period in the same manner as prescribed by § 315.802 of this chapter.

§ 316.305 [Removed]

6. Section 316.305 is removed. 7. Section 316.402 is revised to read as follows:

§ 316.402 Procedures for making temporary appointments.

- (a) Competitive temporary appointments. In accordance with the time limits in § 316.401, an agency may make a temporary appointment under 5 CFR part 332 competitive procedures or under 5 CFR part 333 "outside-the register" procedures when there are insufficient eligibles on the appropriate register.
- (b) Noncompetitive temporary appointments. In accordance with the time limits in § 316.401, an agency may give a noncompetitive temporary appointment, without regard to the requirements of parts 332 and 333 of this chapter, to an individual who is qualified for the position and who is eligible for:

(1) Reinstatement under § 315.401 of this chapter;

- (2) Veterans readjustment appointment under § 307.103 of this chapter. Temporary limited appointments under this section are permitted only at the grade levels authorized for VRA appointments. Such appointments are not VRA appointments and do not lead to conversion to career-conditional appointment:
- (3) Career-conditional appointment under §§ 315.601, 315.604, 315.605, 315.606, 315.607, 315.608, 315.609, or 315.711 of this chapter;
- (4) Appointment under 5 U.S.C. 3112 (veterans with compensable serviceconnected disability of 30% or more). The disability must be documented by a notice of retirement of discharge due to service-connected disability from active military service dated at any time, or by a notice of compensable disability rating from the Department of Veterans Affairs, dated within the last 12 months;
- (5) Appointment under 31 U.S.C. 732(g) for current and former employees of the General Accounting Office;
- (6) Appointment under 28 U.S.C. 602 for current and former employees of the Administrative Office of the U.S. Courts;
- (7) Reappointment on the basis of being a former temporary employee of the agency who was originally appointed from a certificate of eligibles or under the provisions of part 333 of this chapter. An agency may not reappoint a former temporary employee if the individual has already served the

maximum time allowed in § 316.401 or if the position has been filled under temporary appointment for the maximum time allowed in § 316.401. Reappointment must be to the same position or another position appropriate for temporary appointment with the same qualification requirements;

- (8) Reappointment on the basis of being a former temporary employee who was originally appointed from a certificate of eligibles or under the provisions of part 333 of this chapter and who sustained a compensable injury while serving on the temporary appointment. Reappointment must be to the same position or another position appropriate for temporary appointment with the same qualification requirements. If the compensable injury disqualifies the former individual from performing such a position, reappointment may be to any position for which the individual is qualified. Reappointment must be for a minimum of 120 days.
- (c) Extension of temporary appointments. An individual who receives a valid temporary appointment will be eligible for an extension in accordance with § 316.401 even if his or her eligibility for noncompetitive appointment expires or is lost during the authorized period of temporary employment.
- 8. In § 316.403, paragraph (b)(1) is revised to read as follows:

§ 316.403 Designation of provisional appointments.

(b)* * *

(1) Noncompetitive temporary appointments of disabled veterans under § 316.402(b)(5), when the appointments are intended to afford eligibility for conversion in accordance with § 315.707 of this chapter and section 3112 of title 5, United States Code;

9. In § 316.701, paragraph (b)(1) is revised to read as follows:

§ 316.701 Public or private enterprise taken over by Government.

* * (b)* * *

(1) When an agency retains an employee under paragraph (a) of this section in a position which it determines to be a continuing one, the agency gives the employee a status quo appointment and shall decide on a timely basis whether it will convert that individual's employment to career or career-conditional under § 315.701 of this chapter.

10. In § 316.702, paragraphs (b)(1) and (d) are revised to read as follows:

§ 316.702 Excepted positions brought into the competitive service.

* * *

(b)(1) When an agency retains an employee under paragraph (a) of this section who was serving in an excepted position under an indefinite appointment or an appointment without time limit, the agency gives the employee a status quo appointment and may convert that employee's appointment to career or careerconditional under § 315.701 of this chapter.

(d) An employee who was serving under an excepted appointment with a definite time limit longer than 1 year may be retained under a term appointment. The term appointment is subject to all conditions and time limits applicable to term appointments. Service under excepted appointment does not count against the maximum time limit for term appointment in the competitive service.

