

of the Wing Lower Panels Stiffeners Between Ribs 13 and 16 (ATA 57-00-21)," are acceptable for compliance with the requirements of paragraph (f)(1) of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, ANM-116, International Branch, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-1137; fax (425) 227-1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product*: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements*: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2008-0021, dated January 31, 2008; and Dassault Falcon 50/50EX Maintenance Manual, Maintenance Procedure 57-401, "Non-Destructive Check of the Wing Lower Panels Stiffeners Between Ribs 13 and 17 (ATA 57-00-21)," dated July 2008; for related information.

Material Incorporated by Reference

(i) You must use Dassault Falcon 50/50EX Maintenance Manual, Maintenance Procedure 57-401, "Non-Destructive Check of the Wing Lower Panels Stiffeners Between Ribs 13 and 17 (ATA 57-00-21)," dated July 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606; telephone 201-440-6700; Internet <http://www.dassaultfalcon.com>.

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind

Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221 or 425-227-1152.

(4) You may also review copies of the service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on November 26, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

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BILLING CODE 4910-13-P

Government were properly accounted for and collected. On April 26, 1996, the Federal Civil Penalties Inflation Adjustment Act of 1990 was amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104-134) to require each agency to issue regulations to adjust its CMPs for inflation at least every four years. The amendment further provided that any resulting increases in a CMP due to the inflation adjustment should apply only to the violations that occur subsequent to the date of the publication in the **Federal Register** of the increased amount of the CMP. The first inflation adjustment of any penalty shall not exceed ten percent of such penalty.

On October 24, 1996 and November 1, 2000, and again on December 14, 2004, the Department published in the **Federal Register** a schedule of CMP adjusted for inflation as required by law. By this publication, CMPs are again being adjusted for inflation as prescribed by law.

A civil monetary penalty is defined as any penalty, fine, or other sanction that:

1. Is for a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; and,

2. Is assessed or enforced by an agency pursuant to Federal law; and,

3. Is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

This regulation adjusts the civil penalties that are established by law and assessed or enforced by the Department.

The actual penalty assessed for a particular violation is dependent upon a variety of factors. For example, The National Oceanic and Atmospheric Administration (NOAA) Civil Administrative Penalty Schedule (the Schedule), a compilation of internal guidelines that are used when assessing penalties for violations for most of the statutes NOAA enforces, will be interpreted in a manner consistent with this regulation to maintain the deterrent effect of the penalties recommended therein. The penalty ranges in the Schedule are intended to aid enforcement attorneys in determining the appropriate penalty to assess for a particular violation. Pursuant to the notice published in the **Federal Register** (59 FR 19160, April 22, 1994), the Schedule is maintained and made available for inspection by the public at specific locations.

The inflation adjustment was determined pursuant to the methodology prescribed by Public Law 101-410, which requires the maximum CMP, or the minimum and maximum CMP, as applicable, to be increased by

the cost-of-living adjustment. The term “cost-of-living adjustment” was defined in Public Law 104–134 to mean the percentage for each CMP by which the Consumer Price Index (CPI) for June of the calendar year preceding the adjustment exceeds the CPI for the month of June of the calendar year in which the amount of such CMP was last set or adjusted pursuant to law. For the purpose of computing the inflation adjustments, the CPI for June of the calendar year preceding the adjustment means the CPI for June of 2007.

Public Law 101–410 requires each rounded increase to be added to the minimum or maximum penalty amount being adjusted, and the total is the amount of such penalty, as adjusted, subject to the ten percent limitation provided by Public Law 104–134 for the first adjustment.

Rulemaking Requirements

It has been determined that this rule is not significant for purposes of Executive Order 12866.

The Department for good cause finds that notice and opportunity for comment is unnecessary for this rulemaking pursuant to 5 U.S.C. 553(b)(B). It is unnecessary to ask for notice and comment because the Debt Collection Improvement Act of 1996 (the Act) required the head of each agency to adjust its civil monetary penalties no later than October 23, 1996, and at least every four years thereafter, and the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990, as amended by the Act, states how to calculate the inflation adjustments, making such adjustments wholly non-discretionary. This rule merely adjusts the Department’s CMP according to the statutory requirements. For the same reasons, there exists good cause to waive the thirty day delay in effectiveness of the rule, pursuant to 5 U.S.C. 553(d)(3).

Because notice and opportunity for comment are not required by 5 U.S.C. 553, or any other law, a Regulatory Flexibility Analysis is not required and none was prepared. This rule does not contain information collection requirements for purposes of the Paperwork Reduction Act.

List of Subjects in 15 CFR Part 6

Law enforcement, Penalties.

Lisa Casias,

Deputy Chief Financial Officer and Director for Financial Management.

