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**SUPPLEMENTARY INFORMATION:** Orion Corp., Orionintie 1, 02200 Espoo, Finland, filed a supplement to NADA 141-267 for DEXDOMITOR (dexmedetomidine hydrochloride). The supplemental NADA provides for veterinary prescription use of dexmedetomidine hydrochloride injectable solution as a preanesthetic to general anesthesia in cats. The supplemental application is approved as of August 16, 2010, and the regulations in 21 CFR 522.558 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), summaries of the safety and effectiveness data and information submitted to support approval of these applications 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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.

■ 2. In § 522.558, revise paragraph (c)(2)(ii) to read as follows:

#### § 522.558 Dexmedetomidine.

\* \* \* \* \*

(c) \* \* \*  
(2) \* \* \*

(ii) *Indications for use.* For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures; and as a preanesthetic to general anesthesia.

\* \* \* \* \*

Dated: September 24, 2010.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 2010-24494 Filed 9-29-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

[Docket No. FDA-2010-N-0002]

#### New Animal Drugs for Use in Animal Feeds; Melengestrol

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to more accurately reflect the recent approval of two supplemental new animal drug applications (NADAs) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADAs provided for increased levels of monensin in two-way Type C medicated feeds containing melengestrol acetate and monensin, and in three-way Type C medicated feeds containing melengestrol acetate, monensin, and tylosin phosphate for heifers fed in confinement for slaughter. These amendments are being made to improve the accuracy of the regulations.

**DATES:** This rule is effective September 30, 2010.

**FOR FURTHER INFORMATION CONTACT:** Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, email: [suzanne.sechen@fda.hhs.gov](mailto:suzanne.sechen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplements to NADA 125-476 for use of liquid MGA 500 (melengestrol acetate) and RUMENSIN (monensin, USP) single-ingredient Type A

medicated articles to make two-way Type C medicated feeds and to NADA 138-870 for use of liquid MGA 500, RUMENSIN, and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles to make three-way Type C medicated feeds for heifers fed in confinement for slaughter. The supplemental NADAs provided for use of increased levels of monensin, previously approved for single-ingredient monensin Type C medicated feeds under NADA 95-735 (72 FR 653, January 8, 2007). The supplements were approved in October 2009 and the regulations were amended in § 558.342 (21 CFR 558.342) (74 FR 59911, November 19, 2009; 74 FR 61029, November 23, 2009).

Labeling submitted with these supplements also provided for use of a dry MGA 200 Type A medicated article in formulating both the two-way and three-way combination feeds with increased levels of monensin. This was consistent with the February 2009 supplemental approvals under NADA 125-476 and NADA 138-870 of these same two-way and three-way combinations using dry MGA 200 for conditions of use that had been originally approved under Pharmacia & Upjohn Co.'s NADA 124-309 and NADA 138-792. Approval of these supplements in this manner was intended, in part, to simplify administration of the two-way and three-way combinations under a single NADA file for each combination and to treat Pharmacia & Upjohn's applications in a manner consistent with similar applications held by other sponsors. As of February 2009, NADA 124-309 and NADA 138-792 no longer contained the most current approved labeling and were administratively considered part of NADA 125-476 and NADA 138-870, respectively.

FDA has noticed that the regulations in § 558.342 contain entries for use of monensin in these two-way and three-way combinations at the lower use levels. At this time, the regulations are being amended to reflect the conditions of use described in labeling approved in October 2009 under NADA 125-476 and NADA 138-870. These amendments are being made to improve the accuracy of the regulations.

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.

**§ 558.342 [Amended]**

■ 2. In § 558.342, in the table in paragraphs (e)(1)(v), (e)(1)(vi), and (e)(1)(vii), in the “Sponsor” column, remove “000009.”

