–N–0406]

Medical Devices; Hematology and Pathology Devices; Classification of Blood Establishment Computer Software and Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule to classify blood establishment computer software (BECS) and BECS accessories (regulated under product code MMH) into class II (special controls). FDA has identified special controls for BECS and BECS accessories that are necessary to provide a reasonable assurance of safety and effectiveness. FDA is also giving notice that the Agency does not intend to exempt BECS and BECS accessories from premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This rule is effective June 18, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jessica Walker Udechukwu, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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I. Executive Summary

A. Purpose of the Final Rule

FDA is classifying BECS and BECS accessories into class II (special controls). The Agency believes that the special controls established and imposed by this final rule, together with the general controls, will provide reasonable assurance of the safety and effectiveness of these devices. In this final rule, FDA is also revising the definition of BECS accessories from the definition in the proposed rule and responding to comments received on the proposed rule. Lastly, FDA is giving notice that the Agency does not intend to exempt BECS and BECS accessories from the premarket notification requirements of the FD&C Act.

B. Summary of the Major Provisions of the Final Rule

In this final rule, FDA is classifying BECS and BECS accessories into class II (special controls). This rule creates § 864.9165 in 21 CFR part 864, subpart J, to include the identification and classification of BECS and BECS accessories. The classification of BECS and BECS accessories is consistent with the FDA Blood Product Advisory Committee (BPAC) recommendation that the devices be classified as class II (special controls) devices with premarket review.

C. Legal Authority

We are issuing this final rule under section 513(a)(1)(B) of the FD&C Act (21 U.S.C. 360c(a)(1)(B)). FDA has the authority under this provision of the FD&C Act to issue a regulation to establish special controls for class II