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Issued in Washington, DC, on October 5, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 383

[Docket No. OST 2000-8058]

RIN 2105-AC92

Civil Penalties

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21) revised several civil penalty provisions applicable to violations of the aviation economic requirements of Title 49. By this rule, the Department of Transportation (Department) is modifying its regulations to reflect these revised civil penalties. This rule also reviews those civil penalties unaffected by the recent statutory amendments to determine whether they should be adjusted to recognize inflation that has occurred since the adoption of part 383 in 1997. This review is required under the Federal Civil Penalties Inflation Adjustment Act of 1990 and the Debt Collection Improvement Act of 1996.

EFFECTIVE DATE: This rule is effective on November 15, 2000. However, the statutory amendments it reflects became effective on April 5, 2000, by their own terms.

FOR FURTHER INFORMATION CONTACT: Nicholas Lowry, Attorney, Office of Aviation Enforcement and Proceedings (C-70), Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366-9349.

SUPPLEMENTARY INFORMATION:

I. Civil Penalty Adjustments Required by AIR 21.

The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21) among other things amended the statutory provisions proscribing discriminatory practices in air transportation and the civil penalties for violations of those provisions. Section 706 of AIR 21 creates a new section 40127 of Title 49 which

specifically prohibits discrimination by air carriers or foreign air carriers on the basis of race, color, national origin, religion, sex or ancestry. In addition, section 707(a) of AIR 21 extended the anti-discrimination provisions of 49 U.S.C. 41705, the Air Carrier Access Act, which formerly applied only to air carriers, to foreign air carriers, as well.

With respect to the civil penalties the Department may impose, section 707(b) of AIR 21 amended the provisions of 49 U.S.C. 46301(a)(3) to apply a \$10,000 maximum civil penalty to each violation of section 41705. In addition, section 222 of AIR 21 established \$2,500 as the maximum civil penalty amount for each violation of section 40127 or 41712 (the latter of which prohibits unfair and deceptive trade practices and unfair methods of competition).

The recent legislation does not affect the civil penalty provisions applicable to violations of all other aviation economic requirements, or Department rules or orders not proscribed or issued under section 40127, 41705 or 41712. For example, penalties for violations of reporting requirements, cases involving certain unauthorized operations, or cases involving violations of other Department orders or rules not issued pursuant to the authority of 49 U.S.C. 40127, 41705, or 41712, remain at the current level of \$1,100 per violation under AIR 21.

II. Inflation Adjustment of Other Civil Penalty Provisions

The Debt Collection Improvement Act of 1996 (Pub. L. 104-134, sec. 31001) requires each agency to adjust each civil monetary penalty within its jurisdiction by the inflation adjustment described in section 5 of the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410). Section 5 requires the adjustment to be rounded to the nearest multiple of \$1,000 for penalties greater than \$1,000 and less than or equal to \$10,000. The adjustment is to be the percentage increase in the Consumer Price Index (CPI) from June of the calendar year in which the penalty was last adjusted to June of the year preceding the year in which the revision is proposed. Under the 1996 act, agencies are to review civil penalties which they administer at least once every four years. The civil penalties to which the adjustment would apply here are those civil penalty provisions not affected by AIR 21, that is, penalties for all violations other than cases involving 49 U.S.C. 40127, 41705, or 41712 or regulations or orders issued thereunder.

Since the total inflation as measured by the CPI between June 1997 and June 2000 was approximately 7 percent, an

appropriate increase in the civil penalty amount would be \$77. In view of the rounding provision of the statute, therefore, no adjustment of the civil penalty amount is warranted at this time.

III. Waiver of Notice of Proposed Rulemaking

In developing this final rule, we are waiving the usual notice of proposed rulemaking and public comment procedures set forth in the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA provides an exception to the notice and comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary or contrary to the public interest. We have determined that under 5 U.S.C. 553(b)(3)(B) good cause exists for dispensing with the notice of proposed rulemaking and public comment procedures for this rule. Specifically, this rulemaking is required by the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, the Federal Civil Penalties Inflation Adjustment Act of 1990, and the Debt Collection Improvement Act of 1996, with no issues of policy discretion. Accordingly, we believe that opportunity for prior comment is unnecessary and contrary to the public interest, and are issuing these revised regulations as a final rule.

