direct final rule that published in the **Federal Register** of December 4, 2007 (72 FR 68064), to amend certain regulations as the first phase of an incremental approach to modernize or clarify some of the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, as well as harmonize some of the CGMP requirements with those of other foreign regulators and other FDA regulations. The comment period closed February 19, 2008. FDA is withdrawing the direct final rule because the agency received significant adverse comments. FDA will consider the comments received under our usual procedures for notice and comment in connection with the notice of proposed rulemaking that was published in the **Federal Register** of December 4, 2007, as a companion to the direct final rule (72 FR 68113).

DATES: The direct final rule published at 72 FR 68064 on December 4, 2007, is withdrawn as of April 4, 2008.

FOR FURTHER INFORMATION CONTACT:
Mary Malarkey, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, or
Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8268, or
Brian Hasselbalch, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3279.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on December 4, 2007 (72 FR 68064) is withdrawn.

Dated: March 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–7107 Filed 4–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 526, and 558

Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of NADAs; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of seven new animal drug applications (NADAs) because FDA is withdrawing approval of the NADAs.

DATES: This rule is effective April 4, 2008.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9067; e-mail: *pamela.esposito@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the seven NADAs listed below because the products are no longer manufactured or marketed:

Sponsor	NADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Eon Labs Manufacturing, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413	NADA 65–063, Tetracycline capsules	520.2345a (000185)
	NADA 65–345, Chloramphenicol capsules	520.390b (000185)
G.C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201	NADA 65–465, AQUA-MAST (penicillin G procaine)	526.1696a (010515)
International Nutrition, Inc., 7706 "I" Plaza, Omaha, NE 68127	NADA 95–551, TYLAN 5 Premix (tylosin phosphate)	558.625 (043733)
	NADA 109–688, HYGROMIX 2.4 Premix (hygromycin B)	558.274 (043733)
	NADA 109–816, TYLAN 10 SULFA-G Premix (tylosin phosphate and sulfamethazine)	558.630 (043733)
Pfizer, Inc., 235 East 42d St., New York, NY 10017	NADA 103–758, TERAMIX–10 Premix (oxytetracycline)	Not codified

Following the withdrawal of approval of these NADAs, Eon Labs Manufacturing, Inc., is no longer sponsor of an approved application. Therefore, 21 CFR 510.600(c) is amended to remove entries for this sponsor.

As provided below, the animal drug regulations are amended to reflect the withdrawal of approvals. The regulations for penicillin G procaine

intramammary dosage forms (21 CFR 526.1696a) are also amended to correct several errors and to reflect a current format.

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.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520 and 526

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, 526, 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.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for ''Eon Labs Manufacturing, Inc.''; and in the table in paragraph (c)(2) remove the entry for ''000185''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.390b [Amended]

■ 4. In § 520.390b, in paragraph (b)(1), remove '', 000185,''.

§ 520.2345a [Amended]

■ 5. In § 520.2345a, remove paragraph (b)(3).

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 6. The authority citation for 21 CFR part 526 continues to read as follows:

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

■ 7. Revise § 526.1696a to read as follows:

§ 526.1696a Penicillin G procaine.

(a) *Specifications.* Each 10-milliliter single-dose syringe contains penicillin G procaine equivalent to 100,000 units of penicillin G.

(b) *Related tolerances.* See § 556.510 of this chapter.

(c) *Sponsors.* See Nos. 010515 and 050604 in § 510.600(c) of this chapter.

(d) *Conditions of use in lactating cows*—(1) *Amount.* Infuse one 10-milliliter dose into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than three doses, as indicated by clinical response.

(2) *Indications for use.* For the treatment of mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberus* in lactating cows.

(3) *Limitations.* Milk that has been taken from animals during treatment and for 60 hours after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

(e) *Conditions of use in dry cows*—(1) *Amount.* Infuse one 10-milliliter dose into each infected quarter at time of drying-off.

(2) *Indications of use.* For the treatment of mastitis caused by *Streptococcus agalactiae* in dry cows.

(3) *Limitations.* Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk. Animals must not be slaughtered for food within 14 days postinfusion.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.274 [Amended]

■ 9. In § 558.274, amend paragraph (a)(2) by removing ''Nos. 043733 and'' and adding in its place ''No.''.

§ 558.625 [Amended]

■ 10. In § 558.625, remove and reserve paragraph (b)(3).

§ 558.630 [Amended]

■ 11. In § 558.630, amend paragraph (b)(10) by removing ''043733,''.

Dated: March 26, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–7103 Filed 4–3–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 8697]

RIN 1545–AT91

Simplification of Entity Classification Rules; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 8697), that were published in the **Federal Register** on Wednesday, December 18, 1996 (61 FR 66584). The final regulations classify certain business organizations under an elective regime.

DATES: This correction is effective on April 4, 2008 and is applicable on January 1, 1997.

FOR FURTHER INFORMATION CONTACT: Stephen J. Hawes, (202) 622–3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 8697) that is the subject of this correction is under section 7701 of the Internal Revenue Code.

Need for Correction

As published, TD 8697 contains an error that may prove to be misleading and is in need of clarification.

List of Subjects 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 301 is corrected by making the following correcting amendment:

PART 301—PROCEDURE AND ADMINISTATION

■ **Paragraph 1**. The authority citation for part 301 continues to read in part as follows:

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

■ **Par. 2**. Section 301.7701–2(b)(8)(i) is amended by revising the entry for ''Romania, Societe pe Actiuni'' to read as follows:

§ 301.7701–2 Business entities; definitions.

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