[FR Doc. 98-30613 Filed 11-16-98; 8:45 am] BILLING CODE 6325-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-CE-108-AD: Amendment 39-10882; AD 98-23-01]

RIN 2120-AA64

Airworthiness Directives; Parker Hannifan Airborne Dry Air Pumps, **Conversion Kits, and Coupling Kits**

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for

comments.

SUMMARY: This document publishes in the Federal Register an amendment adopting Airworthiness Directive (AD) 98-23-01, which was sent previously to all known U.S. owners and operators of aircraft and engines equipped with certain Parker Hannifin Airborne dry air pumps, conversion kits, and coupling kits, utilizing part number (P/N) B1-19-1 flexible coupling that has a date code resembling a clockface and indicating a manufacture date of either "12/97" or "5-6/98". This AD requires replacing the affected flexible coupling with P/N B1-7-3 flexible coupling (part of Parker Hannifin flexible coupling kit, Airborne P/N 350). The AD resulted from reports

of failure of the affected flexible coupling due to a manufacturing defect of this coupling. The actions specified by this AD are intended to prevent failure of the primary dry air pump caused by defective flexible coupling, which could result in loss of primary attitude and direction references during instrument flight rules (IFR) operations.

DATES: Effective November 20, 1998, to all persons except those to whom it was made immediately effective by priority letter AD 98–23–01, issued October 29, 1998, which contained the requirements of this amendment.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 20, 1998.

Comments for inclusion in the Rules Docket must be received on or before January 5, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket 98–CE–108–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Copies of the applicable service information may be obtained from the Parker Hannifin Corporation, Airborne Division, 711 Taylor Street, Elyria, Ohio 44035; telephone: (440) 937–1315; facsimile: (440) 937–5409. This information may also be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Mr. Roy Boffo, Aerospace Engineer, FAA, Chicago Aircraft Certification Office, Systems and Flight Test Branch, 2300 E. Devon Avenue, Des Plaines, Illinois 60018; telephone: (847) 294–7564; facsimile: (847) 294–7834.

SUPPLEMENTARY INFORMATION:

Discussion

On October 29, 1998, the FAA issued priority letter AD 98–23–01, which applies to aircraft or engines equipped with certain Parker Hannifin Airborne dry air pumps, conversion kits, and coupling kits, utilizing P/N B1-19-1 flexible coupling that has a date code resembling a clockface and indicating a manufacture date of either "12/97" or "5-6/98". This AD requires replacing the affected flexible coupling with P/N B1-7-3 flexible coupling (part of Parker Hannifin flexible coupling kit, Airborne P/N 350), in accordance with Parker Hannifin Airborne Service Letter No. 48, dated October 20, 1998.

That AD resulted from approximately 50 reports of failure of the flexible coupling on certain Parker Hannifin Airborne dry air pumps, conversion kits, and coupling kits installed in aircraft or engines. To this date, no accidents have occurred due to the failure of this coupling. This condition could result in loss of primary attitude and direction references during instrument flight rules (IFR) operations.

This condition is attributed to a manufacturing defect of Lots 1 and 2 of the B1–19–1 flexible coupling. This coupling was shipped between January 1, 1998, and October 13, 1998. Dry air pumps, conversion kits, and flexible coupling kits that incorporate any of the part numbers and serial numbers referenced in the Applicability section of this AD could have this manufacturing defect.

Dry air pumps that could incorporate the part number (P/N) B1–19–1 flexible coupling are installed as original equipment on many airplanes, particularly Cessna, Raytheon, Piper, and Mooney airplanes. In addition, Parker Hannifin holds a parts manufacturer approval (PMA) for field replacements. The dry air pumps are the primary vacuum source on small single-engine airplanes and the secondary vacuum source on larger twin-engine airplanes.

The affected flexible coupling was shipped from Parker Hannifin between January 1, 1998, and October 13, 1998.

Airborne dry air pumps, conversion kits, or coupling kits that were installed or modified prior to January 1, 1998, would not incorporate the affected coupling. A check of the maintenance records would show whether the dry air pump, conversion kit, or coupling kit was installed or modified prior to January 1, 1998.

Those Airborne dry air pumps, conversion kits, or coupling kits installed or modified between January 1, 1998, and October 13, 1998, could incorporate the affected coupling, depending on when the material was received. The coupling could be held as spares or obtained from salvaged parts. For this reason, any dry air pump, conversion kit, or coupling kit with flexible coupling, P/N B1-19-1, that was installed or modified after January 1, 1998, could be affected by the above condition. The flexible coupling has a date code that resembles a clockface and indicates a manufacture date of either "12/97" or "5-6/98".