IV. Regulatory Impact Statement

Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule has been evaluated in accordance with the existing policies and procedures and is considered to be not significant under both Executive Order 12866 and DOT Regulatory Policies and Procedures. The final rule is exempt from review by the Office of Management and Budget (OMB) in accordance with the provisions of Executive Order 12866, because it is limited to the adoption of statutory language, without interpretation. This final rule amends the regulations implementing the civil penalty provisions to comply with AIR-21 and reviews the civil penalties unaffected by the recent statutory amendments to determine if inflation adjustments are necessary in accordance with Federal Civil Penalties Inflation Adjustment Act and the Debt Collection Improvement Act. This rule simply adjusts or sets penalties for those who violate the regulations. As a result, we have determined that there are no economic consequences flowing from this rule.

Indeed, to avoid any costs, regulated entities need only comply with the law.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires an assessment of the impacts of proposed and final rule on small entities. An agency must prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601–612), unless the agency can certify that a regulation will not have a significant economic impact on a substantial number of small entities. This rule imposes no substantive burden and merely amends the existing penalties for those who engage in prohibited conduct to reflect statutory changes. The civil penalties will affect only those who engage in conduct prohibited by statute or related regulations. Those who comply with the law will not be affected by the civil penalties. Accordingly, the Office of the Secretary certifies that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This final rule imposes no new reporting or record keeping requirements necessitating clearance by OMB.

List of Subjects in 14 CFR Part 383

Administrative practice and procedure, Penalties.

Accordingly, the Department of Transportation revises Part 383 of Title 14, as set forth below:

PART 383—CIVIL PENALTIES

Sec.

§ 383.1 Basis and purpose.

§ 383.2 Amount of penalty.

Authority: Secs. 222, 706, 707(b), Pub. L. 106–181, 114 Stat. 61; Pub. L. 101–410, 104 Stat. 890, as amended by sec. 31001, Pub. L. 104–134, 110 Stat. 1321.

§ 383.1 Basis and purpose.

(a) *Basis.* This part implements the civil penalty provisions of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21, Pub. L. 106–181; 114 Stat. 61; April 5, 2000, sections 222, 706, 707(b)), and the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134, section 31001). The Debt Collection Improvement Act requires each agency head to adjust by regulation each civil monetary penalty provided by law by the inflation adjustment described under section 5 of the Federal Civil Penalties Inflation Adjustment Act. We

have applied these guidelines to the civil penalty amounts that were not affected by AIR 21 and, taking into account the inflation that has occurred since the most recent adjustment, have found that no further adjustment is warranted as of June 2000.

(b) *Purpose.* This part states the civil penalty amounts with respect to violations of 49 U.S.C. 40127, 41705 and 41712 and other civil penalties provided in 49 U.S.C. 46301 (a)(1) for violations covered by this chapter.

§ 383.2 Amount of penalty.

A person is liable to the United States Government for a civil penalty of not more than \$10,000 for each violation of 49 U.S.C. 41705 and a civil penalty of not more than \$2,500 for each violation of 49 U.S.C. 40127 or 41712. For other violations of this chapter within the scope of 49 U.S.C. 46301, the civil penalty amount is \$1,100.

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Issued this 20th day of September, 2000, at Washington, D.C.

Rodney E. Slater,

Secretary of Transportation.

[FR Doc. 00–26197 Filed 10–13–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Levamisole Phosphate Injection

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 an abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for use of levamisole phosphate solution by subcutaneous injection for the treatment of various species of gastrointestinal parasites in cattle.

DATES: This rule is effective October 16, 2000.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200–

271 for LEVAMISOLE PHOSPHATE Injectable Solution, 13.65%. The ANADA provides for use of levamisole phosphate solution by subcutaneous injection for the treatment of various species of gastrointestinal parasites in cattle. The ANADA is approved as a generic copy of Schering-Plough Animal Health's NADA 126–742 for LEVASOLE® Injection. ANADA 200–271 is approved as of September 7, 2000, and the regulations are amended in 21 CFR 522.1244 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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)(1) 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 522

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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1244 [Amended]

2. Section 522.1244 *Levamisole phosphate injection* is amended in paragraph (b) by removing “No. 000061” and by adding in its place “Nos. 000061 and 057561”.