Register between January 1, 1999, and December 31, 2000.

Dated: December 13, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–32552 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Tylosin

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 (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA provides for use of tylosin Type A medicated articles to make Type C medicated swine feeds for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.

EFFECTIVE DATE: December 24, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 12–491, which provides for use of 40 and 100 grams per pound (g/lb) tylosin Type A medicated articles to make 100 g/ton tylosin Type C medicated feeds to be fed for 21 days for the prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis.* The supplemental NADA is approved as of November 8, 1996, and the regulations are amended by adding new 21 CFR 558.625(f)(1)(vi)(*e*) to reflect the approval.

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 for food-producing animals qualifies for 3 years of marketing exclusivity beginning November 8, 1996, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.625 is amended by adding new paragraph (f)(1)(vi)(*e*) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(1) * * *

(vi) * * *

(*e*) (1) *Indications for use*. Prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.

(2) *Limitations*. As tylosin phosphate, administer for 21 days.

Dated: December 5, 1996.

Robert C. Livingston,

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

[FR Doc. 96–32549 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 884

[Docket No. 95N–0139]

Medical Devices; Reclassification and Exemption From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying scented or scented deodorized menstrual pads from class II into class I based on new information respecting such device. FDA is also exempting this device, and one already classified generic type of class I device, unscented menstrual pads, from the requirement of premarket notification, with limitations. FDA has determined that manufacturers' submissions of premarket notifications for these devices are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. These exemptions allow the agency to make better use of its resources and thus better serve the public.

DATES: Effective February 24, 1997. Beginning on February 24, 1997, all device manufacturers who have 510(k) submissions pending FDA review for devices falling within a generic category that is subject to this rule, will receive a letter stating that the device is exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 28, 1995 (60 FR 38902), FDA issued a proposed rule to reclassify 112 generic types of class II devices into class I based on new information respecting such devices and to exempt the 112 generic types of devices, and 12 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. Interested persons were given until October 11, 1995, to comment on the proposed rule.

In the Federal Register of January 16, 1996 (61 FR 1117), FDA issued a final rule reclassifying 111 of the 112 generic

types of class II devices included in the July 28, 1995, proposed rule into class I and exempting 111 of them, and 11 of the already classified generic types of class I devices from the requirement of premarket notification, with limitations. In the preamble to the final rule, the agency stated the following: (1) FDA was deferring action on scented or scented deodorized menstrual pads (§ 884.5425 (21 CFR 884.5425)) and unscented menstrual pads (§ 884.5435 (21 CFR 884.5435)) in order to review the comments more closely and to reevaluate whether the devices should be reclassified and/or exempted from the requirement of premarket notification, with limitations; (2) FDA was considering the comments requesting FDA to add 18 additional devices to the list of devices that the agency was reclassifying into class I and/or exempting from the requirement of premarket notification; (3) FDA was considering expanding the reclassification and exemption for the endoscope and accessories to include additional endoscope accessories; and (4) FDA would address all these comments in a future issue of the Federal Register.

During the comment period, FDA received three comments questioning the appropriateness of the proposed reclassification and exemption for scented or scented deodorized menstrual pads (§ 884.5425) and the proposed exemption for unscented menstrual pads (§ 884.5435).

After careful review of the comments and reconsideration of the appropriateness of the proposed reclassification and exemption for scented or scented deodorized menstrual pads (§ 884.5425) and the proposed exemption for unscented menstrual pads (§ 884.5435), the agency has decided to revise: (1) The limitation placed upon the proposed reclassification into class I; (2) the exemptions from the requirement of premarket notification; and (3) the proposed requirements for safety testing.

FDA will address the comments regarding the other devices included in the July 28, 1995, proposed rule in a future issue of the Federal Register.

Three comments questioned the appropriateness of the proposed reclassification and exemption for scented or scented deodorized menstrual pads (§ 884.5425) and the proposed exemption for unscented menstrual pads (§ 884.5435). All three comments requested that the ''made from cotton or rayon'' limitation placed upon the proposed reclassification into class I and the exemption from the requirement of premarket notification be eliminated or revised to provide for a wider range of materials that are currently in use. In addition, two of the comments said that the proposed requirements for safety testing were inappropriate and unnecessary.

