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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–204–AD; Amendment 39–13617; AD 2004–09–27]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Mystere-Falcon 50 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Dassault Model Mystere-Falcon 50 series airplanes, that requires a one-time inspection for improper installation of the electrical wiring for the optional lighting in the cabin, and corrective actions if necessary. This action is necessary to find and fix improper installation of the electrical wiring of the basic/optional cabin lighting, which could result in overheating of the wiring and possible smoke/fire in the cabin during an emergency situation. This action is intended to address the identified unsafe condition.

DATES: Effective June 16, 2004.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 16, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives 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/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Dassault Model Mystere-Falcon 50 series airplanes was published in the **Federal Register** on January 9, 2004 (69 FR 1547). That action proposed to require a one-time inspection for improper installation of the electrical wiring for the optional lighting in the cabin, and corrective actions if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request To Add Revised Service Information

One commenter states that there is an error in the section of the proposed AD titled ''Explanation of Relevant Service Information,'' which references Dassault Service Bulletin F50–318, Revision 1, dated June 12, 2002. The commenter states that the correct reference should be Dassault Service Bulletin F50–318, Revision 2, dated January 15, 2003. The commenter also asks that Revision 2 be added to paragraph (a) of the proposed AD.

The FAA acknowledges the commenter's remarks. Since Revision 2 of the service bulletin was not issued until after the proposed AD was published, we referenced Revision 1 in the proposed AD. Revision 2 is essentially the same as Revision 1 of the referenced service bulletin. We have added references to Revision 2 to paragraphs (a) and (b) of this final rule as another source of service information for accomplishment of the specified actions.

Request To Change Description of Unsafe Condition

The same commenter states that, as written, the unsafe condition specified in the proposed AD is misleading. The unsafe condition states, ''This action is necessary to prevent overheating of optional lighting wiring that was improperly installed in the cabin, and consequent smoke/fire in the cabin.'' The commenter suggests that this wording be changed to read, ''This action is necessary to ensure the basic/optional cabin lighting routing and power supply conform to the certification rules.'' The commenter notes that this language is contained in the referenced service bulletin, and accomplishment of the service bulletin is intended to correct wiring that is installed directly to the batteries, instead of through a dedicated circuit breaker.

We acknowledge the commenter's concern regarding the description of the unsafe condition specified in the proposed AD. The description of the unsafe condition is based on the airworthiness directive issued by the Direction Générale de l'Aviation Civile, which is the airworthiness authority for France. The Discussion section of the proposed AD reads, ''The DGAC advises that due to incorrect routing, wiring for the optional lighting in the cabin may be directly connected to the direct power supply line of the battery bus instead of through a dedicated circuit breaker. In this configuration, an electrical current is generated even after the starter generators and batteries are switched off.'' Although the commenter found the description of the unsafe condition to be misleading, we do not find the commenter's suggested wording to be an adequate description of the effect on the airplane of incorrect routing of the subject wiring. However, we have provided further clarification of the unsafe condition in this final rule. We have changed the statement of the unsafe condition to read, ''This action is necessary to find and fix improper installation of the electrical wiring of the basic/optional cabin lighting, which could result in overheating of the wiring and possible smoke/fire in the cabin during an emergency situation.''

Request to Change Cost Impact Information

One commenter, Dassault Falcon Jet, states that the work hours listed in the proposed AD may be significantly increased if additional wiring alterations are done to the electrical circuit after airplane delivery. The commenter adds that the kits (parts) provided by the manufacturer at no charge were available only through March 2003.

We acknowledge the commenter's concerns; however, additional wiring alterations done to the electrical circuit after airplane delivery are outside the requirements of this AD, thus would not be included in the estimated work hours. In addition, we have been informed by the manufacturer (Dassault Aviation, France) that the kits provided at no charge are available for one year after the effective date of this AD.

Conclusion

After careful review of the available data, including the comments noted above, we have determined that air safety and the public interest require the adoption of the rule with the changes described previously. These changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

We estimate that 175 airplanes of U.S. registry will be affected by this AD.

It will take about 2 work hours per airplane to accomplish the required inspection at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the required inspection on U.S. operators is estimated to be $22,750, or $130 per airplane.

Should an operator have to modify the optional lighting wiring, it takes about 60 work hours at an average labor rate of $65 per work hour. Required parts would be provided by the manufacturer at no charge. Based on these figures, the cost impact of the modification is estimated to be $3,900 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding the following new airworthiness directive:

2004–09–27 Dassault Aviation: Amendment 39–13617. Docket 2002–NM–204–AD.

Applicability: Model Mystere-Falcon 50 series airplanes having serial numbers 2 through 270 inclusive, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To find and fix improper installation of the electrical wiring of the basic/optional cabin lighting, which could result in overheating of the wiring and possible smoke/fire in the cabin during an emergency situation, accomplish the following:

Inspection

(a) Within 13 months after the effective date of this AD: Do a detailed inspection (including measurement of electrical current) of the electrical wiring installation for optional lighting in the cabin to determine if any wiring is directly connected to the battery bus. Do all of the applicable actions per the Accomplishment Instructions of Dassault Service Bulletin F50–318, Revision 1, dated June 12, 2002; or Revision 2, dated January 15, 2003.

