

(78 FR 11572, February 19, 2013). Allowing the airworthiness limitation section (ALS) required by AD 2008–07–11 to remain valid could cause confusion as to what is required and this could introduce an unsafe condition if certain areas were not inspected. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2008–0070; Directorate Identifier 2007–CE–098–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under

Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) 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.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing AD 2008–07–11, Amendment 39–15452 (73 FR 18433, April 4, 2008), and adding the following new AD:

2008–07–11 R1 PILATUS AIRCRAFT LTD.:
Amendment 39–17398; Docket No. FAA–2008–0070; Directorate Identifier 2007–CE–098–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective April 15, 2013.

(b) Affected ADs

This AD rescinds AD 2008–07–11, Amendment 39–15452 (73 FR 18433, April 4, 2008).

(c) Applicability

This AD applies to PILATUS AIRCRAFT LTD. Models PC–12, PC–12/45, and PC–12/47 airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

Issued in Kansas City, Missouri on March 11, 2013.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–06169 Filed 3–22–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, 524, and 529

[Docket No. FDA–2013–N–0002]

New Animal Drug Approvals; Change of Sponsor; Change of Sponsor’s Drug Labeler Code; Gonadorelin Acetate; Isoflurane; Praziquantel; Propofol; Sevoflurane; Triamcinolone Acetonide

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 January 2013. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect changes of sponsorship for an NADA and ANADA, and a change of a sponsor’s drug labeler code.

DATES: This rule is effective March 25, 2013.

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, email: george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review 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 through the Center for Veterinary Medicine's (CVM's) FOIA Electronic Reading Room at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

In addition, FDA is amending the animal drug regulations to reflect changes of sponsorship for an NADA and ANADA, and a change of a sponsor's drug labeler code.

RMS Laboratories, Inc., 1903 East First St., Vidalia, GA 30474, has

informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–210 for GENESIS (triamcinolone acetate) Topical Spray to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137. Following this change of sponsorship, RMS Laboratories, Inc., will no longer be the sponsor of an approved application.

Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–176 for PRAZITECH (praziquantel) Injectable Solution to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.

Abbott Laboratories, North Chicago, IL 60064, has informed FDA of a change in drug labeler code. Accordingly, the Agency is amending the regulations in 21 CFR 510.600 to reflect this change of drug labeler code and to remove entries for RMS Laboratories, Inc., and in 21 CFR parts 522 and 529 to make conforming changes to Abbott Laboratories' product listings.

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 JANUARY 2013

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
200–541	Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.	GONABREED (gonadorelin acetate) Injectable Solution.	1. Original approval as a generic copy of NADA 098–379; and. 2. Supplemental approval for use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination in lactating dairy cows and beef cows. ¹	522.1073	yes	1. CE ² 2. EA/FONSI ³

¹ Supplemental approval under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act.

² The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment (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.

³ Based on its review of an 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 EIS is not required. A finding of no significant impact (FONSI) has been prepared.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 522, 524, and 529

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 the Center for Veterinary Medicine, 21 CFR parts 510, 522, 524, and 529 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. Amend § 510.600 as follows:

■ a. In the table in paragraph (c)(1), revise the entry for "Abbott

Laboratories" and remove the entry for "RMS Laboratories, Inc."; and

■ b. In the table in paragraph (c)(2), remove the entries for "000074" and "067292" and add an entry for "000044" in numerical order.

The addition and revision 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
* * * * *	
Abbott Laboratories, North Chicago, IL 60064	000044
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
000044	Abbott Laboratories, North Chicago, IL 60064.
* * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Add § 522.1073 to read as follows:

§ 522.1073 Gonadorelin acetate.

(a) *Specifications.* Each milliliter of solution contains 100 micrograms (µg) of gonadorelin as gonadorelin acetate.

(b) *Sponsor.* See No. 068504 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Indications for use and amounts.*

(i) For the treatment of ovarian follicular cysts in dairy cattle. Administer 100 µg gonadorelin by intramuscular or intravenous injection.

(ii) For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed-time artificial insemination in lactating dairy cows and beef cows. Administer to each cow 100 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 100 µg gonadorelin by intramuscular injection.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 5. In § 522.1077, revise the section heading to read as set forth below; and in paragraph (c)(3), remove the first sentence.

§ 522.1077 Gonadorelin hydrochloride.

* * * * *

§ 522.1078 [Redesignated as § 522.1075]

■ 6. Redesignate § 522.1078 as § 522.1075.

■ 7. In § 522.1870, revise the section heading and paragraphs (b), (c)(1)(iii), and (c)(2)(iii) to read as follows:

§ 522.1870 Praziquantel.

* * * * *

(b) *Sponsors.* See Nos. 000859 and 061623 in § 510.600(c) of this chapter.

(c) * * *

(1) * * *

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2005 [Amended]

■ 8. In paragraph (b)(2) of § 522.2005, remove “000074” and in its place add “000044”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.2482 [Amended]

■ 10. In paragraph (b) of § 524.2482, remove “067292” and in its place add “051311”.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 11. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1186 [Amended]

■ 12. In paragraph (b) of § 529.1186, remove “000074” and in its place add “000044”.

§ 529.2150 [Amended]

■ 13. In paragraph (b) of § 529.2150, remove “000074” and in its place add “000044”.

Dated: March 20, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013-06748 Filed 3-22-13; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9612]

RIN 1545-BA53

Noncompensatory Partnership Options; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9612) that were published in the **Federal Register** on Tuesday, February 5, 2013 (78 FR 7997) relating to the tax treatment of noncompensatory options and convertible instruments issued by a partnership. The final regulations generally provide that the exercise of a noncompensatory option does not cause the recognition of immediate income or loss by either the issuing partnership or the option holder. The final regulations

also modify the regulations under section 704(b) regarding the maintenance of the partners’ capital accounts and the determination of the partners’ distributive shares of partnership items. The final regulations also contain a characterization rule providing that the holder of a noncompensatory option is treated as a partner under certain circumstances.

DATES: This correction is effective on March 25, 2013 and is applicable on or after February 5, 2013.

FOR FURTHER INFORMATION CONTACT: Benjamin Weaver, at (202) 622-3050 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this document are under sections 171, 704, 721, 761, 1272, 1273, and 1275 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9612) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.704-1 is amended by revising the table in paragraph (b)(5) *Example 35* (ii), and the first sentence of paragraph (b)(5) *Example 35* (iii) to read as follows:

§ 1.704-1 Partner’s distributive share.

* * * * *

(b) * * *

(5) * * *

Example 35. * * *

(ii) * * *

	K		L		M	
	Tax	Book	Tax	Book	Tax	Book
Initial capital account	\$10,000	\$10,000	\$10,000	\$10,000	0	0
Year 1 net income	1,000	1,000	1,000	1,000	0	0
Year 2 net income	1,000	1,000	1,000	1,000	0	0
Year 3 net income	1,000	1,000	1,000	1,000	0	0
Year 4 initial capital account	13,000	13,000	13,000	13,000	0	0