

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

¹These 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007-076, 008-244, 041-955, 049-729, 100-128, and ANADA 200-307, and all supplements and amendments thereto, is hereby withdrawn, effective June 20, 2016.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. 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

specifies that the catch-up adjustment amount will in no case exceed 150% of the penalty amount which was in force at the enactment date of the 2015 Act on November 2, 2015; therefore, the total revised penalty amount will not exceed 250% of the total maximum penalty amount on November 2, 2015.

Specific Changes to 22 CFR Made by This Rule

I. Part 35

The PFRCA, enacted in 1986, authorizes agencies, with approval from the Department of Justice, to pursue individuals or firms for false claims. The maximum liability under the PFRCA is \$5,000 for each false claim, up to a maximum of \$150,000, in addition to twice the amount of the claim submitted contrary to the PFRCA.

According to OMB guidance, the multiplier for the PFRCA (a 1986 statute) is 2.15628; therefore, the new maximum penalty for each false claim or statement is \$10,781, up to a maximum of \$323,442.

II. Part 103

The CWC Act provided domestic implementation of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction. The penalty provisions of the CWC Act are codified at 22 U.S.C. 6761. A person violating 22 U.S.C. 6761(a)(1)(A), *Prohibited acts relating to inspections*, is subject to a civil penalty of an amount not to exceed \$25,000 for each such violation. A person violating 22 U.S.C. 6761(a)(1)(B), *Recordkeeping violations*, is subject to a civil penalty in an amount not to exceed \$5,000 for each such violation.

According to OMB Guidance, the multiplier for the CWC Act (a 1998 statute) is 1.45023. Therefore, the new maximum civil monetary penalty for prohibited acts relating to inspections is \$36,256 for each violation; and the new maximum civil monetary penalty for recordkeeping violations is \$7,251 for each such violation.

III. Part 127

The Assistant Secretary of State for Political-Military Affairs is responsible for the imposition of CMPs under the International Traffic in Arms Regulations (ITAR), which is administered by the Directorate of Defense Trade Controls (DDTC). Each of the penalty provisions of the AECA provides that the CMP for each relevant violation may not exceed \$500,000.

(1) AECA Section 38(e)

The most recent statutory modification of the CMPs provided for under AECA section 38(e), 22 U.S.C. 2778(e), occurred in 1985 when the maximum penalty amount was capped at \$500,000 per violation. According to OMB guidance, the multiplier for AECA section 38(e) is 2.18802; therefore, the new maximum penalty will be \$1,094,010 per violation.

(2) AECA Section 39A(c)

The most recent statutory modification of the CMPs provided for under AECA section 39A(c), 22 U.S.C. 2779a(c), occurred in 1994 when the maximum penalty amount was capped at \$500,000 per violation. According to OMB guidance, the multiplier for AECA section 39A(c) is 1.59089; therefore, the new maximum adjusted penalty level will be \$795,445 per violation.

(3) AECA Section 40(k)

The most recent statutory modification of the CMPs provided for under AECA section 40(k), 22 U.S.C. 2780(k), occurred in 1989 when the maximum penalty amount was capped at \$500,000 per violation. According to OMB guidance, the multiplier for AECA section 40(k) is 1.89361; therefore, the new maximum adjusted penalty level will be \$946,805 per violation.

IV. Part 138

Section 319 of Public Law 101–121, codified at 31 U.S.C. 1352, provides penalties for recipients of federal contracts, grants, and loans who use appropriated funds to lobby the Executive or Legislative Branches of the federal government in connection with a specific contract, grant, or loan. Any person who violates that prohibition is subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such expenditure. The statute also requires each person who requests or receives a federal contract, grant, cooperative agreement, loan, or a federal commitment to insure or guarantee a loan, to disclose any lobbying; the penalty for failure to disclose is not less than \$10,000 and not more than \$100,000 for each such failure.

According to OMB guidance, the multiplier for 31 U.S.C. 1352 (a 1989 statute) is 1.89361. Therefore, the new maximum civil violations under the statute, for both improper expenditures and failure to disclose, are: Not less than \$18,936 and not more than \$189,361.

Effective Date of Penalties

The revised CMP amounts will go into effect on August 1, 2016. All violations for which CMPs are assessed after the

effective date of this rule, regardless of whether the violation occurred before the effective date, will be assessed at the adjusted penalty level.

Future Adjustments and Reporting

The 2015 Act directs agencies to undertake an annual review of CMPs using a formula prescribed by the statute. Hereafter, annual adjustments to CMPs will be made in accordance with the guidance issued by OMB. The Department of State will publish notification of annual inflation adjustments to CMPs in the **Federal Register** no later than January 15 of each year, with the adjusted amount taking effect immediately upon publication. Furthermore, OMB Circular A–136, Financial Reporting Requirements, directs agencies to identify any changes to CMPs in the Agency Financial Report (AFR), including the affected penalties, dates and amounts of adjustments, and applicable statutes and regulations.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is publishing this rule using the “good cause” exception to the Administrative Procedure Act (5 U.S.C. 553(b)), as the Department has determined that public comment on this rulemaking would be impractical, unnecessary, or contrary to the public interest. This rulemaking is mandatory; it implements Public Law 114–74.

