

**§ 556.748 Tylvalosin.**

\* \* \* \* \*

(c) *Related conditions of use.* See §§ 520.2645 and 558.633 of this chapter.

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

■ 17. The authority citation for part 558 continues to read as follows:

**Authority:** 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

■ 18. In § 558.4, in paragraph (d), in the “Category I” table, add an entry in alphabetical order for “Tylvalosin” to read as follows:

**§ 558.4 Requirement of a medicated feed mill license.**

\* \* \* \* \*

(d) \* \* \*

**CATEGORY I**

Drug	Assay limits percent Type A	Type B maximum (200x)	Assay limits percent Type B/C
Tylvalosin .....	90–110	3.86 g/lb	85–115

\* \* \* \* \*

**§ 558.248 [Amended]**

■ 19. Effective June 20, 2016, in § 558.248, revise paragraphs (a) and (b) and remove and reserve paragraph (d)(1)(iii).

The revisions read as follows:

**§ 558.248 Erythromycin.**

(a) *Specifications.* Type A medicated articles containing 5 or 10 percent erythromycin thiocyanate.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

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**§ 558.625 [Amended]**

■ 20. Effective June 20, 2016, in § 558.625, remove paragraph (b)(3) and redesignate paragraphs (b)(4) and (5) as paragraphs (b)(3) and (4).

■ 21. Add § 558.633 to read as follows:

**§ 558.633 Tylvalosin.**

(a) *Specifications.* Type A medicated articles containing 77.12 grams tylvalosin per pound as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.748 of this chapter.

(d) *Special considerations*—(1) Federal law restricts tylvalosin medicated feeds to use under a veterinary feed directive (VFD) and the professional supervision of a licensed veterinarian. See § 558.6 of this chapter for additional requirements.

(2) VFDs for tylvalosin shall not be refilled.

(3) An expiration date of 1 week is required for tylvalosin Type C medicated swine feeds in pelleted or crumbled form.

(e) *Conditions of use in swine*—(1) *Amount.* Administer 38.6 grams tylvalosin per ton of Type C medicated feed (42.5 ppm) as the sole ration for 14 consecutive days.

(2) *Indications for use.* For the control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.

Dated: May 31, 2016.

**Tracey Forfa,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 2016–13517 Filed 6–7–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 520 and 558**

[Docket No. FDA–2016–N–0002]

**New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of five new animal drug applications (NADAs) and an abbreviated new animal drug application (ANADA). This action is being taken at the sponsors’ request because these products are no longer manufactured or marketed.

**DATES:** Withdrawal of approval is effective June 20, 2016.

**FOR FURTHER INFORMATION CONTACT:** Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, [sujaya.dessai@fda.hhs.gov](mailto:sujaya.dessai@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The sponsors of the following applications have requested that FDA withdraw approval of the NADAs and ANADA listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
007–076 <sup>1</sup> .....	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	SULFA–NOX Liquid (sulfaquinoxaline) 3.44% Solution	520.2325a
008–244 <sup>1</sup> .....	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	SULFA–NOX Concentrate (sulfaquinoxaline) 12.85% Solution.	520.2325a

File No.	Sponsor	Product name	21 CFR section
041–955 <sup>1</sup> .....	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	Erythromycin Medicated Premix .....	558.248
049–729 <sup>1</sup> .....	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	PURINA Sulfa (sulfamethazine) 12.5% Solution .....	522.2260a
100–128 <sup>1</sup> .....	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	Supersweet Medipak TYLAN 10 .....	558.625
200–307 <sup>1</sup> .....	Vetoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada J5T 3S5.	Penicillin G Potassium, USP, Soluble Powder .....	520.1696b

<sup>1</sup>These NADAs were identified as being affected by guidance for industry #213, “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,” December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 007–076, 008–244, 041–955, 049–729, 100–128, and ANADA 200–307, and all supplements and amendments thereto, is hereby withdrawn, effective June 20, 2016.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: May 31, 2016.

