

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 adding the following new airworthiness directive (AD):

2012-11-07 Honeywell International, Inc.: Amendment 39-17070; Docket No. FAA-2012-0195; Directorate Identifier 2012-NE-08-AD.

(a) Effective Date

This AD is effective July 5, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Honeywell International, Inc. ALF502L-2C; ALF502R-3; ALF502R-3A; ALF502R-5; LF507-1F; and LF507-1H turbofan engines.

(d) Unsafe Condition

This AD was prompted by two reports of engines experiencing uncontained release of low-pressure (LP) turbine blades. We are issuing this AD to prevent LP turbine overspeed leading to uncontained release of the LP turbine blades and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(f) Initial Check of the Overspeed Trip System

Within 30 operating hours after the effective date of this AD, perform an initial check of the overspeed trip system, in accordance with the applicable paragraphs for your engine as follows:

(1) ALF502L-2C Engines

(i) With engine operating at 65 percent NL (N1) speed (28 to 30 percent if overspeed controller 2-303-052-04 or later is installed), pull toggle lever of cockpit OVERSPEED TEST/RESET switch and hold in the OVERSPEED TEST position.

(ii) Activation of the engine overspeed system shall be verified by:

(A) Engine OVERSPEED TRIP light illuminated in cockpit.

(B) Reduction of engine NH (N2) speed.

(C) When engine NH (N2) speed begins to decrease, retract engine power lever to fuel cutoff position and turn off fuel boost pumps.

(D) Release lever of engine cockpit OVERSPEED TEST/RESET Switch.

(E) When engine is completely shut down, reset the engine Overspeed System by momentarily holding the engine cockpit OVERSPEED TEST/RESET switch on the RESET position.

(F) If engine does not shut down, manually shut down engine and perform a detailed functional test of the overspeed system. Guidance on performing a detailed functional test of the overspeed system can be found in the applicable engine maintenance manual instructions.

(2) ALF502R-3; ALF502R-3A; ALF502R-5, and LF507-1H Engines

(i) With engine operating at ground idle, set engine NL (N1) speed to 30 to 35 percent.

(ii) Press cockpit OVERSPEED TEST switch and hold.

(iii) Activation of the engine overspeed system shall be verified by:

(A) Engine OVERSPEED TRIP light illuminated in cockpit.

(B) Shutdown of the engine [zero NH (N2) speed].

(iv) Release cockpit OVERSPEED TEST switch and retract power lever to fuel cutoff position.

(v) When the engine is completely shut down, reset the engine overspeed system.

(vi) If engine does not shut down, manually shut down engine and perform a detailed functional test of the overspeed system. Guidance on performing a detailed functional test of the overspeed system can be found in the applicable engine manual instructions.

(3) LF507-1F Engines

(i) With engine operating at ground idle, set engine NL (N1) speed to 30 to 35 percent.

(ii) Activate cockpit overspeed test circuit (GRND TEST ENG OVSPD).

(iii) After NL (N1) speed begins to decay, retard the throttle to the fuel cutoff position.

(iv) Verify the following conditions:

(A) Engine shutdown.

(B) Overspeed system light (ENG OVSPD) is illuminated in cockpit.

(v) Reset overspeed system circuit power.

(vi) If engine does not shut down, manually shut down engine and perform a detailed functional test of the overspeed system. Guidance on performing a detailed functional test of the overspeed system can be found in the applicable engine manual instructions.

(g) Repetitive Checks of the Overspeed Trip System

(1) For ALF502L-2C engines, perform repetitive checks of the overspeed trip system at 100-hour intervals of operation, as specified in paragraph (f)(1) of this AD.

(2) For ALF502R-3; ALF502R-3A; ALF502R-5; and LF507-1H engines, perform repetitive checks of the overspeed trip system once every flight day, as specified in paragraph (f)(2) of this AD.

(3) For LF507-1F engines, perform repetitive checks of the overspeed trip system

once every flight day, as specified in paragraph (f)(3) of this AD.

