Labor cost	Parts cost	Total cost per airplane	Total Cost on U.S. operators
2 workhours × $60 = $120	$50	$170	$170 × 5 = $850.

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:

2002–02–01 Eagle Aircraft PTY. Ltd.: Amendment 39–12629; Docket No. 2001–CE–03–AD.

(a) *What airplanes are affected by this AD?* This AD affects Model 150B airplanes, serial numbers 001 through 021, that are certificated in any category.

(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 prevent failure of the throttle control assembly. Such failure could lead to reduced control of the airplane.

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

Actions	Compliance	Procedures
Replace the existing 3/32-inch rivets, which attach the throttle torque tubes to the port and starboard throttle arms, with 1/8-inch solid-head rivets, and replace the 1/8-inch rivet in the starboard bushing of the throttle torque tube with a 5/32-inch screw.	Within the next 100 hours time-in service (TIS) after March 21, 2002 (the effective date of this AD).	In accordance with Eagle Service Bulletin 1067, Revision 1, dated October 21, 1999.

(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, Los Angeles 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, Los Angeles ACO.

Note 1: 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 Fredrick A. Guerin, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone: (562) 627–5232; facsimile: (562) 627–5210.

(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 Eagle Service Bulletin 1067, Revision 1, dated October 21, 1999. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies Eagle Aircraft Pty. Ltd., Lot 700 Cockburn Road, Henderson WA 6166 Australia. You can look at 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.

Note 2: The subject of this AD is addressed in Australian AD Number X-TS/4, effective July 6, 2000.

(i) *When does this amendment become effective?* This amendment becomes effective on March 21, 2002.

Issued in Kansas City, Missouri, on January 24, 2002.

Michael K. Dahl,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–2318 Filed 2–1–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 01–AWP–22]

Revision to Class E Surface Area at Marysville Yuba County Airport, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule, request for comments.

SUMMARY: This action amends the hours of operation for Class E Surface Area airspace at Marysville Yuba County Airport, CA to reflect the fact the airport now provides full-time weather reporting service.

DATES: *Effective Date:* 0901 UTC April 18, 2002. *Comment date:* Comments for inclusion in the Rules Docket must be received on or before March 6, 2002.

ADDRESSES: Send comments on the direct final rule in triplicate to: Federal Aviation Administration, Attn: Manager, Airspace Branch, AWP–520, Docket No. 01–AWP–22, Air Traffic Division, P.O. Box 92007, Los Angeles, California 90009.

The official docket may be examined in the Office of the Regional Counsel, Western-Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business hours at the Office of the Manager, Airspace Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Jeri Carson, Air Traffic Division, Airspace Specialist, AWP–520, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6611.

SUPPLEMENTARY INFORMATION: This action amends the hours of operation for Class E Surface Area airspace at Marysville Yuba County Airport, CA to reflect the fact the airport now provides full-time weather reporting service. Class E airspace areas designated as surface areas for airports are published in Paragraph 6002 of FAA Order 7400.9J dated August 31, 2001, and effective September 16, 2001, which is incorporated by reference in 14 CFR 71.1. The Class E airspace revision listed in this document will be published subsequently in that Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and therefore is issuing it as a direct final rule. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 01–AWP–22.'' The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(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) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9J, Airspace Designations and Reporting Points, dated August 31, 2001, and effective September 16, 2001, is amended as follows:

* * * * *

Paragraph 6002 Class E Airspace Designated as a Surface Area for an airport.

* * * * *

AWP CA E2 Marysville Yuba County Airport, CA [Revised]

Marysville Yuba County Airport, CA
(Lat. 39°05′53″ N, long. 121°34′11″ W)
Marysville VOR/DME
(Lat. 39°05′56″ N, long. 121°34′23″ W)
Marysville Beale AFB, CA
(Lat. 39°08′10″ N, long. 121°26′12″ W)

Within a 4.1-mile radius of Yuba County Airport and within 1.8 miles each side of the Marysville VOR 152° radial, extending from the 4.1-mile radius to 7 miles southeast of the VOR and within 1.8 miles each side of the Marysville VOR 342° radial, extending from the 4.1-mile radius to 7 miles northwest of the VOR, excluding that portion within the Marysville Beale AFB, CA, Class C airspace area.

* * * * *

Issued in Los Angeles, California, on January 8, 2002.