**Tracey Forfa,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 2016–13518 Filed 6–7–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF STATE

### 22 CFR Parts 35, 103, 127, and 138

[Public Notice: 9536]

RIN 1400–AD94

#### Civil Monetary Penalties Inflationary Adjustment

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** This final rule is issued to adjust the civil monetary penalties (CMP) for regulatory provisions maintained and enforced by the Department of State. The Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Act), as amended by the Debt Collection Improvement Act of 1996 (the 1996 Act), required the head of each agency to adjust its CMPs for inflation no later than October 23, 1996 and required agencies to make adjustments at least once every four years thereafter. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015

Act) further amended the 1990 Act by requiring agencies to adjust CMPs, if necessary, pursuant to a “catch-up” adjustment methodology prescribed by the 2015 Act, which mandates that the catch up adjustment take effect no later than August 1, 2016. Additionally, the 2015 Act requires agencies to make annual adjustments to their respective CMPs in accordance with guidance issued by the Office of Management and Budget. The revised CMP adjustments in this rule will apply only to those penalties assessed after its effective date; subsequent annual adjustments are to be published not later than January 15 of each year. In keeping with guidance provided by the Office of Management and Budget, the new penalty levels will apply to all assessments made on or after August 1, 2016, regardless of the date on which the underlying facts or violations occurred.

**DATES:** This final rule is effective August 1, 2016.

**FOR FURTHER INFORMATION CONTACT:**

Alice Kottmyer, Attorney-Adviser, Office of Management, [kottmyeram@state.gov](mailto:kottmyeram@state.gov). ATTN: Regulatory Change, CMP Adjustments, (202) 647–2318.

**SUPPLEMENTARY INFORMATION:** The 1990 Act (Pub. L. 101–410) provided for the regular evaluation of CMPs by federal agencies. Periodic inflationary adjustments of CMPs ensure that the consequences of statutory violations adequately reflect the gravity of such offenses and that CMPs are properly accounted for and collected by the federal government. In April 1996, the 1990 Act was amended by the 1996 Act (Pub. L. 104–134), which required federal agencies to adjust their CMPs at least once every four years. However, because inflationary adjustments to CMPs were statutorily capped at ten percent of the maximum penalty amount, but only required to be calculated every four years, CMPs in many cases did not correspond with the true measure of inflation over the preceding four year period, leading to a

decline in the real value of the penalty. To remedy this decline, the 2015 Act (section 701 of Pub. L. 114–74) requires agencies to adjust the level of CMPs with an initial “catch-up” adjustment through a rulemaking and to make subsequent annual inflationary adjustments to their respective CMPs using a methodology mandated by the legislation.

The 1990 Act defines civil monetary penalty as any penalty, fine, or other sanction that:

- Is for a specific monetary amount as provided for in federal law; or has a maximum amount provided for by federal law; and
- is assessed or enforced by an agency as pursuant to federal law; and,
- is assessed or enforced pursuant to an administrative proceeding or a civil action in the federal courts.

Within the Department of State (Title 22, Code of Federal Regulations), this rule affects four areas:

(1) Part 35, which implements the Program Fraud Civil Remedies Act of 1986 (PFCRA), codified at 31 U.S.C. 3801–3812;

(2) Part 103, which implements the Chemical Weapons Convention Implementation Act of 1998 (CWC Act);

(3) Part 127, which implements the penalty provisions of sections 38(e), 39A(c), and 40(k) of the Arms Export Control Act (AECA) (22 U.S.C. 2778(e), 2779a(c), 2780(k)); and

(4) Part 138, which implements Section 319 of Public Law 101–221, codified at 31 U.S.C. 1352, and prohibits recipients of federal contracts, grants, and loans from using appropriated funds for lobbying the Executive or Legislative Branches of the federal government in connection with a specific contract.

The 2015 Act instructs agencies to make a one-time catch-up adjustment to CMPs using the maximum penalty level or range of minimum and maximum penalties as they were “most recently established or adjusted under a provision of law other than [the 1990] Act.” Nevertheless, the 2015 Act