Regulatory Flexibility Act

Because this rulemaking is exempt from Section 553 of the Administrative Procedures Act, a Regulatory Flexibility Analysis is not required.

Unfunded Mandates Reform Act of 1995

This rule does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary

impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on federal programs and activities do not apply to this rulemaking.

Executive Orders 12866 and 13563

The Department believes that benefits of the rulemaking outweigh any costs, and there are no feasible alternatives to this rulemaking. It is the Department's position that this rulemaking is not an economically significant rule under the criteria of Executive Order 12866, and is consistent with the provisions of Executive Order 13563.

Executive Order 12988

The Department of State has reviewed the proposed amendment in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

List of Subjects

22 CFR Part 35

Administrative practice and procedure, Claims, Fraud, Penalties.

22 CFR Part 103

Administrative practice and procedure, Chemicals, Classified information, Foreign relations, Freedom of information, International organization, Investigations, Penalties, Reporting and recordkeeping requirements.

22 CFR Part 127

Arms and munitions, Exports.

22 CFR Part 138

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth above, 22 CFR parts 127, 35, 103, and 138 are amended as follows:

PART 35—PROGRAM FRAUD CIVIL REMEDIES

■ 1. The authority citation for part 35 is revised to read as follows:

Authority: 22 U.S.C. 2651a; 31 U.S.C. 3801 *et seq.*; Pub. L. 114–74, 129 Stat. 584.

■ 2. In § 35.3:

■ a. Remove “\$5,000” and add in its place “\$10,781”, wherever it occurs.

■ b. Add paragraph (f) to read as follows:

§ 35.3 Basis for civil penalties and assessments.

* * * * *

(f) The maximum penalty for each false claim or statement is \$10,781, up to a maximum of \$323,442.

PART 103—REGULATIONS FOR IMPLEMENTATION OF THE CHEMICAL WEAPONS CONVENTION AND THE CHEMICAL WEAPONS CONVENTION IMPLEMENTATION ACT OF 1998 ON THE TAKING OF SAMPLES AND ON ENFORCEMENT OF REQUIREMENTS CONCERNING RECORDKEEPING AND INSPECTIONS

■ 3. The authority citation for part 103 is revised to read as follows:

Authority: 22 U.S.C. 2651a; 22 U.S.C. 6701 *et seq.*; Pub. L. 114–74, 129 Stat. 584.

§ 103.6 [Amended]

■ 4. Amend § 103.6 to remove “\$25,000” and add in its place “\$36,256” in paragraph (a)(1), and to remove “\$5,000”, and add in its place “\$7,251” in paragraph (a)(2).

PART 127—VIOLATIONS AND PENALTIES

■ 5. The authority citation for part 127 is revised to read as follows:

Authority: Sections 2, 38, and 42, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2791); 22 U.S.C. 401; 22 U.S.C. 2651a; 22 U.S.C. 2779a; 22 U.S.C. 2780; E.O. 13637, 78 FR 16129; Pub. L. 114–74, 129 Stat. 584.

■ 6. Section 127.10 is amended by revising paragraph (a) to read as follows:

§ 127.10 Civil penalty.

(a)(1) The Assistant Secretary of State for Political-Military Affairs is authorized to impose a civil penalty, as follows:

(i) For each violation of 22 U.S.C. 2778, an amount not to exceed \$1,094,010;

(ii) For each violation of 22 U.S.C. 2779a, an amount not to exceed \$795,445; and

(iii) For each violation of 22 U.S.C. 2780, an amount not to exceed \$946,805.

(2) The civil penalty may be either in addition to, or in lieu of, any other liability or penalty which may be imposed.

* * * * *

PART 138—NEW RESTRICTIONS ON LOBBYING

■ 7. The authority citation for part 138 is revised to read as follows:

Authority: 22 U.S.C. 2651a; 31 U.S.C. 1352; Pub. L. 114–74, 129 Stat. 584.

§ 138.400 [Amended]

■ 8. Amend § 138.400 by removing “\$10,000” and “\$100,000”, and adding in their place “\$18,936” and “\$189,361” respectively, wherever they occur.

Dated: June 1, 2016.

Lisa Aguirre,

Managing Director, Directorate of Defense Trade Controls Department of State.

[FR Doc. 2016–13455 Filed 6–7–16; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9770]

RIN 1545–BN39

Certain Transfers of Property to Regulated Investment Companies [RICs] and Real Estate Investment Trusts [REITs]; Final and Temporary Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations effecting the repeal of the *General Utilities* doctrine by the Tax Reform Act of 1986 and preventing abuse of the Protecting Americans from Tax Hikes Act of 2015. The temporary regulations impose corporate level tax on certain transactions in which property of a C corporation becomes the property of a REIT. The temporary regulations affect RICs, REITs, C corporations the property of which becomes the property of a RIC or a REIT, and their shareholders. The text of these temporary regulations also serves as the text of part of the proposed regulations in the related notice of proposed rulemaking (REG–126452–15) set forth in the Proposed Rules section in this issue of the **Federal Register**.

DATES: These regulations are effective June 7, 2016.