

exterior skin surface in the skin area at least 3/4 inch around the edges of the horizontal stabilizer openings as shown in Figure 1 of this AD.

(d) At intervals not to exceed 100 hours TIS after completing the FPI:

(1) Remove all four horizontal stabilizer supports, P/N 206-023-100-all dash numbers, from the tailboom and the horizontal stabilizer.

(2) Visually inspect the entire edge of the horizontal stabilizer opening on both sides of the tailboom for any crack using a 10-power or higher magnifying glass as shown in Figure 1 of this AD.

(e) Within 600 hours TIS, inspect and modify the tailboom in accordance with the Accomplishment Instructions, Parts I, II, and III of Bell Helicopter Textron Canada Alert Service Bulletin 206L-99-115, Revision F, dated April 14, 2001 (ASB).

(f) After modifying a tailboom in accordance with paragraph (e) of this AD or installing a tailboom modified in accordance with paragraph (e) of this AD, at intervals not to exceed 1200 hours TIS, inspect the modified tailboom in accordance with the Accomplishment Instructions, Part IV, of the ASB.

(g) If a crack is found during any check or inspection required by this AD, before further flight, replace the cracked tailboom with an airworthy tailboom modified according to the requirements of paragraph (e) of this AD or with an airworthy tailboom, P/N 206-033-004-181.

**Note 2:** Modifying the tailboom in accordance with revisions before Revision F of ASB 206L-99-115 is acceptable for the modifications required by paragraph (e) of this AD.

(h) Inspecting and modifying the tailboom in accordance with paragraph (e) of this AD is terminating action for the requirements of paragraphs (a) through (d) of this AD. Installing an airworthy tailboom, P/N 206-033-004-181, constitutes terminating action for the requirements of this AD.

(i) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(j) Special flight permits may be issued for a one-time flight, not to exceed 5 hours TIS and a maximum of one landing in accordance with 14 CFR 21.197 and 21.199, to operate the helicopter to a location where the requirements of this AD can be accomplished. The visual preflight check required by paragraph (b) of this AD must be accomplished before making a one-time flight.

(k) Inspecting and modifying the tailboom shall be done in accordance with the Accomplishment Instructions, Bell Helicopter Textron Alert Service Bulletin

206L-99-115, Revision F, dated April 14, 2001. 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 Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101, telephone (817) 280-3391, fax (817) 280-6466. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(l) This amendment becomes effective on January 27, 2003.

**Note 4:** The subject of this AD is addressed in Transport Canada (Canada) AD CF-98-42R3, dated February 17, 2000.

Issued in Fort Worth, Texas, on December 9, 2002.

**David A. Downey,**

*Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 02-31752 Filed 12-20-02; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 2000-CE-60-AD; Amendment 39-12985; AD 2002-25-09]

RIN 2120-AA64

#### **Airworthiness Directives; Air Tractor, Inc. Models AT-250, AT-300, AT-301, AT-302, AT-400, AT-400A, AT-401, AT-401A, AT-402, AT-402A, AT-501, AT-502, and AT-502A Airplanes**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) that applies to certain Air Tractor, Inc. (Air Tractor) Models AT-250, AT-300, AT-301, AT-302, AT-400, AT-400A, AT-401, AT-401A, AT-402, AT-402A, AT-501, AT-502, and AT-502A airplanes. This AD requires you to install an overturn skid plate in the cockpit area. This AD is the result of reports of foreign material entering the cabin area during an overturn skid of the affected airplanes. The actions specified by this AD are intended to minimize the possibility of dirt or mud penetrating the cockpit in case of an aircraft overturn. Such mud and dirt penetration into the cockpit could lead to pilot asphyxia or injury.

**DATES:** This AD becomes effective on February 10, 2003.

The Director of the Federal Register approved the incorporation by reference

of certain publications listed in the regulations as of February 10, 2003.