Note 1: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Corrective Actions

(b) If any electrical wiring is found to be directly connected to the battery bus during the inspection required by paragraph (a) of this AD, before further flight, do all the applicable corrective actions (*e.g.*, modifying the existing wiring, doing a detailed inspection of any modified wiring installation to ensure it matches the wiring diagram, and testing the modified wiring installation) per the Accomplishment Instructions of Dassault Service Bulletin F50–318, Revision 1, dated June 12, 2002; or Revision 2, dated January 15, 2003.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(d) The actions shall be done in accordance with Dassault Service Bulletin F50–318, Revision 1, dated June 12, 2002; or Dassault Service Bulletin F50–318, Revision 2, dated January 15, 2003. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or 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/code_of_federal_regulations/ibr_locations.html.*

Note 2: The subject of this AD is addressed in French airworthiness directive 2002–086–036(B) R1, dated March 20, 2002.

Effective Date

(e) This amendment becomes effective on June 16, 2004.

Issued in Renton, Washington, on April 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–10246 Filed 5–11–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 335

[Docket No. 1978N–036T]

RIN 0910–AC82

Antidiarrheal Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph (FM) for over-the-counter (OTC) antidiarrheal drug products to include relief of travelers' diarrhea as an indication for products containing bismuth subsalicylate. Travelers' diarrhea occurs in travelers and is most commonly caused by an infectious agent. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: This rule is effective June 11, 2004.

FOR FURTHER INFORMATION CONTACT: Mary S. Robinson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 21, 1975 (40 FR 12902), FDA published under 21 CFR 330.10(a)(6) an advance notice of proposed rulemaking to establish a monograph for OTC antidiarrheal drug products, together with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products, which evaluated these drug classes. FDA published the proposed rule in the **Federal Register** of April 30, 1986 (51 FR 16138), as a tentative final monograph.

FDA discussed a travelers' diarrhea claim for bismuth subsalicylate in the final rule for OTC antidiarrheal drug products (68 FR 18869, April 17, 2003). Travelers' diarrhea is an acute diarrheal illness occurring among travelers, particularly those visiting developing countries where sanitation is suboptimal. Most cases of travelers' diarrhea are caused by infectious agents, acquired through the ingestion of fecally contaminated food and/or water. Bacterial pathogens account for the great majority of episodes. Overall, one of the most common etiologic agents in travelers' diarrhea are enterotoxigenic *Escherichia coli*, which are responsible for 50 to 75 percent of episodes in certain areas of the world. Other recognized enteropathogens can be isolated from most of the remainder of cases, but with great regional differences in prevalence. Viruses (rotavirus, Norwalk-like virus) and protozoa (amebas, Giardia) are collectively responsible for fewer than 10 percent of cases of travelers' diarrhea.

FDA discussed the clinical data for this claim in section II, comment 3 of the final rule for OTC antidiarrheal drug products (68 FR 18869 at 18871). FDA has determined that the data support the use of bismuth subsalicylate in treating the symptoms of travelers' diarrhea. Accordingly, FDA is amending the FM to include an indication [''controls'' or ''relieves'' ''travelers' diarrhea''] for OTC antidiarrheal drug products containing bismuth subsalicylate identified in 21 CFR 335.10(a).

II. FDA's Conclusions on the Comment

In response to the proposal, FDA received one comment, which is on public display in the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The comment agreed completely with the proposal to amend the FM for OTC antidiarrheal drug products to include the additional indication for travelers' diarrhea for products containing bismuth subsalicylate. The comment encouraged FDA to expeditiously amend the FM so this indication can be used on appropriate OTC drug products.

FDA agrees with the comment and is providing that this final rule be effective 30 days after its date of publication.

III. FDA's Final Conclusions

FDA is amending the FM for OTC antidiarrheal drug products to make the following additions:

- Definitions in 21 CFR 335.3(c): ''Travelers' diarrhea. A subset of diarrhea occurring in travelers that is most commonly caused by an infectious agent.''
- Indications in 21 CFR 335.50(b)(1) for products containing bismuth subsalicylate: [select one of the following: ''controls'' or ''relieves''] *** ''travelers' diarrhea'']. If both ''diarrhea'' and ''travelers' diarrhea'' are selected, each shall be preceded by a bullet in accordance with 21 CFR 201.66(b)(4) and (d)(4) of this chapter and the heading ''Uses'' shall be used.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

FDA concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. As discussed in this section of the document, FDA has determined that this final rule will not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this final rule is to provide an additional (optional) claim for OTC antidiarrheal drug products containing bismuth subsalicylate. Manufacturers can add this claim to