

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Standards Staff, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4146; fax: (816) 329-4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) Reporting Requirements: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI Luftfahrt-Bundesamt (LBA) AD No. D-2007-353, dated December 28, 2007, and RUAG Aerospace Defence Technology Dornier 228 Alert Service Bulletin No. ASB-228-269, dated March 23, 2007, for related information.

Material Incorporated by Reference

(i) You must use RUAG Aerospace Defence Technology Dornier 228 Alert Service Bulletin No. ASB-228-269, dated March 23, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

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

(2) For service information identified in this AD, contact RUAG Aerospace Services, Customer Support, P.O. Box 1253, 82231 Wessling, Germany.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; 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/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on April 18, 2008.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-9055 Filed 4-25-08; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2008-0476; Directorate Identifier 2008-CE-018-AD; Amendment 39-15491; AD 2008-09-10]

RIN 2120-AA64

Airworthiness Directives; Air Tractor, Inc. Models AT-300, AT-301, AT-302, AT-400, and AT-400A Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) to supersede AD 2003-06-01, which applies to all Air Tractor, Inc. (Air Tractor) Models AT-300, AT-301, AT-302, and AT-400A airplanes that have aluminum spar caps; certain Air Tractor Models AT-400 airplanes that have aluminum spar caps; and all Models AT-300 and AT-301 airplanes that have aluminum spar caps and are or have been converted to turbine power. AD 2003-06-01 requires replacing the wing spar lower caps at a specified safe life limit; allows extending the safe life limit on certain airplanes if a wing lower spar cap splice rework is done; allows a limited time of continued operation beyond the safe life limit provided parts are ordered, the replacement is scheduled, and repetitive inspections reveal no cracks; and requires a report of any cracks found during any inspection to the FAA. This AD results from a recent report of cracks found on a Model AT-301 airplane at hours below the modification time specified in AD 2003-06-01. Consequently, this AD retains the wing spar lower cap replacement and reporting requirements from AD 2003-06-01 and adds a repetitive eddy-current inspection. We are issuing this AD to detect and correct cracks in the wing centerline splice joint. If not detected and corrected, these cracks could result in the wing separating from the airplane during flight.

DATES: This AD becomes effective on May 8, 2008.

On May 8, 2008, the Director of the Federal Register approved the incorporation by reference of Snow Engineering Co. Service Letter #55, revised October 4, 2004, listed in this AD.

As of April 4, 2003, (68 FR 13221, March 19, 2003), the Director of the Federal Register approved the incorporation by reference of Snow Engineering Co. Service Letter #55, revised October 23, 2002, and Snow Engineering Co. Process Specification Number 197, revised June 4, 2002, listed in this AD.

We must receive any comments on this AD by June 27, 2008.

ADDRESSES: Use one of the following addresses to comment on this AD.

- **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:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

To get the service information identified in this AD, contact Air Tractor, Inc., P.O. Box 485, Olney, Texas 76374; telephone: (940) 564-5616; facsimile: (940) 564-5612.

To view the comments to this AD, go to <http://www.regulations.gov>. The docket number is FAA-2008-0476; Directorate Identifier 2008-CE-018-AD.

FOR FURTHER INFORMATION CONTACT: Rob Romero, Aerospace Engineer, FAA, Fort Worth Airplane Certification Office (ACO), 2601 Meacham Boulevard, Fort Worth, Texas 76193-0150; telephone: (817) 222-5102; facsimile: (817) 222-5960; or Andrew McAnaul, Aerospace Engineer, FAA, Fort Worth ACO (c/o MIDO-43), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; telephone: (210) 308-3365; facsimile: (210) 308-3370.

SUPPLEMENTARY INFORMATION:**Discussion**

An incident on an Air Tractor Model AT-400A where the wing separated from the airplane caused us to issue AD 2002-13-02, Amendment 39-12789 (67 FR 44024, July 1, 2002). Investigation revealed that the right-hand lower spar cap failed due to fatigue at the 3/8-inch outboard bolt, which is located 6.5 inches outboard of the fuselage centerline.