**ADDRESSES:** You may get the service information referenced in this AD from Air Tractor, Inc., P.O. Box 485, Olney, Texas 76374. You may view this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000-CE-60-AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

#### **FOR FURTHER INFORMATION CONTACT:**

Andrew McAnaul, Aerospace Engineer, FAA, Fort Worth Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193-0150; telephone: (817) 222-5156; facsimile: (817) 222-5960.

#### **SUPPLEMENTARY INFORMATION:**

##### **Discussion**

*What events have caused this AD?*  
The FAA has received accident reports on Air Tractor Models AT-301 and AT-401 airplanes. The reports indicate that the aircraft skids tail first after an overturn, the windshield and curved overturn tube act as a scoop, foreign material enters the cockpit if the top of the canopy is damaged, and this foreign material then enters into the cabin area and possibly contributes to pilot deaths.

*Has FAA taken any action to this point? We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Air Tractor Models AT-250, AT-300, AT-301, AT-302, AT-400, AT-400A, AT-401, AT-401A, AT-402, AT-402A, AT-501, AT-502, and AT-502A airplanes. This proposal was published in the Federal Register as a notice of proposed rulemaking (NPRM) on August 29, 2002 (67 FR 55360). The NPRM proposed to require you to install an overturn skid plate in the cockpit area. The actions specified by this proposed AD are intended to minimize the possibility of dirt or mud penetrating the cockpit in case of an aircraft overturn.*

*What is the potential impact if FAA took no action? Such mud and dirt penetration into the cockpit could lead to pilot asphyxia or injury.*

*Was the public invited to comment?*  
The FAA encouraged interested persons to participate in the making of this amendment. The following presents the comments received on the proposal and FAA's response to each comment:

**Comment Issue No. 1: Remove the Air Tractor Model AT-502A Designation From the Applicability**

*What is the commenter's concern?*  
 The commenter states that the Air Tractor Model AT-502A airplanes did not start production until after serial numbers applicable to the AD. Furthermore, the commenter states skid plates were installed on all Model AT-502A airplanes during factory production. The commenter wants Air Tractor Model AT-502A airplanes removed from the applicability section of the final rule AD action.

*What is FAA's response to the concern?* We do not concur. Air Tractor confirms that there is the possibility of one Model AT-502A airplane (converted from an early production AT-503, and with one of the affected serial numbers) in operation that did not receive the skid plate installation.

We are not changing the final rule AD action based on this comment.

**Comment Issue No. 2: Correct Wording in the Summary and Related AD Section**

*What is the commenter's concern?*  
 The commenter states that the following sentence in the NPRM Summary and proposed AD paragraph 2(c) is misleading: "The proposed AD is the result of reports of foreign material entering the cabin area and contributing to accidents of the affected airplanes." The commenter states that the sentence is misleading in that it implies that entering foreign material has caused an accident and does not indicate that an accident (an overturn of the aircraft) has already occurred. The commenter wants the sentence corrected to indicate the possibility of foreign material entering the cockpit after an accident where the aircraft has overturned.

*What is FAA's response to the concern?* We agree with the commenter. The final rule AD Summary and AD paragraph 2(c) will be changed to indicate the possibility of foreign material entering the cockpit after an accident where the aircraft has overturned.

We will change the final rule AD action to incorporate these changes.

**FAA's Determination**

*What is FAA's final determination on this issue?* We carefully reviewed all available information related to the subject presented above and determined that air safety and the public interest require the adoption of the rule as proposed except for the changes discussed above and minor editorial questions. We have determined that these changes and minor corrections:

- Provide the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

**Cost Impact**

*How many airplanes does this AD impact?* We estimate that this AD affects 845 airplanes in the U.S. registry.

*What is the cost impact of this AD on owners/operators of the affected airplanes?* We estimate the following costs to accomplish the modification:

Labor cost	Parts cost	Total cost per airplane	Total cost U.S. operators
6 workhours × \$60 = \$360 .....	\$300	\$660	845 × \$660 = \$557,700

**Regulatory Impact**

*Does this AD impact various entities?*  
 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.

