animals. Such frequent visits can be expensive.

Allowing veterinarians additional time to issue official animal health documents following inspection will enable those veterinarians to inspect animals less frequently. Therefore, this rule will economically benefit large livestock facilities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0032.

List of Subjects

9 CFR Part 160

Veterinarians.

9 CFR Part 161

Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 160 and 161 are amended as follows:

PART 160—DEFINITION OF TERMS

1. The authority citation for part 160 continues to read as follows:

Authority: 15 U.S.C. 1828; 21 U.S.C. 105, 111–114, 114a, 114a–1, 115, 116, 120, 121, 125, 134b, 134f, 612, and 613; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 160.1 is amended by adding, in alphabetical order, the following definitions:

§ 160.1 Definitions.

* * * * *

Issue. The distribution by an accredited veterinarian of an official animal health document that he or she has signed.

* * * * *

Regular health maintenance program. An arrangement between an accredited veterinarian and a livestock producer whereby the veterinarian inspects every animal on the premises of the producer at least once every 30 days.

* * * * *

PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

3. The authority citation for part 161 continues to read as follows:

Authority: 15 U.S.C. 1828; 21 U.S.C. 105, 111–114, 114a, 114a–1, 115, 116, 120, 121, 125, 134b, 134f, 612, and 613; 7 CFR 2.17, 2.51, and 371.2(d).

4. Section 161.3 is amended as follows:

a. By revising paragraphs (a) and (b) to read as set forth below.

b. In paragraph (c), by removing the phrase ''or sign'' in the first sentence.

c. In paragraph (k), by removing the phrase ''or sign'' in the first sentence.

§ 161.3 Standards for accredited veterinarian duties.

* * * * *

(a) An accredited veterinarian shall not issue a certificate, form, record or report which reflects the results of any inspection, test, vaccination or treatment performed by him or her with respect to any animal, other than those in regular health maintenance programs, unless he or she has personally inspected that animal within 10 days prior to issuance.

(1) Following the first two inspections of a herd or flock as part of a regular health maintenance program, an accredited veterinarian shall not issue a certificate, form, record or report which reflects the results of any inspection, test, vaccination or treatment performed by him or her with respect to any animal in that program, unless he or she has personally inspected that animal within 10 days prior to issuance.

(2) Following the third and subsequent inspections of a herd or flock in a regular health maintenance program, an accredited veterinarian shall not issue a certificate, form, record or report which reflects the results of any inspection, test, vaccination or treatment performed by him or her with respect to any animal in that program, unless he or she has personally inspected that animal within 30 days prior to issuance.

(b) An accredited veterinarian shall not issue, or allow to be used, any certificate, form, record or report, until, and unless, it has been accurately and fully completed, clearly identifying the animals to which it applies, and showing the dates and results of any inspection, test, vaccination, or treatment the accredited veterinarian has conducted, except as provided in paragraph (c) of this section, and the dates of issuance and expiration of the document. Certificates, forms, records, and reports shall be valid for 30 days following the date of inspection of the animal identified on the document. The accredited veterinarian shall distribute copies of certificates, forms, records, and reports according to instructions issued to him or her by the Veterinarian-in-Charge.

* * * * *

Done in Washington, DC, this 27th day of July 1995.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–19181 Filed 8–3–95; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94–ANE–10; Amendment 39–9328; AD 95–16–08]

Airworthiness Directives; AlliedSignal, Inc. TPE331 Series Turboprop and TSE331 Series Turboshaft Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to AlliedSignal, Inc. (formerly Allied-Signal, Inc., Garrett Engine Division, Garrett Turbine Engine Company, and AiResearch Manufacturing Co. of Arizona) TPE331 series turboprop and TSE331 series turboshaft engines, that requires a record check of engine records to determine if any repair, assembly, modification, or installation work was performed by Fliteline Maintenance, formerly located in Wharton, Texas, or Mr. Eugene E. Shanks, or Mr. Carl Ramirez (collectively referred to as ''Fliteline''). In addition, for engines determined to have repair, assembly, modification, or installation work

performed by Fliteline, this action requires verification of all life limited components, inspection of affected components, and verification of compliance with all applicable AD's. This amendment is prompted by the results of a Federal Aviation Administration (FAA) investigation involving engines repaired, assembled, modified, or installed by Fliteline. The actions specified by this AD are intended to prevent uncontained failure of turbine rotors, fire, or loss of aircraft control.