The airplanes affected by AD 2002–13–02 have a similar type design to that of the accident airplane. AD 2002–13–02 required inspecting (one-time) the wing centerline splice joint for cracks and, if any crack was found, replacing the affected wing spar lower cap; reporting the results of the inspection to the FAA; and replacing the wing spar lower caps after a certain amount of usage.

The inspection reports submitted to the FAA (as required in AD 2002–13–02) revealed a Model AT–400A airplane with a cracked spar cap. The damage was significant enough to require spar cap replacement. Based on this damage and the results of the inspection reports, we determined that the mandatory replacement time for the wing spar lower cap on the affected turbine engine powered airplanes should be reduced.

This prompted us to issue AD 2003–06–01, Amendment 39–13088 (68 FR 13221, March 19, 2003) to supersede AD 2002–13–02. AD 2003–06–01 requires replacing the wing spar lower caps at a specified safe life limit; allows extending the safe life limit on certain airplanes if a wing lower spar cap splice rework is done; allows a limited time of continued operation beyond the safe life limit provided parts are ordered, the replacement is scheduled, and repetitive inspections reveal no cracks; and requires a report of any cracks found during any inspection to the FAA.

The FAA recently received a report of cracks found on a Model AT–301 airplane with less hours than the modification time specified in AD 2003–06–01. Based on this incident, we reevaluated the fatigue management plan for the AT–300 and AT–400 series airplanes that have aluminum spar caps without part number 20990–1/–2 steel web plate installed. We have determined that repetitive eddy-current inspections are needed on these airplanes in order to detect any cracks that may develop on the wing spar lower cap before reaching the safe life limit.

This condition, if not corrected, could result in the wing separating from the airplane during flight.

Relevant Service Information

The manufacturer has issued the following service information to address this situation:

- Snow Engineering Co. Service Letter #55, revised October 23, 2002, which includes procedures and information for doing the wing lower spar cap splice joint modification rework on all AT–300 and AT–301 series airplanes;

- Snow Engineering Co. Service Letter #55, revised October 4, 2004, which includes revised procedures and information for doing the wing lower spar cap splice joint modification rework on all AT–300 and AT–301 series airplanes; and

- Snow Engineering Co. Process Specification Number 197, revised June 4, 2002, which provides procedures for accomplishing eddy current inspections of the wing lower spar caps.

FAA's Determination and Requirements of This AD

We are issuing this AD because we evaluated all the information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design. This AD supersedes AD 2003–06–01 with a new AD that:

- Requires repetitive eddy-current inspections;
- Requires you to replace the wing spar lower caps at specified times;
- Allows you to extend the time for replacement on certain airplanes if a wing lower spar cap splice rework is done;
- Requires you to inspect the wing lower spar cap immediately prior to modification; and
- Requires you to report any cracks found during the inspections to the FAA.

We are not retaining from AD 2003–06–01 the provision to allow a limited time of continued operation beyond the safe life limit.

In preparing this rule, we contacted type clubs and aircraft operators to get technical information and information on operational and economic impacts. We did not receive any information through these contacts. If received, we would have included a discussion of any information that may have influenced this action in the rulemaking docket.

FAA's Determination of the Effective Date

Since an unsafe condition exists that requires the immediate adoption of this AD, we determined that notice and opportunity for public comment before issuing this AD are impracticable, and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and an opportunity for public comment. We invite you to send any written relevant data, views, or arguments regarding this

AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number “FAA–2008–0476; Directorate Identifier 2008–CE–018–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the AD in light of 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 concerning this AD.

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.

Regulatory Findings

We determined that 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 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket that contains the AD, the regulatory evaluation, any comments received, and other information on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone (800) 647-5527) is located at the street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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 removing Airworthiness Directive (AD) 2003-06-01, Amendment 39-13088 (68 FR 13221, March 19, 2003), and by adding a new AD to read as follows:

2008-09-10 Air Tractor, Inc.: Amendment 39-15491; Docket No. FAA-2008-0476; Directorate Identifier 2008-CE-018-AD.

