DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0365; Product Identifier 2017–NM–155–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes), and Model A310 series airplanes. This proposed AD was prompted by a determination that more restrictive maintenance requirements and airworthiness limitations are necessary. This proposed AD would require revising the maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and airworthiness limitations. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 28, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.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.

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–2018–0365; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0365; Product Identifier 2017–NM–155–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2017–0203, dated October 12, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes), and Model A310 series airplanes. The MCAI states:

> Maintenance requirements and airworthiness limitations for the Airbus A310, A300–600 and A300–600ST family aeroplanes, which are approved by EASA, are currently defined and published in the Airbus A310 and A300–600 Airworthiness Limitations Section (ALS) documents. Certification Maintenance Requirements (CMR) for the Airbus A310 and A300–600, which are approved by EASA, are specified in the Airbus A310 and A300–600 (including A300–600ST) ALS Part 3 documents. These instructions have been identified as mandatory for continuing airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition.
>
> EASA previously issued [EASA] AD 2013–0072 [which corresponds to FAA AD 2015–08–06, Amendment 39–18142 (80 FR 23230, April 27, 2015) (''AD 2015–08–06'')] to require the implementation of the maintenance requirements and associated airworthiness limitations as specified in Airbus A310 and A300–600 ALS Part 3 documents at original issue.
>
> Since that [EASA] AD was issued, new or more restrictive maintenance requirements and airworthiness limitations were approved by EASA. Consequently, Airbus published Revision 01 of the A310 ALS Part 3 and A300–600 ALS Part 3, compiling all ALS Part 3 changes approved since original issue.
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> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2013–0072, which is superseded, and requires accomplishment of the actions specified in A310 ALS Part 3 Revision 01 and A300–600 ALS Part 3 Revision 01.

This NPRM would require revising the maintenance or inspection program to incorporate certain maintenance requirements and airworthiness limitations. We are issuing this AD to prevent safety-significant latent failures that would, in combination with one or more other specific failures or events, result in a hazardous or catastrophic failure condition of avionics, hydraulic systems, fire detection systems, fuel systems, or other critical systems. 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–2018–0365.

Relationship Between Proposed AD and AD 2015–08–06

This NPRM would not supersede AD 2015–08–06. Rather, we have determined that a stand-alone AD would be more appropriate to address the changes in the MCAI. This NPRM would require revising the maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance requirements and airworthiness limitations. Accomplishment of the proposed actions would then terminate all requirements of AD 2015–08–06.

Related Service Information Under 1 CFR Part 51

Airbus has issued A300–600 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance

Requirements (CMR), Revision 01, dated August 28, 2017, and A310 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 01, dated August 28, 2017. This service information describes mandatory maintenance tasks that operators must perform at specified intervals. These documents are distinct since they apply to different airplane models. 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.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

This proposed AD requires revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (j)(1) of this proposed AD. The request should include a description of changes to the required actions that will ensure the continued damage tolerance of the affected structure.

Costs of Compliance

We estimate that this proposed AD affects 127 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

We have determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although this figure 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 proposed 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 to the Director of the System Oversight Division.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 this proposed regulation:

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.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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):

Airbus: Docket No. FAA–2018–0365; Product Identifier 2017–NM–155–AD.

(a) Comments Due Date

We must receive comments by June 28, 2018.

(b) Affected ADs

This AD affects AD 2015–08–06, Amendment 39–18142 (80 FR 23230, April 27, 2015) (''AD 2015–08–06'').

(c) Applicability

This AD applies to all Airbus Model A300 B4–601, B4–603, B4–620, B4–622; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R and F4–622R airplanes; Model A300 C4–605R Variant F airplanes; and Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes; certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by a determination that more restrictive maintenance requirements and airworthiness limitations are necessary. We are issuing this AD to prevent safety-significant latent failures that would, in combination with one or more other specific failures or events, result in a hazardous or catastrophic failure condition of avionics, hydraulic systems, fire detection systems, fuel systems, or other critical systems.

(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 Airbus A300–600 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance

Requirements (CMR), Revision 01, dated August 28, 2017; or Airbus A310 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 01, dated August 28, 2017; as applicable. The initial compliance time for accomplishing the actions is at the applicable time specified in Airbus A300–600 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 01, dated August 28, 2017; or Airbus A310 Airworthiness Limitations Section (ALS) Part 3, Certification Maintenance Requirements (CMR), Revision 01, dated August 28, 2017; as applicable; 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 (j)(1) of this AD.

(i) Terminating Action

Accomplishing the actions required by paragraph (g) of this AD terminates all requirements of AD 2015–08–06.

(j) 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 (k)(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's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0203, dated October 12, 2017, 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–2018–0365.

(2) 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.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.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.

Issued in Des Moines, Washington, on April 27, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–09981 Filed 5–11–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 343

[Docket No. FDA–1977–N–0025]

Partial Withdrawal of Proposed Amendment to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of partial withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a partial withdrawal of a proposed rule published in the **Federal Register** of August 21, 2002 (2002 proposed rule). The proposed rule, if finalized, would have amended FDA's tentative final monograph (TFM) for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products to include ibuprofen as a generally recognized as safe and effective (GRASE) analgesic/antipyretic active ingredient for OTC use. FDA is withdrawing this proposed rule due to changes in our understanding of ibuprofen since FDA issued the proposed rule. FDA is not withdrawing those portions of the 2002 proposed rule to amend its regulations to include consistent pregnancy and allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients.

DATES: As of May 14, 2018, FDA withdraws the proposed additions to §§ 343.3 and 343.10, and proposed revisions to §§ 343.20 and 343.50 published on August 21, 2002 (67 FR 54139).

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 document 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: Kevin Lorick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5413, Silver Spring, MD 20993–0002, 301–796–6696, *Kevin.Lorick@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 16, 1988 (53 FR 46204), FDA published a proposed rule in the form of a TFM that proposed conditions under which OTC IAAA drug products would be generally recognized as safe and effective and not misbranded. On August 21, 2002 (67 FR 54139), FDA published a proposed rule that would have amended that TFM to include ibuprofen as a proposed GRASE analgesic/antipyretic active ingredient for OTC use. The 2002 proposed rule, if finalized, would have allowed manufacturers to market ibuprofen drug products for OTC use without submission of a new drug application (NDA), if all conditions of the monograph and other requirements were satisfied. At that time, ibuprofen drug products were marketed OTC under NDAs or abbreviated new drug applications (ANDAs) approved by FDA. This is still the case today—all ibuprofen drug products in the OTC marketplace are covered by NDAs or ANDAs. FDA is not aware of any ibuprofen drug products marketed under the TFM.

In the same 2002 proposed rule, the Agency proposed to update FDA regulations in 21 CFR part 201 to include consistent pregnancy and allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients. This proposal, if finalized, would update pregnancy, allergy, and asthma statements required in the labeling of certain IAAA products. FDA is not