Relevant Service Information

Parker Hannifin issued Airborne Service Letter No. 48, dated October 20, 1998, which specifies procedures for:

- —Removing the dry air pump from the aircraft;
- —Inspecting and identifying the P/N B1-19-1 flexible coupling; and
- —Replacing the P/N B1-19-1 flexible coupling with P/N B1-7-3 flexible coupling (part of Parker Hannifin flexible coupling kit, Airborne P/N 350).

The FAA's Determination and Explanation of the AD

Since an unsafe condition has been identified that is likely to exist or develop in other aircraft or engines equipped with the above-referenced flexible coupling, the FAA issued priority letter AD 98–23–01 to prevent failure of the primary dry air pump caused by defective flexible coupling, which could result in loss of primary attitude and direction references during IFR operations.

Determination of the Effective Date of the AD

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual letters issued on October 29, 1998, to all known U.S. operators of aircraft or engines equipped with the abovereferenced flexible coupling. These conditions still exist, and the AD is hereby published in the Federal Register as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective as to all persons.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting immediate flight safety and, thus, was not preceded by notice and opportunity to comment, 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 above. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD 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 AD 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. 98–CE–108–AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

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 an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, 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 a new airworthiness directive (AD) to read as follows:

98–23–01 Parker Hannifin Corporation:Amendment 39–10882; Docket No. 98–CE–108–AD.

Applicability: The following Airborne dry air pumps, conversion kits, and coupling kits, with flexible coupling, part number (P/N) B1–19–1, that:

- 1. Have a date code resembling a clockface on the coupling and indicating a manufacture date of either "12/97" or "5–6/98"; and
- 2. Are installed in, but not limited to, the following aircraft or engine models, certificated in any category, that are listed in the Appendix to this AD:

Item	Part number	Serial numbers
Dry Air Pump Conversion Kit Conversion Kit Coupling Kit	211CC-9 E211CC 212CW	2AP1 through 10AP319. 1AP1 through 2AP5. 11AN543 through 11AN642 and 2AP1 through 7AP442. 2AP1 through 7AP286. 1AP1 through 7AP492. 12AN719 through 12AN940 and 1AP1 through 9AP3510. 2AP1 through 7AP95. 12AN521 through 12AN660 and 1AP1 through 10AP2695. 4AP120 through 4AP122 and 8AP256 through 8AP258. 2AP30 through 2AP43, 4AP134, 4AP136, and 4AP137. 1AP1 through 1AP3. 1AP through 9AP and N/A (see Note 1 below).

Note 1: Some of the part number 350 coupling kits incorporated serial numbers 1AP through 9AP, while others were marked with "N/A" in the serial number block.

Note 2: The affected flexible coupling was shipped from Parker Hannifin between January 1, 1998, and October 13, 1998. Dry air pumps, conversion kits, or coupling kits that were installed or modified prior to January 1, 1998, would not incorporate the affected coupling. This AD allows the aircraft owner or pilot to check the maintenance records to determine whether the dry air pump, conversion kit, or coupling kit was installed or modified since January 1, 1998. See paragraph (d) of this AD for authorization.

Note 3: This AD applies to any aircraft or engine equipped with Airborne dry air pumps, conversion kits, and coupling kits, that have flexible coupling, part number (P/N) B1–19–1. Aircraft or engines with the P/N B1–19–1 flexible coupling are affected

regardless of whether they have been modified, altered, or repaired in the area subject to the requirements of this AD. For aircraft or engines 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 (f) 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 the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated in the body of this AD, unless already accomplished.

To prevent failure of the primary dry air pump caused by defective flexible coupling, which could result in loss of primary attitude and direction references during instrument flight rules (IFR) operations, accomplish the following:

(a) Within 2 calendar days after the effective date of this AD or prior to further flight after the effective date of this AD, whichever occurs later, replace any affected flexible coupling with P/N B1–7–3 flexible coupling (part of Parker Hannifin flexible coupling kit, Airborne P/N 350) in accordance withParker Hannifin Airborne Service Letter No. 48, dated October 20, 1998.

- (b) If parts have been ordered from Parker Hannifin, but are not available, accomplish the following:
 - (1) Operate the aircraft in visual flight rules (VFR) conditions only;
- (2) Operate the aircraft during daytime hours only; and
- (3) When parts become available, replace the coupling prior to further flight.
- (c) As of the effective date of this AD, no person shall install, on any aircraft or engine,

any of the affected Airborne dry air pumps, conversion kits, and coupling kits, with part number (P/N) B1–19–1 flexible coupling that has a date code resembling a clockface on the coupling and indicating a manufacture date of either "12/97" or "5–6/98".

- (d) The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may check the maintenance records to determine whether the existing dry air pump, conversion kit, or coupling kit was installed or modified since January 1, 1998. If the dry air pump, conversion kit, or coupling kit was not installed or modified since January 1, 1998, the AD does not apply and the owner/operator must make an entry into the aircraft records showing compliance with this AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).
- (e) Special flight permits may be issued in accordance with sections 21.197 and 21.199

- of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished, provided that:
- (1) The aircraft is operated in VFR conditions only; and
- (2) The aircraft is operated during daytime hours only.
- (f) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Chicago Aircraft Certification Office (ACO), 2300 E. Devon Avenue, Des Plaines, Illinois 60018. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Chicago ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Chicago ACO.

- (g) The replacement required by this AD shall be done in accordance with Parker Hannifin Airborne Service Letter No. 48, dated October 20, 1998. 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 Parker Hannifin Corporation, Airborne Division, 711 Taylor Street, Elyria, Ohio 44035. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.
- (h) This amendment becomes effective on November 20, 1998, except those persons to whom it was made immediately effective by priority letter AD 98–23–01, issued October 29, 1998, which contained the requirements of this amendment.

APPENDIX TO AD 98-23-01; DOCKET NO. 98-CE-108-AD

Part name	Part No.	Airplane/engine make/model
Part name Dry Air Pump	Part No. 211CC, 215CC, E211CC	Airplane/engine make/model AIRPLANES Aerospatiale / TB9, TB10, TB20. Beech / 19, 19A, B19, 23, B23, C23, 24, A24, A24R, B24R, C24R, 76, 77, E95. Cessna / F152, FA152, 172, FR172K, R172K, 177, 177RG, FR182, R182, TR182, T182, T303, 336, 337, F337, T337G, P337, FT337, 411, 411A, 421A, 421B, 421C. Grumman / AAA1B, AA1C, AA5A, AA5B, GA7. Lake / LA-4-200, 250. Maule / M4-210. Mooney / M20B, M20C, M20D, M20E, M20F, M20G, M20J, M20K. Navion / G, H. Piper / PA-18, PA18-150, PA-22-108, PA-23-235, PA-23-250, PA-24-180, PA-24-250, PA-24-260, PA-24-400, PA-28-140, PA-28-150, PA-28-151, PA-28-160, PA-28-161, PA-28-180, PA-28-180, PA-28-151, PA-28-160, PA-28-161, PA-28-201, PA-28R-201T, PA-28RT-201T, PA-28RT-201T, PA-28RT-201T, PA-28RT-201T, PA-28RT-201T, PA-28RT-300, PA-31-350, PA-31-350, PA-31-350, PA-31-350, PA-32-260, PA-32-300, PA-32R-300, PA-32R-301T, PA-32R-301T, PA-32R-301T, PA-32R-301T, PA-34-200, PA-34-200T, PA-38-112, PA-39, PA-44-180T.
Dry Air Pump	211CC-9, 215CC-9	44–1801. Rockwell / 100, 112, 112A, 112B, 112TC, 112TCA, 114, 114A, 180. Lovaux Ltd. / Optica OA7, Series 300 (FLS Aerospace). ENGINES Textron Lycoming / 0–235, 0–290, 0–320, 0–360, 0–435, 0–540, IO–320. IO–360, IO–540, IO–720, TIO–360, TIO–540, GO–480, GSO–480. Continental / 0–300, GO–300, IO–360, TSIO–360, TSIO–520, GTSIO–520. United Aircraft / PT6A, PT6B. AIRPLANES Cessna / 150, A150K, A150K, A150M, F150K, F150L, F150M, FA150K,
		FA150L, FA150M, 152, A152, 172, 177, 337. ENGINES Textron Lycoming / 0–320. Continental / C90–16, 0–200.
Dry Air Pump	212CW, E212CW, 216CW	AIRPLANES Beech / A23, A23A, E33, E33A, F33A, F33C, V35A, V35A-TC, 36, A36, A36TC, B36TC, B55, 58, 76. Britten Norman / BN-2A. Cessna / 152, A152, 172, 180, 182H thru M, 182N and P, F182, R182, TR182, T182, 185, U206, TU206, 207, T207, 210, T210, P210, T303, 310P, 310P, 335, 340, 340A, 401, 401A, 401B, 402, 402A, 402B, 414, 414A. Helio / H295. Maule / M4-220. Mooney / M20K, M22. Navion / G, H. Piper / PA-31-325, PA-31-350, PA-31P-350, PA-34-200, PA-34-200T, PA-39, PA-44-180, PA-44-180T, PA-46-310P, PA-46-350.

APPENDIX TO AD 98-23-01; DOCKET No. 98-CE-108-AD-Continued

Part name	Part No.	Airplane/engine make/model
		ENGINES
		Textron Lycoming / LIO-360, GO-435, TIO-541.
		Continental / E-185, E-225, IO-346, O-470, IO-470, TSIO-470, IO-520.
		Franklin / 6A–335, 6A–350.
Conversion Kit	300–1	Cessna / 172A, 172B thru 172H.
		Piper / PA-22-108, PA-22-135, PA-22S-135, PA-22-150, PA-22S-150, PA-
		22–160, PA–22S–160.
Conversion Kit	300–2	Beech / 35 thru S35, 35–33 thru 35–A33, 35–B33.
		Cessna / 175 thru 175A, 175B, 175C, P172D, 180 thru 180H, 182 thru 182H,
		185 thru 185D, 210, 210A thru 210J, 210-5, 210-5A.
Conversion Kit	300–3	Cessna / 150, 150A thru 150H.
Coupling Kit	350	Coupling kit may have been put on any of the above list airplanes or engines.

Issued in Kansas City, Missouri, on November 4, 1998.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98-30170 Filed 11-16-98: 8:45 am] BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 121, and 125 [Docket No. 28537; SFAR 50-2]

Special Flight Rules in the Vicinity of Grand Canyon National Park

AGENCY: Federal Aviation Administration (FAA), DOT. **ACTION:** Final rule; correcting amendment: correction.

SUMMARY: This document contains a correction to the final rule published in the Federal Register (63 FR 23604) on April 29, 1998. The final rule corrected an error in the February 26, 1997, final rule, which inadvertently removed section 3 of SFAR No. 50-2 concerning special flight rules in the vicinity of Grand Canyon National Park. The April 1998 final rule corrected the error by reinstating section 3.

EFFECTIVE DATE: November 17, 1998. FOR FURTHER INFORMATION CONTACT: David L. Catey, (202) 267-8166.

Correction of Publication

In final rule FR Doc. 98–11335, on page 23604 in the **Federal Register** issue of April 29, 1998, make the following

On page 23604, in the first column, in the heading, "14 CFR Parts 91, 93, 121, and 135" should read "14 CFR Parts 91, 121, and 135"

On page 23604, in the first column, in the heading, "[Docket No. 28537; Amendment Nos. 91–257, 121–270, 135-72, 93-76]" should read "[Docket No. 28437; SFAR 50-2]".

Issued in Washington, DC, on November 4,

Donald P. Byrne,

Assistant Chief Counsel.

[FR Doc. 98-30090 Filed 11-16-98; 8:45 am] BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone **Acetate and Estradiol Benzoate**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of American Home Products Corp. The supplemental NADA provides for the use of a trenbolone acetate and estradiol benzoate ear implant in heifers fed in confinement for slaughter for increased rate of weight gain.

EFFECTIVE DATE: November 17, 1998. FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0217. SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St. NW., Ft. Dodge, IA 50501, filed supplemental NADA 141-043 that provides for use of an implantation containing 200 milligrams (mg) trenbolone acetate and 28 mg estradiol benzoate (Synovex® Plus) in heifers fed in confinement for slaughter for increased rate of weight gain. The supplemental NADA is approved as of

September 30, 1998, and the regulations are amended in 21 CFR 522.2478 by adding paragraph (c)(2) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

-In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305). Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food producing animals qualifies for 3 years of marketing exclusivity beginning September 30, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use in confined heifers for increased rate of weight gain for which the supplemental application is approved.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement

is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

-Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to