Effective Date

(a) This AD becomes effective on May 8, 2008.

Affected ADs

(b) This AD supersedes AD 2003-06-01, Amendment 39-13088.

Applicability

(c) This AD applies to the following airplanes that are certificated in any category:

(1) Models AT-300, AT-301, AT-302, and AT-400A airplanes, all serial numbers, that have aluminum spar caps;

(2) Models AT-400 airplanes, serial numbers 400-0244 through 400-0415, that have aluminum spar caps; and

(3) Models AT-300 and AT-301 airplanes, all serial numbers that have aluminum spar caps and are or have been converted to turbine power.

Unsafe Condition

(d) This AD is the result of service reports and analysis done on wing lower spar caps of Air Tractor, Inc. airplanes. The actions specified by this AD are intended to prevent fatigue cracks from occurring in the wing lower spar cap before the established safe life is reached. Fatigue cracks in the wing lower spar cap, if not detected and corrected, could result in failure of the spar cap and lead to wing separation and loss of control.

Compliance

(e) To address this problem, you must do the following, unless already done:

(1) For all affected airplanes without steel web plates, part numbers (P/N) 20990-1 or 20990-2, or steel spar caps installed, eddy-current inspect the left and right wing spar lower cap outboard holes for cracks following Snow Engineering Co. Process Specification #197, revised June 4, 2002. Do the inspections at the following compliance times:

Affected airplanes	Initial compliance time	Repetitive compliance time
(i) For all airplanes	Initially inspect upon reaching 3,500 total hours time-in-service (TIS) on the wing spar lower cap or within the next 10 hours TIS after May 8, 2008 (the effective date of this AD), whichever occurs later.	Repetitively inspect thereafter at intervals not to exceed 450 hours TIS until the wing spar center splice joint modification or the required wing spar lower cap replacement. After each replacement, initially inspect upon reaching 3,500 total hours TIS on either wing spar lower cap, and repetitively inspect thereafter at intervals not to exceed 450 hours TIS until the wing spar center splice joint modification or the required wing spar lower cap replacement.
(ii) Airplanes that have had an eddy-current inspection done on the wing spar lower cap within the last 450 hours TIS before the effective date of this AD.	You may take credit for that inspection. Continue with the required repetitive inspection intervals.	Repetitively inspect thereafter at intervals not-to-exceed 450 hours TIS from the time of the last inspection until the wing spar center splice joint modification or the required wing spar lower cap replacement. After each replacement, initially inspect upon reaching 3,500 total hours TIS on either wing spar lower cap, and repetitively inspect thereafter at intervals not to exceed 450 hours TIS until the wing spar center splice joint modification or the required wing spar lower cap replacement.

(2) For all affected Models AT-300 and AT-301 airplanes with reciprocating engines, the 450-hour repetitive inspections required in this AD are terminated after the wing spar center splice joint modification is incorporated in accordance with paragraph

(g) of this AD or when the wing lower spar caps are replaced. The replacement specified in paragraph (f)(2) of this AD is still applicable.

(3) If cracks are found during any inspection required in paragraphs (e)(1)(i),

(e)(1)(ii), or (g)(2) of this AD, replace the wing lower spar cap before further flight.

(f) Replace each wing lower spar cap in accordance with the applicable maintenance manual, as follows:

