

Given the stringent requirements for fuel-tank flammability, the fuel-vapor ignition prevention, and the ignition-source prevention requirements in these special conditions will prevent “. . . catastrophic failure . . . due to ignition of fuel or vapors,” as stated in § 25.981(a). Thus, the overall level of safety achieved by these special conditions is considered equivalent to that which would be required by compliance with § 25.981(a)(3) and (b).

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. 25–13–36–SC for Airbus Model A350–900 series airplanes was published in the **Federal Register** on December 19, 2013 (78 FR 76775). No comments were received, and the special conditions are adopted as proposed.

Applicability

As discussed above, these special conditions apply to Airbus Model A350–900 series airplanes. Should Airbus apply later 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 Airbus Model A350–900 series 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 Airbus Model A350–900 series airplanes.

1. Definitions

Most of the terms used in the special conditions described in Alternative Fuel Tank Structural Lightning Protection Requirements either have the common dictionary meaning or are defined in Advisory Circular 25.1309–1A, *System*

Design and Analysis, dated June 21, 1988.

The following definitions are the only terms intended to have a specialized meaning when used in these special conditions:

(a) *Basic Airframe Structure*. Includes design elements such as structural members, structural joint features, and fastener systems including airplane skins, ribs, spars, stringers, etc., and associated fasteners, joints, coatings, and sealant. Basic airframe structure may also include those structural elements that are expected to be removed for maintenance, such as exterior fuel-tank access panels and fairing-attachment features, provided maintenance errors that could compromise associated lightning-protection features would be evident upon an exterior, preflight inspection of the airplane and would be corrected prior to flight.

(b) *Permanent System-Supporting Structure*. Includes static, permanently attached structural parts (such as brackets) that are used to support system elements. It does not include any part intended to be removed, or any joint intended to be separated, to maintain or replace system elements or other parts, unless that part removal or joint separation is accepted by the FAA as being extremely remote.

(c) *Manufacturing Variability*. Includes tolerances and variability that the design and production specifications allow, as well as anticipated errors or escapes from the manufacturing and inspection processes.

(d) *Extremely Remote*. Conditions that are not anticipated to occur to each airplane during its total life, but which may occur a few times when considering the total operational life of all airplanes of one type. Extremely remote conditions are those having an average probability per flight hour on the order of 1×10^{-7} or less, but greater than on the order of 1×10^{-9} .

(e) *Extremely Improbable*. Conditions that are so unlikely that they are not anticipated to occur during the entire operational life of all airplanes of one type. Extremely improbable conditions are those having an average probability per flight hour of the order of 1×10^{-9} or less.

2. Alternative Fuel-Tank Structural Lightning-Protection Requirements

For lightning-protection features that are integral to fuel-tank basic airframe structure or permanent system-supporting structure, as defined in this these special conditions Definitions, for which Airbus shows and the FAA finds

compliance with § 25.981(a)(3) to be impractical, the following requirements may be applied in lieu of the requirements of § 25.981(a)(3):

(a) Airbus must show that the airplane design meets the requirements of part 25, Appendix M, as amended by Amendment 25–125, for all fuel tanks installed on the airplane.

(b) Airbus must show that the design includes at least two independent, effective, and reliable lightning-protection features (or sets of features) such that fault tolerance to prevent lightning-related ignition sources is provided for each area of the structural design to be shown compliant with these special conditions in lieu of compliance with the requirements of § 25.981(a)(3). Fault tolerance is not required for any specific design feature if:

(1) For that feature, providing fault tolerance is shown to be impractical, and

(2) Fuel-tank vapor ignition due to that feature and all other non-fault-tolerant features, when their fuel-tank vapor-ignition event probabilities are summed, is shown to be extremely improbable.

(c) Airbus must perform an analysis to show that the design, manufacturing processes, and airworthiness limitations section of the instructions for continued airworthiness include all practical measures to prevent, and detect and correct, failures of structural lightning-protection features due to manufacturing variability, aging, wear, corrosion, and likely damage.

Issued in Renton, Washington, on August 15, 2014.

Jeffrey E. Duven,

Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–21245 Filed 9–5–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 314, 329, and 600

[Docket No. FDA–2008–N–0334]

RIN 0910–AF96

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled “Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements” that appeared in the **Federal Register** of June 10, 2014 (79 FR 33072). The document amended FDA’s postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. The document was published with an incorrect RIN number. This document corrects the error.

DATES: *Effective date:* September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993-0002, 301-796-1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2014, in FR Doc. 2014-13480, the following correction is made:

1. On page 33073, in the third column, the RIN number heading is corrected to read “RIN 0910-AF96”.

Dated: September 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21266 Filed 9-5-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310, 314, 329, and 600

[Docket No. FDA-2008-N-0334]

RIN 0910-AF96

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Corrections

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; corrections.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document entitled “Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Correction” that appeared in the **Federal Register** of August 14, 2014 (79 FR 47655). The document published without the required RIN number and in the Notice category. This document corrects those errors.

DATES: *Effective Date:* September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993-0002, 301-796-1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 2014, in FR Doc. 2014-19255, the following correction is made:

1. On page 47655, in the first column, add the heading “RIN 0910-AF96” between the Docket No. and the title of the document.

Dated: September 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21267 Filed 9-5-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 558

[Docket No. FDA-2014-N-0002]

New Animal Drugs; Buprenorphine; Carprofen; Danofloxacin; Follicle Stimulating Hormone; Ractopamine; Salinomycin; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July 2014. FDA is

also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to add a cross reference to a tolerance.

DATES: This rule is effective September 8, 2014.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July 2014, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine (CVM) FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

Also, the animal drug regulations are being amended in 21 CFR 522.955 to add a cross reference to a tolerance for an inactive vehicle in an injectable dosage form product. This amendment is being made to improve the accuracy of the regulations.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.