EFFECTIVE DATE; September 5, 1995.

FOR FURTHER INFORMATION CONTACT: Joseph Costa, Aerospace Engineer, Los Angeles Aircraft Certification Office, FAA, Transport Airplane Directorate, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (310) 627–5246, fax (310) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to AlliedSignal, Inc. (formerly Allied-Signal, Inc., Garrett Engine Division, Garrett Turbine Engine Company, and AiResearch Manufacturing Co. of Arizona) TPE331 series turboprop and TSE331 series turboshaft engines was published in the **Federal Register** on August 5, 1994 (59 FR 39983). That action proposed to require a record check of engine records to determine if any repair, assembly, modification, or installation work was performed by Fliteline Maintenance, formerly located in Wharton, Texas, or Mr. Eugene E. Shanks, or Mr. Carl Ramirez (collectively referred to as ''Fliteline''). In addition, for engines determined to have repair, assembly, modification, or installation work performed by Fliteline, this action requires verification of all life limited components, inspection of affected components, and verification of compliance with all applicable AD's.

The Federal Aviation Administration (FAA) received a report of an aircraft accident involving an Ayres S2R–600 aircraft, with a modified AlliedSignal, Inc. (formerly Allied-Signal, Inc., Garrett Engine Division, Garrett Turbine Engine Company, and AiResearch Manufacturing Co. of Arizona) Model TPE331–1–151A turboprop engine installed. The FAA has determined that the engine installed on the accident aircraft was a configuration not approved for that aircraft and was improperly modified. The unapproved configuration and improper modification on that engine were performed by Mr. Eugene E. Shanks, the owner of Fliteline Maintenance, a domestic repair station, formerly located in Wharton, Texas. Since this accident, the FAA conducted further investigation of other AlliedSignal, Inc. TPE331 series engines repaired or maintained by Mr. Eugene E. Shanks under the name of Fliteline Maintenance. On these engines, the FAA found that the requirements of some applicable AD's had not been performed when the engine records indicated that the work had been performed, the records for life limited turbine components indicated more useful life than the components actually had remaining, parts were installed that are not approved for aircraft use, and modifications that had been performed without approved data. In addition, the FAA has determined that the records maintained by Fliteline Maintenance on the engines it repaired, assembled, or modified do not identify all of the suspect engine models and serial numbers. These conditions, if not corrected, could result in uncontained failure of turbine rotors, fire, or loss of aircraft control.

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

One commenter concurs with the rule as proposed.

Two commenters describe their service history of safe operation with aircraft and engines maintained by Fliteline. Therefore the commenters conclude that no AD is necessary. The FAA does not concur. The FAA's investigation has revealed a substantial number of component and AD discrepancies on many engines maintained by Fliteline. These discrepancies constitute an unsafe condition that exists or is likely to develop on engines of the same type design. This AD corrects that unsafe condition.

One commenter states that an AD is not necessary because every operator that has maintenance performed by Fliteline should know exactly the configuration and condition of their engine because that operator pays the bills. The commenter believes that an Advisory Circular (AC) might be in order, not an AD. The FAA does not concur. An AC provides guidance and information for complying with a related Federal Aviation Regulation(s). This AD identifies those products in which the FAA has found an unsafe condition and prescribes the actions each operator must take to correct that unsafe condition.