Affected airplanes	Initial replacement compliance time	Repetitive replacement/inspection compliance time
(1) For all affected Models AT-300 and AT-301 airplanes with reciprocating engines and that do not incorporate the wing spar center splice joint modification.	Upon reaching 5,000 total hours TIS on either wing spar lower cap or within the next 25 hours TIS after April 4, 2003 (the effective date of AD 2003-06-01), whichever occurs later.	Replace each time the safe life limit of 5,000 total hours TIS on either wing spar lower cap is reached. After each replacement, inspect as specified in paragraph (e)(1) of this AD until the wing spar center splice joint modification or the required wing spar lower cap replacement.
(2) For all affected Models AT-300 and AT-301 airplanes with reciprocating engines that do incorporate the wing spar center splice joint modification done in accordance paragraph (g) of this AD.	Upon reaching the safe life limit of 7,000 total hours TIS on either wing spar lower cap or within the next 25 hours TIS after April 4, 2003 (the effective date of AD 2003-06-01), whichever occurs later.	Replace each time the safe life limit of 7,000 total hours TIS on either wing spar lower cap is reached. After each replacement, inspect as specified in paragraph (e)(1) of this AD until the wing spar center splice joint modification or the required wing spar lower cap replacement.
(3) For all affected AT-302, AT-400, and AT-400A airplanes with aluminum spar caps; and all affected Models AT-300 and AT-301 airplanes with aluminum spar caps that are or have ever been converted to turbine power.	Upon reaching 4,450 total hours TIS on either wing spar lower cap or within the next 25 hours TIS after April 4, 2003 (the effective date of AD 2003-06-01), whichever occurs later.	Replace each time the safe life limit of 4,450 total hours TIS on the wing spar lower cap is reached. After each replacement inspect as specified in paragraph (e)(1) of this AD until the required wing spar lower cap replacement.

(g) For airplanes specified in paragraph (f)(1) of this AD, you may extend the safe life limit of the wing spar lower cap to 7,000 hours TIS by incorporating the wing spar center splice joint modification following the procedures in Snow Engineering Co. Service Letter #55, revised October 23, 2002; or Snow Engineering Co. Service Letter #55, revised October 4, 2004, with the following requirements:

(1) This modification must be done no earlier than 4,600 total hours TIS on the wing spar lower cap and no later than 5,000 total hours TIS on the wing spar lower cap.

(2) Immediately before incorporating the modification, you must do an eddy-current inspection for cracks following Snow Engineering Co. Process Specification #197, revised June 4, 2002.

(3) After each replacement, inspect as specified in paragraph (e)(1) of this AD until the wing spar center splice joint modification or the required wing spar lower cap replacement.

(h) Eddy-current inspections required by this AD must be done by one of the following:

(1) A level 2 or 3 inspector certified in eddy-current inspection using the guidelines established by the American Society for Nondestructive Testing or NAS 410; or

(2) A person authorized to perform AD maintenance work and who has completed and passed the Air Tractor, Inc. training course on eddy-current inspection on wing lower spar caps.

Note 1: We are not retaining from AD 2003-06-01 the provision to allow a limited time of continued operation beyond the safe life limit provided parts are ordered, the replacement is scheduled, and repetitive inspections reveal no cracks. That provision was put in AD 2003-06-01 to prevent airplanes from being inadvertently grounded if parts were not available. If parts availability were to ever become a problem in the future, the owner/operator could

request an alternative method of compliance following the procedures in 14 CFR 39.19 and this AD.

(i) Report the results of any inspection required by this AD where cracks are found to the FAA.

(1) Submit this report within 10 days after the inspection.

(2) Use the form (Figure 1 of this AD) and submit it to FAA, Fort Worth Airplane Certification Office (ACO), 2601 Meacham Boulevard, Fort Worth, Texas 76193-0150; telephone: (817) 222-5156; facsimile: (817) 222-5960.

(3) The Office of Management and Budget (OMB) approved the information collection requirements contained in this regulation under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and assigned OMB Control Number 2120-0056.

BILLING CODE 4910-13-P

AD 2008-09-10 INSPECTION REPORT

1. Inspection Performed By:	2. Phone:
3. Airplane Model:	4. Airplane Serial Number:
5. Engine Model Number:	6. Airplane Total Hours TIS:
7. Wing Total Hours TIS:	8. Lower Spar Cap Hours TIS:
9. Has the lower spar cap been inspected before? (eddy-current, dye penetrant, magnetic particle, ultrasound) ☐ Yes ☐ No	9a. If yes, Date: _____ Inspection Method: _____ Lower Spar Cap Hours TIS: _____ Cracks found? ☐ Yes ☐ No
10. Has there been any major repair or alteration performed to the spar cap? ☐ Yes ☐ No	10a. If yes, specify (Description and Hours TIS)
11. Date of AD inspection: _____	
12. Inspection Results: (Note: Report <u>only</u> if cracks are found)	12a. ☐ Left Hand ☐ Right Hand
12b. Crack Length: _____	12c. Does drilling hole to next larger size remove all traces of the crack(s)? ☐ Yes ☐ No
12d. Corrective Action Taken:	