(h) Definition

For the purpose of this AD, a flight day is a 24-hour period during which at least one flight is indicated.

(i) Signing Off of Daily Repetitive Checks

Upon starting the daily repetitive checks, only one sign-off is required attesting to the daily check implementation.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Los Angeles Aircraft Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(k) Related Information

For more information about this AD, contact Robert Baitoo, Aerospace Engineer, Los Angeles Aircraft Certification Office, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; phone: 562-627-5245; fax: 562-627-5210; email: robert.baitoo@faa.gov.

Issued in Burlington, Massachusetts, on May 23, 2012.

Peter A. White,

Manager Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012-13082 Filed 5-30-12; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 748****Applications (Classification, Advisory, and License) and Documentation****CFR Correction**

■ In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of April 1, 2012, on page 459, in Supplement 7 to part 748, in the fourth column of the table, the two entries for “National Semiconductor Hong Kong Limited” are removed.

[FR Doc. 2012-13246 Filed 5-30-12; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 510, 516, 520, 522, and 558**

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Altrenogest; Dexamethasone; Flornfenicol

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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during April 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective May 31, 2012.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA's Center for Veterinary Medicine (CVM) is adopting use of a monthly **Federal Register** document to codify approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs). CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during April 2012, as listed in table 1 of this document. FDA is also informing the public of the availability, where applicable, of environmental review documents required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data,

summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (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. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL 2012

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA summary	NEPA review
141-246	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	AQUAFLO (florfenicol) Type A medicated article.	Supplemental approval to: (1) Increase the permitted concentrations in Type C feeds; (2) add an indication for the control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> ; (3) add an indication for the control of mortality due to streptococcal septicemia associated with <i>Streptococcus iniae</i> in freshwater-reared warmwater finfish; and (4) increase the withdrawal period to 15 days. This approval renders § 516.1215 obsolete.	516.1215, 558.261.	yes	EA/FONSI. ¹
200-456	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861.	Dexamethasone Injectable Solution.	Original approval of a generic copy of NADA 012-559.	522.540	yes	CE. ²
200-481	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.	ALTRESYN (altrenogest) Solution 0.22%.	Original approval of a generic copy of NADA 131-310.	520.48	yes	CE. ²

¹ Based on its review of an environmental assessment (EA) submitted by the sponsor, the Agency has concluded that this action will not have a significant impact on the human environment and that an environmental impact statement is not required. A finding of no significant impact (FONSI) has been prepared.

² The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an EA or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling,

Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

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, 516, 520, 522, 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: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for “Ceva Sante Animale”; and in the table in paragraph (c)(2), numerically add an entry for “013744” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
 (c) * * *
 (1) * * *

Firm name and address	Drug labeler code
Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France	013744

(2) * * *

Drug labeler code	Firm name and address
013744	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

§ 516.1215 [Removed]

■ 4. Remove § 516.1215.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 6. In § 520.48, revise paragraph (b) to read as follows:

§ 520.48 Altrenogest.

(b) *Sponsors.* See sponsor listings in § 510.600(c) of this chapter:
 (1) No. 000061 for use as in paragraph (d) of this section.
 (2) No. 013744 for use as in paragraph (d)(1) of this section.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 8. In § 522.540, revise the section heading and paragraphs (a)(2)(ii) and (a)(3)(iii) to read as follows:

§ 522.540 Dexamethasone.

(a) * * *
 (2) * * *

(ii) *Sponsors.* See Nos. 054925 and 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) * * *

(iii) Do not use in horses intended for human food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 9. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 10. In § 558.261, revise paragraphs (a)(2) and (c)(2)(i), and the table in paragraph (e)(2) to read as follows:

§ 558.261 Florfenicol.

(a) * * *
 (2) 500 grams per kilogram for use as in paragraph (e)(2) of this section.

(c) * * *

(2) * * *

(i) For freshwater-reared finfish, must not exceed 15 days from the date of issuance.