Three commenters state that the FAA should attempt to identify the engines and life limited components by engine serial number rather than including every TPE331 engine in the applicability. The commenters state that AD applicability is too broad and unnecessary. The FAA does not concur. The FAA has determined that Fliteline performed maintenance on a wide range of engine models and life limited turbine components. In addition, Fliteline did not produce a reliable and comprehensive list of suspect engines and models. Therefore, the applicability of the AD encompasses a number of engine models and requires a records search to determine which life limited components are affected by the AD.

One commenter states that Mr. Ramirez's name should be removed from the AD because he identified a list of TPE331 series engine on which he performed maintenance, including serial numbers: P–06045, P–06460C, P–20050, P–20288, P–20411, P–34004, P–34010, P–34013, P–34015, P–40222, P–40227, P–61041, P–90252C, P–91094C, P–92129, P–92159, and P–92190. The FAA does not concur. The FAA was unable to verify that the list provided by Mr. Ramirez represented a complete list of all the engines maintained by him. Therefore the FAA could not justify removing his name from the AD.

One commenter states that 50% of the engines maintained by Fliteline were single engine restricted category aircraft that were certified under the predecessors to the Federal Aviation Regulations and implied that these engines should not be affected by the AD. The FAA does not concur. Airworthiness Directives issued under part 39 of the Federal Aviation Regulations apply to all identified products when an unsafe condition exists and when that condition is likely to exist and develop in other products of the same type design, regardless of the certification basis.

Two commenters state that the compliance time in paragraph (a) in the NPRM is unreasonably short for airlines with many suspect engines or with high utilization. The FAA concurs in part. The FAA's investigation has shown that it is very unlikely that a single owner would operate a fleet of engines maintained by Fliteline. However, the overall scope of the records review has increased. The records review now encompasses aircraft maintenance records and purchase receipts along with engine maintenance records. In addition, the FAA has determined that the 20 hour compliance time to complete paragraph (a) is not essential to maintain safety and therefore is not necessary. The AD has, therefore, been changed to require accomplishing paragraphs (a) and (b) within 400 cycles

in service after the effective date of this AD.

One commenter indicates that records of maintenance performed by Fliteline are no longer available due to Original Equipment Manufacturer (OEM) log book or life limited part log format changes or due to one-year maintenance records retention requirements. The commenter states that the records review requirements of paragraph (a) should be limited only to the last 12 months. The FAA does not concur. Life limited part logs must be kept for the life of the part regardless of the life limited part log format. In addition, other records may be required to be kept for a period longer than 12 months; therefore, the FAA has determined not to limit the record search to 12 months.

One commenter mentions that ''other pertinent data'' stated in paragraph (a) of the NPRM needs a better definition. The FAA concurs and has clarified this statement in this final rule by specifying the review of engine life limited part logs, engine repair and maintenance records, maintenance and purchase receipts, and aircraft records.

One commenter asks whether a list of persons or facilities, which performed maintenance on their engines, may be used for the records review requirement in paragraph (a) of the NPRM. The FAA does not concur that a list of persons or facilities constitutes a review of engine records as specified in paragraph (a) of this final rule. However, such a list, with additional assurances, may be adequate. Operators may apply for an alternative method of compliance using the procedures in paragraph (c) of this final rule.

One commenter states that the words, ''any repair, assembly, modification, or installation,'' as stated in paragraph (a) of the NPRM, are over inclusive, because not all of Fliteline's maintenance actions are related to the corrective actions required by this AD. The FAA concurs in part. The FAA has deleted the word ''installation'' from paragraph (a) of this final rule because installation includes engine installation about which the FAA is not concerned. The FAA has determined, however, to keep the words ''any engine repair, assembly, and modification,'' because the discrepancies noted in engines repaired by Fliteline are related to these actions.

One commenter states that life limited part logs of spare turbine wheels possibly received from Fliteline should be reviewed. The FAA agrees that operators must validate all Fliteline life limited part log entries for all life limited turbine components. This final rule has been revised to also include life limited turbine components received from Fliteline.