Dated: September 24, 2010.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Parts 1 and 602**

[TD 9501]

RIN 1545-BI28

**Furnishing Identifying Number of Tax Return Preparer**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document contains final regulations under section 6109 of the Internal Revenue Code (Code) that provide guidance on how the IRS will define the identifying number of tax return preparers and set forth requirements on tax return preparers to furnish an identifying number on tax returns and claims for refund of tax they prepare. Additional provisions of the regulations provide that tax return preparers must apply for and regularly renew their preparer identifying number as the IRS may prescribe in forms, instructions, or other guidance.

**DATES:** *Effective Date:* These regulations are effective on September 30, 2010.

*Applicability Date:* For dates of applicability, see § 1.6109-2(i).

**FOR FURTHER INFORMATION CONTACT:** Stuart Murray at (202) 622-4940 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Paperwork Reduction Act**

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-2176. The collection of information in these final regulations is in § 1.6109-2(d) and (e). This information is required in order for the IRS to issue identifying numbers to tax return preparers who are eligible to receive them.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

**Background**

This document contains final amendments to regulations under section 6109 of the Code relating to furnishing a tax return preparer's identifying number on tax returns and claims for refund of tax. Section 6109(a)(4) requires tax return preparers to furnish on tax returns and claims for refund of tax an identifying number, as prescribed, to ensure proper identification of the preparer, the preparer's employer, or both. In addition, section 6109(c) authorizes the Secretary “to require such information as may be necessary to assign an identifying number to any person.” The requirement to furnish an identifying number on tax returns and claims for refund of tax applies to information returns described in § 301.7701-15(b)(4) and to electronically filed tax returns.

In 2009 the IRS conducted a comprehensive review of tax return preparers, culminating in Publication 4832, *Return Preparer Review* (Rev. 12-2009) (the Report). The Report recommended that tax return preparers be required to obtain and use a preparer tax identification number (PTIN) as the exclusive preparer identifying number. The Report also recommended that the IRS establish new eligibility standards to prepare tax returns—including testing, continuing education, and Federal tax compliance checks. The proposed regulations adopted several of the recommendations made in the Report. The Treasury Department and

the IRS conclude that adopting these provisions in the final regulations will increase tax compliance and help to ensure that tax return preparers are knowledgeable, skilled, and ethical.

To implement recommendations made in the Report, on March 26, 2010, the Treasury Department and the IRS published in the **Federal Register** (75 FR 14539) a notice of proposed rulemaking (REG-134235-08) proposing amendments to § 1.6109-2 regarding the identifying number that a tax return preparer must furnish on tax returns and claims for refund of tax. A public hearing was held on the proposed regulations on May 6, 2010. The IRS received written public comments responding to the proposed regulations.

**Summary of Comments and Explanation of Revisions**

Over 200 written comments were received in response to the notice of proposed rulemaking. All comments were considered and are available for public inspection. Most of the comments are summarized in this preamble.

*1. Requiring the Use of PTINs*

The final regulations adopt the proposed amendments to § 1.6109-2, which provide that for tax returns or refund claims filed after December 31, 2010, tax return preparers must obtain and exclusively use the identifying number prescribed by the IRS in forms, instructions, or other guidance, rather than a social security number (SSN), as the identifying number to be included with the tax return preparer's signature on a tax return or claim for refund. Prior to these final regulations, the identifying number of a tax return preparer was the tax return preparer's SSN or an alternative number as prescribed by the IRS. The alternative number that the IRS has prescribed is a PTIN. After December 31, 2010, tax return preparers can only use a PTIN (or other number that the IRS prescribes in the future as a replacement to the PTIN) and may not use an SSN as a preparer identifying number unless the IRS directs otherwise. For tax returns or claims for refund filed before January 1, 2011, the identifying number of a tax return preparer will remain the preparer's SSN or PTIN.

The requirement to use a PTIN will allow the IRS to better identify tax return preparers, centralize information, and effectively administer the rules relating to tax return preparers. The final regulations will also benefit taxpayers and tax return preparers and help maintain the confidentiality of SSNs. Most of the comments received