(e) * * *
 (2) * * *

Florfenicol in grams/ton of feed	Indications for use	Limitations
(i) 182 to 2,724	Catfish: For the control of mortality due to enteric septicemia of catfish associated with <i>Edwardsiella ictaluri</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 milligrams (mg) florfenicol per kilogram (kg) of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> and furunculosis associated with <i>Aeromonas salmonicida</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Florfenicol in grams/ton of feed	Indications for use	Limitations
(iii) 182 to 2,724	Freshwater-reared finfish: For the control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> .	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish for freshwater-reared warmwater finfish and 10 mg florfenicol per kg of fish for other freshwater-reared finfish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(iv) 273 to 2,724	Freshwater-reared warmwater finfish: For the control of mortality due to streptococcal septicemia associated with <i>Streptococcus iniae</i> .	Feed as a sole ration for 10 consecutive days to deliver 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Dated: May 24, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-13095 Filed 5-30-12; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

[FHWA Docket No. FHWA-2012-0037]

RIN 2125-AF45

Truck Size and Weight; Technical Correction

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Final rule; technical correction.

SUMMARY: This rule makes a technical correction to the regulations that govern Longer Combination Vehicles (LCV) for the States of Oregon and Nebraska. The amendments contained herein make no substantive changes to FHWA regulations, policies, or procedures.

DATES: This rule is effective July 2, 2012.

FOR FURTHER INFORMATION CONTACT: John Nicholas, Truck Size and Weight Program Manager, Office of Freight Management and Operations, (202) 366-2317; or Bill Winne, Office of the Chief Counsel, (202) 366-1397. Both are located at 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours for FHWA are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded by accessing the Office of the Federal Register's home page at: <http://www.archives.gov> or the Government Printing Office's Web page at: <http://www.gpoaccess.gov/nara>.

Background

This rulemaking makes technical corrections to the regulations in appendix C of 23 CFR part 658 that govern length of trailers in Oregon and the length of permit duration in Nebraska. The regulations on LCV's were frozen as of July 1, 1991, in accordance with Section 1023 of the Intermodal Surface Transportation Efficiency Act (ISTEA)¹ but a provision was made available in 23 CFR 658.23(f) that requires the FHWA Administrator to review petitions to correct any errors in Appendix C. The States of Oregon and Nebraska have petitioned the Federal Highway Administrator to make corrections to items they found to be incorrect in accordance with 23 CFR 658.23(f), and certified those provisions were in effect as of July 1, 1991.

Oregon Department of Transportation petitioned the FHWA Administrator that the section of Appendix C that describes operational conditions for triple trailers on Oregon's Interstate highways is not accurate. Oregon's law that was in effect at the time Appendix C was adopted, June 1, 1991, required only that the trailers be “* * * reasonably uniform in length,” rather than of “equal length” as stated in

Appendix C. The substitution of language, “reasonably uniform in length,” will correct the language and bring it into conformance with Oregon statutes of that time.²

Nebraska Department of Roads petitioned the FHWA Administrator to change 120 days for the maximum duration of a permit, as currently written in Appendix C, to allow 150 days for the maximum permit time as included in Nebraska Statutes in July 1991. The substitution of 150 days for the current 120 days will correct the language and bring it into conformance with Nebraska statutes of that time.³

Rulemaking Analyses and Notice

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The FHWA finds that notice and comment for this rule is unnecessary and contrary to the public interest because it will have no substantive impact, is technical in nature, and relates only to management, organization, procedure, and practice. The amendments to the rule are based upon the explicit language of statutes that were enacted subsequent to the promulgation of the rule. The FHWA does not anticipate receiving meaningful comments. States, local governments, motor carriers, and other transportation stakeholders rely upon the regulations corrected by this action. These corrections will reduce confusion

¹ Public Law 105-240, 105 Stat. 1914, 1951 (Dec. 18, 1991) (codified at 23 U.S.C. 127(d)).

² Oregon Vehicle Code 812.210 (1991-1992).

³ Neb. Rev. Stat. 39-6,181 (Cum. Supp. 1986).