One commenter questions the use of engine manufacturer and repair station data to verify the life limited part logs. The commenter suggests that the FAA lacks the authority to require operators to verify the life limited part logs with data from the engine manufacturer or repair stations when those parties are not required to keep that data. The FAA does not concur. The data needed to accomplish the requirements of paragraph (b)(1)(ii) of the AD may be available from manufacturers or repair stations. However, paragraph (b)(1)(iii) provides that if the data is not available the component must be removed from service. The FAA has the authority to require operators to take actions necessary to correct the unsafe condition identified in this AD.

One commenter requests that the AD clarify the method for validating life limited part log entries. This commenter also questions whether documentation was required for compliance. The commenter suggests that paragraph (b)(1)(ii) requires a validation entry on each life limited part log to reflect compliance with this AD. The FAA concurs in part. Each registered owner or operator need only make a single entry in the maintenance records indicating compliance with this AD per Federal Aviation Regulation part 91.417 (a)(2)(v). However, the FAA recommends that documentation validating all Fliteline life limited part log entries be kept in the engine records or attached to the life limited part log.

Several commenters state that paragraph (b) does not have any provisions for relief if another engine entry (i.e., beyond nut removal) was accomplished by a different maintenance organization after maintenance performed by Fliteline. A commenter suggests the AD provide a credit, which will reduce unnecessary AD effort, which clearly addresses the possibility of an earlier entry and validation by an FAA approved maintenance facility or person after maintenance by Fliteline. The FAA concurs. Paragraph (b)(1)(i) of this final rule has been revised to allow credit for engine inspections and overhauls accomplished subsequent to maintenance performed by Fliteline. Paragraph (b)(2) of this final rule has also been revised to allow credit for complete engine overhaul accomplished by the engine manufacturer, FAA certified repair station, or FAA certified mechanic, other than Fliteline.

One commenter recommends that the phrase ''disassembled beyond shaft nut removal'' referenced in paragraph (b)(1) in the NPRM should be clarified to state ''disassembled beyond aft turbine mainshaft nut removal.'' The FAA concurs and has revised this final rule accordingly.

One commenter states that the FAA offers no comment on the cost of doing the initial record check on each engine referenced by the NPRM's applicability. The commenter recommends that the FAA address the time expended and cost of reviewing records. The FAA concurs and has revised the estimated number of engines, labor and cost involved in the initial record search in accordance with paragraph (a) in this AD.

One commenter questions the FAA's economic analysis stating that it does not include the cost of expendable parts. The FAA concurs. The FAA has re-evaluated the costs to correct improper maintenance as required by paragraph (b) in the compliance section of this AD and has revised the economic analysis section accordingly.

One commenter suggests that the FAA include the business address for Fliteline Maintenance in the AD. The FAA concurs in part. Fliteline Maintenance is no longer doing business as a certified repair station at its former location. The FAA has, however, decided to include the former location of Fliteline in the AD in order to avoid confusion with any other repair facility in the country using that name. The AD has been revised accordingly.

Several commenters take issue with the NPRM's discussion section. Since those comments did not directly suggest that the FAA needed to make changes to the rule as proposed, the FAA does not address them. To the extent those comments could be read to suggest a change to the rule, the FAA has addressed those comments in the preceding paragraphs.

The FAA has changed the compliance time in paragraph (b) of this final rule from 100 hours time in service to 400 cycles in service after the effective date of this AD. This change is based on data received from the engine manufacturer concerning replacement parts availability and a determination that a compliance interval based on engine cycles is more appropriate for the affected components.

In addition, the FAA has clarified the aircraft applicability in this final rule by adding the words ''models'' and ''series.'' Also, since publication of the NPRM, the Los Angeles Aircraft Certification Office has moved and the contact information has been revised accordingly.

After careful review of the available data, including the comments noted

above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously.

The FAA estimates that 7,000 engines installed on aircraft of U.S. registry will be affected by the initial records search described in paragraph (a) of the compliance section. The FAA has estimated that the initial records search will take approximately two hours per engine and that the average labor rate is $60. per work hour. Furthermore, the FAA estimates that 350 engines installed on aircraft of U.S. registry will be affected by paragraph (b) of this AD, that it will take approximately 120 work hours per engine to accomplish the actions required by paragraph (b), and that the average labor rate is $60 per work hour. It will also take an estimated three work hours per engine to accomplish an additional records review, and the FAA estimates that parts will cost approximately $16,000 per engine. Based on these figures, the FAA estimates that total cost impact of the AD on U.S. operators is estimated to be $9,023,000.

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.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

95–16–08 AlliedSignal, Inc.: Amendment 39–9328. Docket 94–ANE–10.

Applicability: AlliedSignal, Inc. (formerly Allied-Signal, Inc., Garrett Engine Division, Garrett Turbine Engine Company, and AiResearch Manufacturing Co. of Arizona), TPE331–25, –43, –1, –2, –3, –5, –6, –8, –10, –11, and –12 series, and -55B and -61A Model turboprop engines; and TSE331–3U Model turboshaft engines. These engines are installed on but not limited to Mitsubishi MU–2B series (MU–2 series); Construcciones Aeronauticas, S.A. (CASA) C–212 series; Jetstream 3101 and 3201 series; Fairchild SA226 and SA227 series; Prop-Jets, Inc. Model 400; Cessna Model 441; Twin Commander Aircraft Corp. 680, 690, and 695 series, and Model 681; Rockwell Commander or Ayres Corp. S–2R series; Short Brothers and Harland, Ltd. SC7; Dornier 228 Series; Beech Aircraft Corp. 18 and 45 series and Models JRB–6, 3N, 3NM, 3TM, and B100; Pilatus PC–6 series; DeHavilland DH 104 Dove series; Grumman Model TS–2A; Grumman American Model G–164C; and Schweitzer Aircraft Corp. Model G–164 series aircraft.

Note: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any engine from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent uncontained failure of turbine rotors, fire, or loss of aircraft control, accomplish the following:

(a) Within 400 cycles in service (CIS) after the effective date of this AD, review engine life limited part logs, engine repair and maintenance records, maintenance purchase receipts, and aircraft maintenance records (collectively referred to as ''records'') to identify any engine repair, assembly, or modification that was performed by, or any life limited turbine components received from Fliteline Maintenance, located in Wharton, Texas, domestic repair station certificate number GR2R856K; or Mr. Eugene E. Shanks, mechanic certificate number 1914482; or Mr. Carl Ramirez, mechanic certificate number 466432551 (collectively referred to as ''Fliteline'').

(b) Within 400 CIS after the effective date of this AD, for engines or components identified in accordance with paragraph (a) of this AD, accomplish the following:

(1) If records or other pertinent information indicate that the engine was disassembled beyond aft turbine mainshaft nut removal from the tie bolt by Fliteline, verify life limited turbine components and take appropriate action by the following methods:

(i) Remove, disassemble the engine, compare, and match each component's part number (P/N) and serial number (S/N) against that engine's issued life limited part logs. Engine hot section inspection or overhaul normally requires comparing and matching of turbine components with the life limited part logs. An engine hot section inspection or overhaul, subsequent to maintenance by Fliteline, and performed by the engine manufacturer, an FAA certified repair station, or an FAA certified mechanic, other than Fliteline, constitutes compliance with paragraph (b)(1)(i) of this AD.

(ii) Validate all Fliteline life limited part log entries by utilizing the component's hourly and cyclic life immediately before the Fliteline entry, as determined by records of the engine manufacturer or FAA certified repair stations other than Fliteline. A life limited part log entry is defined as a removal or installation record. Photocopied life limited part logs may be used provided component history can be established.

Note: Engine manufacturer record and service information referred to in the AD can be attained by calling AlliedSignal Engines Customer Information Center, telephone (800) 338–3378 or (602) 231–5287.

