Issued in Des Moines, Washington, on December 6, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–27130 Filed 12–14–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0805; Product Identifier 2018–NM–103–AD; Amendment 39–19527; AD 2018–25–16]

RIN 2120–AA64

Airworthiness Directives; Airbus Defense and Space S.A. (Formerly Known as Construcciones Aeronauticas, S.A.) Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Defense and Space S.A. Model CN–235, CN–235–200 and CN–235–300 airplanes. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD requires revising the maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 22, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 22, 2019.

ADDRESSES: For service information identified in this final rule, contact Airbus Defense and Space, Services/Engineering Support, Avenida de Aragón 404, 28022 Madrid, Spain; telephone +34 91 585 55 84; fax +34 91 585 31 27; email *MTA.TechnicalService@airbus.com.* You may view this service information 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 on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0805.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0805; 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 (phone: 800–647–5527) 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: Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Defense and Space S.A. Model CN–235, CN–235–200 and CN–235–300 airplanes. The NPRM published in the **Federal Register** on October 9, 2018 (83 FR 50539). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The NPRM proposed to require revising the maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations.

We are issuing this AD to address fatigue cracking, damage, and corrosion in principal structural elements; such fatigue cracking, damage, and corrosion could result in reduced structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0134, dated June 25, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Defense and Space S.A. Model CN–235, CN–235–200, and CN–235–300 airplanes. The MCAI states:

> The airworthiness limitations and/or certification maintenance instructions for the EADS–CASA CN–235 aeroplanes, which are approved by EASA, are currently defined and published in the Airbus D&S CN–235 ALL [Airworthiness Limitations List] DT–86–3001 document. These instructions have been identified as mandatory for continued airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition [*i.e.,* fatigue cracking, damage, and corrosion in principal structural elements, which could result in reduced structural integrity of the airplane].
>
> For the reason described above, this [EASA] AD requires accomplishment of the actions specified in the ALL.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0805.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have 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 Service Information Under 1 CFR Part 51

Airbus Defence and Space has issued Technical Document DT–86–3001, CN–235 Airworthiness Limitations List, Issue R, dated March 20, 2018. This service information describes airworthiness limitations for airplane systems, structural inspections, safe life structural items, and safe life system items.

This service information 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

We estimate that this AD affects 9 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

We have determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), we

have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

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.

We are 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) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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):

2018–25–16 Airbus Defense and Space S.A. (Formerly Known as Construcciones Aeronauticas, S.A.): Amendment 39–19527; Docket No. FAA–2018–0805; Product Identifier 2018–NM–103–AD.

(a) Effective Date

This AD is effective January 22, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Defense and Space S.A. (formerly known as Construcciones Aeronauticas, S.A.) Model CN–235, CN–235–200, and CN–235–300 airplanes, all manufacturer serial numbers, certificated in any category, with an original certificate of airworthiness or original export certificate of airworthiness issued on or before March 20, 2018. This AD does not apply to Model CN–235–300 airplanes in a Maritime Patrol (SM01) configuration.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. We are issuing this AD to address fatigue cracking, damage, and corrosion in principal structural elements; such fatigue cracking, damage, and corrosion could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate the information specified in Airbus Defence and Space Technical Document DT–86–3001, CN–235 Airworthiness Limitations List, Issue R, dated March 20, 2018. The initial compliance times for doing the tasks are at the applicable times specified in Airbus Defence and Space Technical Document DT–86–3001, CN–235 Airworthiness Limitations List, Issue R, dated March 20, 2018, or within 90 days after the effective date of this AD, whichever occurs later.

(h) No Alternative Actions or Intervals

After accomplishment of the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals, may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) 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)(2) 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 corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus Defense and Space S.A.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0134, dated June 25, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0805.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220.

(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) Airbus Defence and Space Technical Document DT–86–3001, CN–235 Airworthiness Limitations List, Issue R, dated March 20, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus Defense and Space, Services/Engineering Support, Avenida de Aragón 404, 28022 Madrid, Spain; telephone: +34 91 585 55 84; fax: +34 91 585 31 27; email: *MTA.TechnicalService@airbus.com.*

(4) You may view this service information 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on November 29, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–26621 Filed 12–14–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–2017–C–2902]

Listing of Color Additives Subject to Certification; D&C Yellow No. 8; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of October 26, 2018, for the final rule that appeared in the **Federal Register** of September 25, 2018, and that amended the color additive regulations to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution.

DATES: The effective date of final rule published in the **Federal Register** of September 25, 2018 (83 FR 48373) is confirmed: October 26, 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: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1075.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 25, 2018 (83 FR 48373), we amended the color additive regulations to add § 74.3708, ''D&C Yellow No. 8,'' (21 CFR 74.3708) to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution.

We gave interested persons until October 25, 2018, to file objections or requests for a hearing. We explained that, to file an objection, among other things, persons must specify with particularity the provision(s) to which they object. We also explained that if a person who properly submits an objection wants a hearing, he or she must specifically request a hearing and that failure to do so will constitute a waiver of the right to a hearing (83 FR 48373 at 48375).

We received seven comments regarding our decision to amend the color additive regulations to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution. None of the comments, however, specified with particularity the provision(s) of the regulation to which they objected nor specifically requested a hearing. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of September 25, 2018, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the September 25, 2018, final rule. Accordingly, the amendments issued in the final rule became effective October 26, 2018.

Dated: December 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27234 Filed 12–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA-2013–N–1529]

RIN 0910–AH75

Medical Device Classification Procedures: Incorporating Food and Drug Administration Safety and Innovation Act Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations governing classification and reclassification of medical devices to conform to the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA is also making additional changes unrelated to the FDASIA requirements, to update its regulations governing the classification and reclassification of medical devices. FDA is taking this action to codify the procedures and criteria that apply to the classification and reclassification of medical devices and to provide for classification of devices in the lowest regulatory class consistent with the public health and the statutory scheme for device regulation.

DATES: This rule is effective March 18, 2019.

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For information concerning the final rule as it relates to devices regulated by the Center for Devices and Radiological Health (CDRH):* Ana Loloei, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002.

For information concerning the final rule as it relates to devices regulated by the Center for Biologics Evaluation and Research (CBER): Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire