

Inspection and Corrective Action

(a) For airplanes equipped with windshield units that have accumulated fewer than 2,500 total flight cycles as of the effective date of this AD: Within 6 months after 3 the effective date of this AD, accomplish a one-time general visual inspection of the aft edges of the left and right main windshields to determine whether a placard having part number (P/N) CSB-NP-139321-002-1 is installed, per the Accomplishment Instructions of Bombardier Service Bulletin 601R-56-004, dated August 16, 2001.

(1) If a placard having P/N CSB-NP-139321-002-1 is installed, no further action is required by this AD.

(2) If a placard having a P/N other than CSB-NP-139321-002-1 is installed, before further flight, accomplish the corrective actions (including modifying the main windshields by replacing nine of the hi-lok pins installed in the lower forward corner of the windshields with hi-lok pins having a reduced diameter shank, installing a placard having the correct P/N on the inner retainer near the part identification placard located along the aft edge of the window, and replacing any torn or deformed gasket), per the Accomplishment Instructions of the service bulletin.

Note 2: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

Note 3: Bombardier Service Bulletin 601R-56-004, dated August 16, 2001, references PPG Industries, Inc., Service Bulletin CSB-NP-139321-002, Revision C, dated July 31, 2001, as an additional source of service information for accomplishment of the modification of the left and right main windshields.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

Special Flight Permit

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to

a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(d) The actions shall be done in accordance with Bombardier Service Bulletin 601R-56-004, dated August 16, 2001. The incorporation by reference of that document was approved previously by the Director of the Federal Register as of August 14, 2003 (68 FR 41059, July 10, 2003). Copies may be obtained from Bombardier, Inc., Canadair, Aerospace Group, PO Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the *Office of the Federal Register*, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 5: The subject of this AD is addressed in Canadian airworthiness directive CF-2001-35R1, dated September 27, 2001.

Effective Date

(e) The effective date of this amendment remains August 11, 2003.

Issued in Renton, Washington, on August 11, 2003.

Neil D. Schalekamp,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectible Dosage Form New Animal Drugs; Trenbolone and Estradiol

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 abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot steers for increased rate of weight gain and improved feed efficiency.

DATES: This rule is effective August 15, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl.,

Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-346. The supplemental ANADA provides for the use of COMPONENT TE-200 (trenbolone acetate and estradiol), a subcutaneous implant containing 200 milligrams (mg) trenbolone acetate and 20 mg estradiol in steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Ivy Laboratories' COMPONENT TE-200 is approved as a generic copy of Intervet, Inc.'s REVALOR-200, approved under NADA 140-992. The application is approved as of April 21, 2003, and the regulations are amended in 21 CFR 522.2477 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 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 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 the 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.

§ 522.2477 [Amended]

■ 2. Section 522.2477 *Trenbolone acetate and estradiol* is amended in paragraph (b)(1) by adding “(d)(1)(i)(C),” after “(d)(1)(i)(B).”

Dated: August 1, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-20797 Filed 8-14-03; 8:45 am]

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 300**

[TD 9086]

RIN 1545-BA54

User Fees for Processing Offers To Compromise

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains amendments to the regulations relating to user fees to provide for the imposition of user fees for the processing of offers to compromise. The charging of user fees implements the Independent Offices Appropriations Act.

EFFECTIVE DATE: November 1, 2003.

FOR FURTHER INFORMATION CONTACT: Concerning cost methodology, Eva Williams, 301-492-5395; concerning the regulations, G. William Beard, 202-622-3620 (not toll free numbers).

SUPPLEMENTARY INFORMATION:**Background**

This document amends the regulations relating to user fees to provide for the imposition of user fees for the processing of offers to compromise. The charging of user fees implements the Independent Offices Appropriations Act (IOAA), which is codified at 31 U.S.C. 9701. On November 6, 2002, a notice of proposed rulemaking (REG-103777-02) was published in the **Federal Register**. Approximately 149 comments were received. A public hearing on the regulations was held on February 13, 2003. The final regulations adopt the rules of the proposed regulations.