(iii) If the P/N, S/N, hourly and cyclic lives or the life limited part log of each life limited turbine component do not match or can not be validated, remove the component from service prior to further flight and replace with a serviceable component.

(2) Verify that any requirements of AD's signed off by Fliteline were actually accomplished by visual examination or reinspection of the affected components in accordance with the applicable AD. A complete engine overhaul or other maintenance necessary to accomplish applicable AD requirements, subsequent to maintenance by Fliteline, and performed by the engine manufacturer, an FAA certified repair station, or an FAA certified mechanic, other than Fliteline, constitutes compliance with paragraph (b)(2) of this AD.

(c) 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, Los Angeles Aircraft Certification Office. The request should be forwarded through an appropriate FAA Principal Maintenance Inspector, who may add comments and then

send it to the Manager, Los Angeles Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(d) 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 aircraft to a location where the requirements of this AD can be accomplished.

(e) This amendment becomes effective on September 5, 1995.

Issued in Burlington, Massachusetts, on July 26, 1995.

James C. Jones,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 95–19230 Filed 8–1–95; 2:30 pm]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

Animal Drugs, Feeds, and Related Products; Piperazine Adipate Powder, Diprenorphine Hydrochloride Injection, Etorphine Hydrochloride Injection, and Certain Nitrofuran and Buquinolate Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions reflecting approval of 16 new animal drug applications (NADA's) held by Proctor & Gamble Pharmaceuticals, Inc., Happy Jack, Inc., and Lemmon Co. The NADA's provide for the use of piperazine adipate powder, diprenorphine hydrochloride (diprenorphine HCl) injection, etorphine HCl injection, certain nitrofuran dosage form products, and separately approved Type A medicated articles containing buquinolate or certain other drugs in manufacturing several Type C medicated feeds for chickens. In a notice published in the July 21, 1995, issue of the **Federal Register**, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION: In a notice published in the July 21, 1995, issue of the **Federal Register** (60 FR 37651), FDA is withdrawing approval of the following NADA's:

NADA No.	Drug name	Sponsor name and address
10–158	Furamazone, bismuth subsalicylate bolus	Proctor & Gamble Pharmaceuticals, Inc., P.O. Box 191, Norwich, NY 13815.
10–358	Nitrofurantoin tablets and boluses	Do.
12–291	Nitrofurantoin oral suspension	Do.
12–612	Nitrofurazone, nifuroxime, diperodon HCl ear solution	Do.
34–716	Buquinolate	Do.
35–314	Buquinolate and bacitracin zinc	Do.
35–315	Buquinolate, bacitracin zinc, and penicillin	Do.
35–317	Buquinolate and penicillin	Do.
35–327	Buquinolate, bacitracin methylene disalicylate (bacitracin MD), and penicillin.	Do.
35–329	Buquinolate and bacitracin MD	Do.
38–657	Buquinolate and chlortetracycline	Do.
39–925	Buquinolate and roxarsone combination	Do.
39–926	Buquinolate and roxarsone	Do.
41–744	Nitrofurantoin sodium injection	Do.
95–017	Etorphine HCl injection and diprenorphine HCl injection	Lemmon Co., Sellersville, PA 18960.
115–580	Piperazine adipate powder	Happy Jack, Snow Hill, NC 28580.

The sponsors requested withdrawal of approval of the NADA's. This final rule removes 21 CFR 520.1560, 520.1560a, 520.1560b, 520.1801, 520.1801a, and 522.1563; amends 21 CFR 522.723 and 522.883 to reflect the withdrawal of approval of these NADA's; removes and reserves 21 CFR 524.1580a and 558.105; and amends 21 CFR 558.62, 558.128, 558.325, 558.460, and 558.530.

In addition, 21 CFR 510.600(c) is amended to remove the entries for Proctor & Gamble Pharmaceuticals, Inc., from the list of approved drug sponsors because it no longer holds any approved NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Proctor & Gamble Pharmaceuticals, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''000149''.