■ For the reasons set forth in the preamble, subtitle A of Title 15 of the Code of Federal Regulations is amended as follows:

PART 6—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS

- 1. The authority citation for part 6 continues to read as follows:

Authority: Sec. 4, as amended, and sec. 5, Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 104–134, 110 Stat. 1321, 28 U.S.C. 2461 note.

- 2. Section 6.4 is revised as follows:

§ 6.4 Adjustments to penalties.

The civil monetary penalties provided by law within the jurisdiction of the respective agencies or bureaus of the Department, as set forth below in this section, are hereby adjusted in accordance with the inflation adjustment procedures prescribed in Section 5, Pub. L. 101–410, from the amounts of such penalties in effect prior to December 11, 2008, to the amounts of such penalties, as thus adjusted, except for the penalties stated in paragraphs (e)(26) and (e)(27), which became effective on January 12, 2007, and except for the penalties stated in paragraphs (a)(4) and (e)(3) which became adjusted on October 16, 2007 and January 12, 2007, respectively.

(a) Bureau of Industry and Security.
 (1) 15 U.S.C. 5408(b)(1), Fastener Quality Act—Violation, from \$27,500 to \$32,500.

(2) 22 U.S.C. 6761(a)(1)(A), Chemical Weapons Convention Implementation Act—Inspection Violation, from \$25,000 to \$25,000.

(3) 22 U.S.C. 6761(a)(1)(B), Chemical Weapons Convention Implementation Act—Record Keeping Violation, from \$5,000 to \$5,000.

(4) 50 U.S.C. 1705(a), International Emergency Economic Powers Act (2007)—Violation, from \$50,000 to \$250,000.

(b) Bureau of the Census. (1) 13 U.S.C. 304, Collection of Foreign Trade Statistics—Delinquency on Delayed Filing of Export Documentation; maximum penalty for each day's delinquency, from \$1,000 to \$1,000; maximum per violation, from \$10,000 to \$10,000.

(2) 13 U.S.C. 305(b), Collection of Foreign Trade Statistics—Violations, from \$10,000 to \$10,000.

(c) Economics and Statistics Administration. 22 U.S.C. 3105(a), International Investment and Trade in Services Act—Failure to Furnish Information; minimum, from \$2,500 to \$2,500; maximum, from \$27,500 to \$32,500.

(d) International Trade Administration. (1) 19 U.S.C. 81s, Foreign Trade Zone—Violation, from \$1,100 to \$1,100.

(2) 16 U.S.C. 1677(f)(4), U.S.-Canada FTA Protective Order—Violation, from \$120,000 to \$130,000.

(e) National Oceanic and Atmospheric Administration. (1) 15 U.S.C. 5623(a)(3), Land Remote Sensing Policy Act of 1992, from \$11,000 to \$11,000.

(2) 15 U.S.C. 5658(c), Land Remote Sensing Policy Act of 1992, from \$11,000 to \$11,000.

(3) 16 U.S.C. 773f(a), Northern Pacific Halibut Act of 1982 (2007), from \$27,500 to \$200,000.

(4) 16 U.S.C. 783, Sponge Act (1914), from \$550 to \$650.

(5) 16 U.S.C. 957, Tuna Conventions Act of 1950 (1962);

(i) Violation/Subsection (a), from \$27,500 to \$32,500.

(ii) Subsequent Violation/Subsection (a), from \$65,000 to \$70,000.

(iii) Violation/Subsection (b), from \$1,100 to \$1,100.

(iv) Subsequent Violation/Subsection (b), from \$5,500 to \$6,500.

(v) Violation/Subsection (c), from \$130,000 to \$140,000.

(6) 16 U.S.C. 971e(e), Atlantic Tunas Convention Act of 1975 (1995), from \$130,000 to \$140,000.

(7) 16 U.S.C. 972f(b), Eastern Pacific Tuna Licensing Act of 1984;

(i) Violation/Subsections (a)(1)–(3), from \$27,500 to \$32,500.

(ii) Subsequent Violation/Subsections (a)(1)–(3), from \$60,000 to \$65,000.

(iii) Violation/Subsections (a)(4)–(5), from \$5,500 to \$6,500.

(iv) Subsequent Violation/Subsections (a)(4)–(5), from \$5,500 to \$6,500.

(v) Violation/Subsection (a)(6), from \$130,000 to \$140,000.

(8) 16 U.S.C. 973f(a), South Pacific Tuna Act of 1988, from \$325,000 to \$350,000.

(9) 16 U.S.C. 1174(b), Fur Seal Act Amendments of 1983, from \$11,000 to \$11,000.

(10) 16 U.S.C. 1375(a)(1), Marine Mammal Protection Act of 1972 (1981), from \$11,000 to \$11,000.

(11) 16 U.S.C. 1385(e), Dolphin Protection Consumer Information Act (1990), from \$120,000 to \$130,000.

(12) 16 U.S.C. 1437(d)(1), National Marine Sanctuaries Act (1992), from \$130,000 to \$140,000.