Offers To Compromise

Section 7122 of the Internal Revenue Code (Code) gives the IRS the authority to compromise any civil or criminal case arising under the internal revenue laws, prior to the referral of that case to

the Department of Justice. Section 7122 also directs the IRS to prescribe guidelines for officers and employees of the IRS to determine whether an offer to compromise is adequate and should be accepted. Guidelines are contained in § 301.7122-1. Pursuant to § 301.7122-1(b), an offer may be accepted if there is doubt as to liability, if there is doubt as to collectibility, or if acceptance will promote effective tax administration. Pursuant to § 301.7122-1(b)(3), offers may be accepted to promote effective tax administration if either: (1) The IRS determines that, although collection in full could be achieved, collection of the full liability would cause the taxpayer economic hardship within the meaning of § 301.6343-1, or (2) there are no other grounds for compromise and there are compelling public policy or equity considerations.

When an offer to compromise is received, an initial determination is made as to whether the offer is processable. Currently, an offer is returned as nonprocessable if the taxpayer is in bankruptcy, has not filed required tax returns, or has not submitted the offer to compromise on the proper form. Absent these conditions, the offer is accepted for processing and cannot be rejected without an independent administrative review of the decision to reject and, if the taxpayer chooses to appeal the rejection, independent review by the Office of Appeals. Even though an offer accepted for processing may later be returned to the taxpayer if the taxpayer fails to provide requested information or the IRS determines that the offer was submitted solely to delay collection, such an offer may not be returned before a managerial review of the proposed return is completed pursuant to § 301.7122-1(f)(5)(ii).

Explanation of Provisions

The final regulations establish a \$150 user fee for the processing of certain offers to compromise tax liabilities pursuant to § 301.7122-1. The user fee will not apply to offers based solely on doubt as to liability and offers made by low income taxpayers whose incomes are at or below the poverty guidelines set by the Department of Health and Human Services (DHHS), or such other measure the IRS may adopt.

Offers based on doubt as to liability are excepted from the user fee based on the inequity of the IRS charging a fee to compromise an uncertain liability when a compromise is based upon a redetermination or reevaluation of the taxpayer's liability for a tax (and the agreed upon amount may, in fact,

provide for the full payment of the amount actually owed).

Offers from low income taxpayers are excepted from the fee in light of section 7122(c)(3)(A), which prohibits the IRS from rejecting an offer from a low income taxpayer solely on the basis of the amount offered. Section 7122(c)(3)(A) literally applies to the rejection of an offer, rather than the return of an offer for failure to pay a user fee. Requiring payment of a user fee from a low income taxpayer would undermine section 7122(c)(3)(A) in cases where the taxpayer does not have the ability to pay the fee. Offers from low income taxpayers are therefore excepted.

Taxpayers with offers that do not fall within the doubt as to liability or low income exceptions will submit the user fee along with the offer to compromise. If the offer is accepted to promote effective tax administration or is accepted based on doubt as to collectibility and a determination that collecting more than the amount offered would create economic hardship within the meaning of §§ 301.6343-1, the fee will be applied to the amount of the offer or, if the taxpayer requests, refunded to the taxpayer. In other cases, the payment of the fee will be taken into account in determining the acceptable amount of the offer and therefore the taxpayer in total will pay no more than the taxpayer would have paid without the fee. While the fee will not be refunded if an offer is withdrawn, rejected, or returned as nonprocessable after acceptance for processing, no additional fee will be charged if a taxpayer resubmits an offer the IRS determines to have been rejected or returned in error.

Comments on the Proposed Regulation

Most of the comments on the proposed regulations did not favor the fee. The comments focused on three concerns: The fee would create an additional financial hardship on taxpayers who are already experiencing hardship; the income level for the low income exception to the fee was too low; and the fee should not be imposed until the offer to compromise is administered more effectively and efficiently. For the following reasons, these final regulations follow the proposed regulations without change.

The most frequent concern in the comments was that the fee would cause additional financial hardship for taxpayers who are already experiencing financial hardship. The exception for low income taxpayers, however, excludes those taxpayers most likely to be disadvantaged by the user fee.