*Does this AD involve a significant rule or regulatory action?* 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 copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy

of it may be obtained by contacting 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, under 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. FAA amends § 39.13 by adding a new AD to read as follows:

**2002-25-09 Air Tractor, Inc.:** Amendment 39-12985; Docket No. 2000-CE-60-AD.

(a) *What airplanes are affected by this AD?*  
 This AD affects the following airplane models and serial numbers that are certificated in any category:

Models	Serial Nos.
AT-250, AT-300, AT-301, AT-302, AT-400, AT-400A, AT-401, AT-401A, AT-402, and AT-402A.	All through 0829.
AT-501, AT-502, and AT-502A.	All through 0147.

(b) *Who must comply with this AD?*  
 Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?*  
 The actions specified by this AD are intended to minimize the possibility of dirt or mud penetrating the cockpit in case of an aircraft overturn. Such mud and dirt penetration into the cockpit could lead to pilot asphyxia or injury.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
Install overturn skid plate, part number (P/N) 11411-1-500, or FAA-approved equivalent P/N.	Within the next 180 days after February 10, 2003 (the effective date of this AD), unless already accomplished..	In accordance with Snow Engineering Company Service Letter #97, dated March 23, 1991, Revised October 3, 2000, and the applicable maintenance manual.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

- (1) Your alternative method of compliance provides an equivalent level of safety; and
- (2) The Manager, Fort Worth Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Fort Worth ACO.

**Note:** This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Andrew McAnaul, Aerospace Engineer, FAA, Fort Worth Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193-0150; telephone: (817) 222-5156; facsimile: (817) 222-5960.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Snow Engineering Company Service Letter # 97, dated March 23, 1991, Revised October 3, 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You may get copies from Air Tractor, Inc., P.O. Box 485, Olney, Texas 76374. You may view copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on February 10, 2003.

Issued in Kansas City, Missouri, on December 13, 2002.

**Dorenda D. Baker,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 02-31998 Filed 12-20-02; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 341

[Docket No. 76N-052G]

RIN 0910-AA01

#### **Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Human Use; Final Monograph for Combination Drug Products**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph that establishes conditions under which over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic (cough-cold) combination drug products are generally recognized as safe and effective and not misbranded as part of its ongoing review of OTC drug products. FDA is issuing this final rule after considering public comments on the agency's proposed regulation (tentative final monograph) and new data and information on OTC cough-cold combination drug products that have come to the agency's attention.

**DATES:** This regulation is effective December 23, 2004.

**FOR FURTHER INFORMATION CONTACT:** Cazemiro R. Martin or Gerald M. Rachanow, 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 September 9, 1976 (41 FR 38312), FDA published,

under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel), which was the advisory review panel that evaluated these products. The agency's proposed regulation for OTC cough-cold combination drug products was published in the **Federal Register** of August 12, 1988 (53 FR 30522).

Final rules for these OTC drug products were published in segments: Anticholinergic (50 FR 46582, November 8, 1985), bronchodilator (51 FR 35326, October 2, 1986), antitussive (52 FR 30042, August 12, 1987), expectorant (54 FR 8494, February 28, 1989), antihistamine (57 FR 58356, December 9, 1992), and nasal decongestant (59 FR 43386, August 23, 1994). This document on combination drug products, general issues, and miscellaneous ingredients is the final segment. In response to the proposed rule for OTC cough-cold combination drug products, the agency received 21 comments, which are on public display in the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. This final monograph addresses all comments and objections, except as discussed below.

In the **Federal Register** of July 27, 1995 (60 FR 38636), FDA published a final rule establishing that cough-cold combination drug products containing theophylline are not generally recognized as safe and effective and are misbranded for OTC use. In the **Federal Register** of September 27, 2001 (66 FR 49276), FDA published a partial final rule for cough-cold combination drug products containing a bronchodilator, stating that combinations containing any oral bronchodilator and any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient are not generally recognized as safe and effective and are misbranded for OTC use. The combinations in these two final rules are listed in § 310.545(a)(6)(iv)(B) and (a)(6)(iv)(D),