(13) 16 U.S.C. 1540(a)(1), Endangered Species Act of 1973;

(i) Knowing Violation of Section 1538 (1988), from \$27,500 to \$32,500.

(ii) Other Knowing Violation (1988), from \$13,200 to \$13,200.

(iii) Otherwise Violation (1978), from \$550 to \$650.

(14) 16 U.S.C. 1858(a), Magnuson-Stevens Fishery Conservation and Management Act (1990), from \$130,000 to \$140,000.

(15) 16 U.S.C. 2437(a)(1), Antarctic Marine Living Resources Convention Act of 1984;

- (i) Violation, from \$5,500 to \$6,500.
- (ii) Knowing Violation, from \$11,000 to \$11,000.

(16) 16 U.S.C. 2465(a), Antarctic Protection Act of 1990;

- (i) Violation, from \$5,500 to \$6,500.
- (ii) Knowing Violation, from \$11,000 to \$11,000.

(17) 16 U.S.C. 3373(a), Lacey Act Amendments of 1981;

- (i) Sale and Purchase Violation, from \$11,000 to \$11,000.

- (ii) Marking Violation, from \$275 to \$275.

- (iii) False Labeling Violation, from \$11,000 to \$11,000.

- (iv) Other than Marking Violation, from \$11,000 to \$11,000.

(18) 16 U.S.C. 3606(b)(1), Atlantic Salmon Convention Act of 1982 (1990), from \$130,000 to \$140,000.

(19) 16 U.S.C. 3637(b), Pacific Salmon Treaty Act of 1985 (1990), from \$130,000 to \$140,000.

(20) 16 U.S.C. 4016(b)(1)(B), Fish and Seafood Promotion Act of 1986; minimum from \$500 to \$500; maximum from \$5,500 to \$6,500.

(21) 16 U.S.C. 5010(a)(1), North Pacific Anadromous Stocks Act of 1992, from \$120,000 to \$130,000.

(22) 16 U.S.C. 5103(b)(2), Atlantic Coastal Fisheries Cooperative Management Act (1993), from \$130,000 to \$140,000.

(23) 16 U.S.C. 5154(c)(1), Atlantic Striped Bass Conservation Act (1990), from \$130,000 to \$140,000.

(24) 16 U.S.C. 5507(a)(1), High Seas Fishing Compliance Act of 1995, from \$120,000 to \$130,000.

(25) 16 U.S.C. 5606(b), Northwest Atlantic Fisheries Convention Act of 1995, from \$130,000 to \$140,000.

(26) 16 U.S.C. 6905(c), Western and Central Pacific Fisheries Convention Implementation Act (2007); new penalty \$140,000.

(27) 16 U.S.C. 7009(c), Pacific Whiting Act of 2006 (2007); new penalty \$140,000.

(28) 22 U.S.C. 1978(e), Fishermen's Protective Act of 1967 (1971);

- (i) Violation, from \$11,000 to \$11,000.
- (ii) Subsequent Violation, from \$27,500 to \$32,500.

(29) 30 U.S.C. 1462(a), Deep Seabed Hard Mineral Resources Act (1980), from \$27,500 to \$32,500.

(30) 42 U.S.C. 9152(c)(1), Ocean Thermal Energy Conversion Act of 1980, from \$27,500 to \$32,500.

■ 3. Section 6.5 is revised to read as follows:

§ 6.5 Effective date of adjustments.

The adjustments made by § 6.4 of this part, of the penalties there specified, are effective on December 11, 2008, and said penalties, as thus adjusted by the adjustments made by § 6.4 of this part, shall apply only to violations occurring after December 11, 2008, and before the effective date of any future inflation adjustment thereto made subsequent to December 11, 2008 as provided in § 6.6 of this part.

[FR Doc. E8-29263 Filed 12-10-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2008-N-0039]

New Animal Drugs for Use in Animal Feeds; Ractopamine

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 of a supplemental new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for an increased level of monensin in four-way combination Type C medicated feeds containing ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter; and a revision to bacterial pathogen nomenclature.

DATES: This rule is effective December 11, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-424 that provides for use of OPTAFLEXX (ractopamine hydrochloride), HEIFERMAX 500 (melengestrol acetate), and RUMENSIN (monensin), and TYLAN (tylosin phosphate) Type A medicated articles to make dry and liquid four-way combination Type C medicated feeds used for increased rate of weight gain,

improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for suppression of estrus (heat); and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. The supplemental NADA provides for an increased level of monensin in four-way combination Type C medicated feeds containing ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter; and a revision to bacterial pathogen nomenclature. The supplemental NADA is approved as of November 13, 2008, and the regulations in 21 CFR 558.500 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 in 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.500 [Amended]

■ 2. In § 558.500, in the table in paragraph (e)(2)(x), in the "Limitations" column, remove "No. 000009" and in its