Mail report to: Andrew McAnaul, Fort Worth ACO, ASW-150 (c/o MIDO-43),
100 Reunion Place, Suite 650, San Antonio, Texas 78216

Figure 1

BILLING CODE 4910-13-C**Alternative Methods of Compliance (AMOCs)**

(j) The Manager, Fort Worth ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Rob Romero, Aerospace Engineer, FAA, Fort Worth ACO, 2601 Meacham Boulevard, Fort

Worth, Texas 76193-0150; telephone: (817) 222-5102; facsimile: (817) 222-5960; or Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o MIDO-43), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; telephone: (210) 308-3365; facsimile: (210) 308-3370. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector

(PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(k) AMOCs approved for AD 2003-06-01 are approved for this AD.

Special Flight Permit

(l) Under 14 CFR part 39.23, we are limiting the special flight permits for this AD by the following conditions:

- (1) Operate only in day visual flight rules (VFR).
- (2) Ensure that the hopper is empty.
- (3) Limit airspeed to 135 miles per hour (mph) indicated airspeed (IAS).
- (4) Avoid any unnecessary g-forces.
- (5) Avoid areas of turbulence.
- (6) Plan the flight to follow the most direct route.

Material Incorporated by Reference

(m) You must use Snow Engineering Co. Service Letter #55, revised October 23, 2002; Snow Engineering Co. Service Letter #55, revised October 4, 2004; and Snow Engineering Co. Process Specification Number 197, revised June 4, 2002, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of Snow Engineering Co. Service Letter #55, revised October 4, 2004, under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) On April 4, 2003, (68 FR 13221, March 19, 2003), the Director of the Federal Register approved the incorporation by reference of Snow Engineering Co. Service Letter #55, revised October 23, 2002, and Snow Engineering Process Specification Number 197, revised June 4, 2002.

(3) For service information identified in this AD, contact Tractor, Inc., P.O. Box 485, Olney, Texas 76374.

(4) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Kansas City, Missouri 64106; 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.

Issued in Kansas City, Missouri, on April 18, 2008.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-9058 Filed 4-25-08; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 2004N-0018]

Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) (non-IND foreign clinical studies) as support for an IND or application for marketing approval for a drug or biological product. The final rule replaces the requirement that these studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki (Declaration) issued by the World Medical Association (WMA), specifically the 1989 version (1989 Declaration), with a requirement that the studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee (IEC). The final rule updates the standards for the acceptance of foreign clinical studies not conducted under an IND and helps ensure the protection of human subjects and the quality and integrity of data obtained from these studies.

DATES: This rule is effective October 27, 2008.

FOR FURTHER INFORMATION CONTACT:

Janet Norden, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993-0002, 301-796-2270; and Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

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I. Background

In the **Federal Register** of June 10, 2004 (69 FR 32467), we published a proposed rule that would revise our regulations in part 312 (21 CFR part 312) on the conditions under which we will accept non-IND foreign clinical studies as support for an IND, a new drug application (NDA), or a biologics license application (BLA). As discussed in section III.A of this document, we revised the language used to refer to an application (other than an IND) that may be supported by non-IND foreign clinical studies from "NDA or BLA" or "marketing application" to "application for marketing approval," which we define as an application under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) or section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), to make it clear that the regulation also applies to foreign clinical studies supporting abbreviated new drug applications (ANDAs). Previous § 312.120(a) stated that we generally accepted for review non-IND foreign clinical studies provided they were well designed, well conducted, performed by qualified clinical investigators, and conducted in accordance with ethical principles acceptable to the world community. With respect to such ethical principles, § 312.120(c)(1) stated that for a foreign clinical study not conducted under an IND to be used to support an