John Clancy,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 02–2538 Filed 2–1–02; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 211, 226, 510, and 514

[Docket No. 88N–0038]

RIN 0910–AA02

Records and Reports Concerning Experience With Approved New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is amending its requirements for records and reports of adverse experiences and other information for approved new animal drugs. This interim final rule more clearly defines the kinds of information to be maintained and submitted by new animal drug applicants for a new animal drug application (NADA) or an abbreviated new animal drug application (ANADA). In addition, the interim final rule revises the timing and content of certain reports to enhance their usefulness. The regulation will provide for protection of public and animal health and reduce unnecessary recordkeeping and reporting requirements.

DATES: This interim rule is effective August 5, 2002. Submit written or electronic comments on new information on the interim final rule and the information collection requirements by April 5, 2002. Please note the agency will not consider any comments that have been previously considered during this rulemaking.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the Internet at http://www.fda.gov/dockets/ecomments. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William C. Keller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6641, or wkeller@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of December 17, 1991 (56 FR 65581), FDA (we) published a proposed rule (the proposed rule for records and reports) to revise § 510.300 (21 CFR 510.300) and to redesignate it as § 514.80 (21 CFR 514.80). This regulation implements section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(l)) which provides that, following approval of an NADA or ANADA, applicants must establish and maintain records and make reports to the agency as prescribed by regulation or order. We proposed the revision in order to more clearly define the kinds of information to be maintained and submitted by the applicant and to revise the timing and content of certain reports to enhance the usefulness of the information.

After considering comments submitted in response to the proposed rule for records and reports, FDA is adopting the rule in modified form. The scope and coverage of this interim final rule differs in some respects from the proposed rule for records and reports. The proposed rule for records and reports covered NADAs, ANADAs, and medicated feed applications (MFAs). In contrast, the interim final rule covers only NADAs and ANADAs. The Animal Drug Availability Act of 1996 (ADAA) (21 U.S.C. 360b(a) and 360b(m)) amended the statutory provisions in the act regarding medicated feeds and eliminated MFAs. Therefore, the interim final rule does not address MFAs. However, the interim final rule retains reporting requirements for serious adverse drug experiences with feeds incorporating approved Type A medicated articles.

While the proposed rule for records and reports proposed to remove 21 CFR 510.310, which addressed records and reports for new animal drugs approved before June 20, 1963, we issued a final rule that revoked this provision in response to the Administration's ''Reinventing Government Initiative'' (61 FR 37680, July 19, 1996).

The proposed rule for records and reports followed a style and format similar to the human drug records and reports regulations in part 314 (21 CFR part 314). The interim final rule maintains a similar style and format, but removes many of the proposed records and reports requirements that are not necessary to monitor animal drugs.

In response to concerns over duplicate reporting, FDA has removed proposed § 514.82, which concerned records and reports from manufacturers, packers, labelers, and distributors other than the applicant. However, the agency has retained certain record and report requirements for nonapplicants (defined in new § 514.3(f)) in § 514.80(b) of this interim final rule.

For purposes of clarity, the agency has made some changes to the text and organization of the interim final rule. The following list provides examples of changes not intended to affect the substantive requirements of the rule:

- All definitions in the proposed rule for records and reports have been consolidated in new § 514.3 *Definitions*. Specifically, definitions for the terms ''applicant'' and ''nonapplicant'' that appeared in text of the proposed rule for records and reports have now been moved to § 514.3.
- Proposed § 514.80(a) discussed the requirements for ''establish[ing] and maintain[ing] records and mak[ing] reports'' in one paragraph. For easier reading, FDA has broken the paragraph down in this interim final rule to discuss the recordkeeping and reporting requirements separately.
- New § 514.80(a)(2) discusses the reporting requirements in slightly greater detail than had been done in the proposed rule. This is intended to provide a road map of the requirements contained in other parts of the interim rule.
- Final § 514.80(a)(5) was added to clarify that the records and reports referred to in this section are in addition to those required by the current good manufacturing practice regulations.
- The interim final rule combines the proposed periodic adverse drug experience reports with the proposed annual reports (designated as § 514.80(d)(3) and (d)(4), respectively, in the proposed rule), because both reports require the same information. The combined report, which is now found at § 514.80(b)(4), is entitled ''Periodic drug experience report'' in the interim final rule.
- Reporting requirements for reports of adverse drug experiences in the