

(1) Where EASA AD 2019-0206 refers to February 21, 2018, this AD requires using the effective date of this AD.

(2) The "Remarks" section of EASA AD 2019-0206 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2019-0206 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3218; email kathleen.arrigotti@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2019-0206, dated August 20, 2019.

(ii) [Reserved]

(3) For information about EASA AD 2019-0206, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email ADs@easa.europa.eu; Internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) You may view this material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0723.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on January 10, 2020.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2020-01044 Filed 1-23-20; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2019-0722; Product Identifier 2019-NM-141-AD; Amendment 39-19820; AD 2020-01-14]

RIN 2120-AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A300 series airplanes. This AD was prompted by a report that indicated that bleed and air conditioning systems were contaminated by hydraulic fluid, and by an investigation that revealed that hydraulic fluid contaminations caused the failure of check valves installed on the hydraulic reservoir air pressurization system. This AD requires repetitive functional tests of the hydraulic reservoir air pressurization lines, and repair or replacement if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 28, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 28, 2020.

ADDRESSES: For the material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this IBR material on the EASA website at <https://ad.easa.europa.eu>. You may view this IBR material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. It is also available in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0722.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0722; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3225; email Dan.Rodina@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019-0190, dated July 31, 2019 ("EASA AD 2019-0190") (also referred to as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for all Airbus SAS Model A300 series airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A300 series airplanes. The NPRM published in the **Federal Register** on October 28,

2019 (84 FR 57663). The NPRM was prompted by a report that indicated that bleed and air conditioning systems were contaminated by hydraulic fluid, and by an investigation that revealed that hydraulic fluid contaminations caused the failure of check valves installed on the hydraulic reservoir air pressurization system. The NPRM proposed to require repetitive functional tests of the hydraulic reservoir air pressurization lines, and repair or replacement if necessary.

The FAA is issuing this AD to address bleed and air conditioning systems contaminated by hydraulic fluid, which, if not detected and corrected, could lead to leakage of pressurization check valves, and, in case of pressurization line rupture, to loss of a hydraulic system, possibly resulting in reduced

control of the airplane. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. We have considered the comment received. The Air Line Pilots Association, International (ALPA) stated that it supports NPRM.

Conclusion

The FAA reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and

- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related IBR Material Under 1 CFR Part 51

EASA AD 2019-0190 describes procedures for repetitive functional tests of the hydraulic reservoir air pressurization lines, and repair or replacement if necessary. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 1 airplane of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × \$85 per hour = \$170	\$0	\$170	\$170

* Table does not include estimated costs for reporting.

The FAA estimates that it would take about 1 work-hour per product to comply with the reporting requirement in this AD. The average labor rate is \$85 per hour. Based on these figures, the

FAA estimates the cost of reporting the inspection results on U.S. operators to be \$85.

The FAA estimates the following costs to do any necessary on-condition

actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
3 work-hours × \$85 per hour = \$255	\$10,000	\$10,255

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120-0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to Information

Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds

necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, 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.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2020-01-14 Airbus SAS: Amendment 39-19820; Docket No. FAA-2019-0722; Product Identifier 2019-NM-141-AD.

(a) Effective Date

This AD is effective February 28, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A300 B2-1A, B2-1C, B2K-3C, B2-203, B4-2C, B4-103, and B4-203 airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic power.

(e) Reason

This AD was prompted by a report that bleed and air conditioning systems were contaminated by hydraulic fluid, and an investigation revealed that hydraulic fluid contaminations caused the failure of check

valves installed on the hydraulic reservoir air pressurization system. The FAA is issuing this AD to address this condition, which, if not detected and corrected, could lead to leakage of the pressurization check valves, and, in case of pressurization line rupture, to loss of a hydraulic system, possibly resulting in reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2019-0190, dated July 31, 2019 (“EASA AD 2019-0190”).

(h) Exceptions to EASA AD 2019-0190

(1) Where EASA AD 2019-0190 refers to its effective date, this AD requires using the effective date of this AD.

(2) The “Remarks” section of EASA AD 2019-0190 does not apply to this AD.

(3) Paragraph (4) of EASA AD 2019-0190 specifies to report accomplishment of each test and any repair or replacement to Airbus within a certain compliance time. For this AD, report that action at the applicable time specified in paragraph (h)(3)(i) or (ii) of this AD.

(i) If the action was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the action was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2019-0190 that contains RC procedures and

tests: Except as required by paragraph (i)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(4) Paperwork Reduction Act Burden Statement:

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory as required by this AD; the nature and extent of confidentiality to be provided, if any. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177-1524.

(j) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206-231-3225; email Dan.Rodina@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2019-0190, dated July 31, 2019.

(ii) [Reserved]

(3) For information about EASA AD 2019-0190, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) You may view this material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the

FAA, call 206-231-3195. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0722.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on January 14, 2020.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2020-01043 Filed 1-23-20; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, 556, and 558

[Docket No. FDA-2019-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsor; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July, August, and September 2019. FDA is 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 make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective January 24, 2020, except for amendatory instruction number 3 to 21 CFR 510.600, number 8 to 21 CFR 520.1807, number 21 to 21 CFR 529.1115, and number 24 to 21 CFR 556.513, which are effective February 3, 2020.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2019, 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 office of the Dockets Management Staff (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 CVM FOIA Electronic Reading Room: <https://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: <https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2019

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 1, 2019 ...	200-639	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	MONOVET (monensin) Type A Medicated Article.	Cattle and goats.	Original approval as a generic copy of NADA 095-735.	FOI Summary.
July 2, 2019 ...	141-519	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	PROHEART 12 (moxidectin) for Extended-Release Injectable Suspension.	Dogs	Original approval for prevention of heartworm disease caused by <i>Dirofilaria immitis</i> for 12 months in dogs 12 months of age and older; and for treatment of existing larval and adult hookworm (<i>Ancylostoma caninum</i> and <i>Uncinaria stenocephala</i>) infections.	FOI Summary.
July 5, 2019 ...	113-645	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	ESTRUMATE (cloprostrenol injection) ...	Cattle	Supplemental approval for synchronization of estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows.	FOI Summary.
July 26, 2019	141-255	Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248.	35% PEROX-AID (hydrogen peroxide) Concentrated Immersion Solution.	Finfish	Supplemental approval for the control of mortality in freshwater-reared coldwater finfish, fingerling and adult freshwater-reared coolwater finfish, and fingerling and adult freshwater-reared warmwater finfish due to saprolegniasis associated with fungi in the family Saprolegniaceae; for the treatment and control of <i>Gyrodactylus</i> spp. in freshwater-reared salmonids; and for the control of mortality in freshwater-reared warmwater finfish due to external columnaris associated with <i>Flavobacterium columnare</i> .	FOI Summary.
August 27, 2019.	141-465	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	Avilamycin and monensin Type C medicated feeds.	Chickens	Supplemental approval of a revised age restriction caution statement for broiler feeds.	FOI Summary.
August 27, 2019.	141-467	Do.	Avilamycin and narasin Type C medicated feeds.	Chickens	Supplemental approval of a revised age restriction caution statement for broiler feeds.	FOI Summary.