The agency has decided to revise the limitation placed upon the reclassification and exemption for scented or scented deodorized menstrual pads (§ 884.5425) into class I and the exemption for unscented menstrual pads (§ 884.5435). FDA has concluded, based on new information that, when these devices are made of common cellulosic and synthetic material with an established safety profile, general controls will provide reasonable assurance of the safety and effectiveness of these devices. Finally, FDA has concluded that the exemption for class I scented or scented deodorized menstrual pads (§ 884.5425) and unscented menstrual pads (§ 884.5435) will be limited and would apply only to menstrual pads made of common cellulosic and synthetic material with an established safety profile. For the two devices for which exemptions are being granted, FDA has concluded that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule would reduce the regulatory burden for all manufacturers of menstrual pads covered by this rule, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director of the Center for Devices and Radiological Health, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 884.5425 is amended by revising paragraph (b) to read as follows:

§ 884.5425 Scented or scented deodorized menstrual pad.

* * * * *

(b) *Classification*. (1) Class I (general controls) for menstrual pads made of common cellulosic and synthetic material with an established safety profile. The devices subject to this paragraph (b)(1) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. This exemption does not include the intralabial pads and reusable menstrual pads.

(2) Class II (special controls) for scented or scented deodorized menstrual pads made of materials not described in paragraph (b)(1).

3. Section 884.5435 is amended by revising paragraph (b) to read as follows:

§ 884.5435 Unscented menstrual pad.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device is made of common cellulosic and synthetic material with an established safety

profile. This exemption does not include the intralabial pads and reusable menstrual pads.

Dated: December 16, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–32550 Filed 12–23–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8700]

RIN 1545–AS30

Mark to Market for Dealers in Securities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final regulations providing guidance to enable taxpayers to comply with the mark-to-market requirements applicable to dealers in securities. The Revenue Reconciliation Act of 1993 amended the applicable tax law. These regulations provide guidance to dealers in securities.

DATES: These final regulations are effective December 24, 1996, except paragraph (a) of § 1.475(c)–1T is removed effective December 24, 1996, and the remainder of § 1.475(c)–1T is removed effective January 23, 1997.

For dates of applicability, see § 1.475(e)–1.

FOR FURTHER INFORMATION CONTACT: Robert B. Williams at (202) 622–3960 or Jo Lynn Ricks at (202) 622–3920 (not toll-free numbers).

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 (44 U.S.C. 3507) under control number 1545–1496. Responses to this collection of information are required for a taxpayer to obtain the benefit of an exemption from marking to market under section 475 for those securities (see § 1.475(b)–2) and for a consolidated group of taxpayers to obtain the benefit of treating inter-member transactions as customer transactions for purposes of the definition of dealer in securities (the intragroup-customer election, § 1.475(c)–1(a)(3)(iii)).

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.

The estimated annual burden per recordkeeper regarding § 1.475(b)–2 varies from .25 to 3 hours, depending on individual circumstances, with an estimated average of 1 hour. Section 1.475(b)–4 (formerly § 1.475(b)–2T), which permitted a taxpayer to add or remove certain identifications on or before January 31, 1994, does not impose a recordkeeping burden into the future. The estimated burden per respondent in making the intragroup-customer election in §§ 1.475(c)–1(a)(3)(iii) varies from .25 to 1 hour, depending on individual circumstances, with an estimated average of .5 hour.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this 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 regulations under section 475 (relating to mark-to-market accounting for dealers in securities). Section 475 was added by section 13223 of the Revenue Reconciliation Act of 1993, Public Law 103–66, 107 Stat. 481, and is effective for all taxable years ending on or after December 31, 1993.

On December 29, 1993, temporary regulations (TD 8505, 58 FR 68747) (hereinafter sometimes referred to as the temporary regulations) and cross-referenced proposed regulations (FI–72–93, 58 FR 68798) (hereinafter sometimes referred to as the 1993 proposed regulations) were published to furnish guidance on several issues, including the scope of exemptions from the mark-to-market requirements, certain transitional issues relating to the scope of exemptions, and the meaning of the statutory terms *security, dealer in securities,* and *held for investment.* Various comments were received regarding those regulations, and a hearing was held on April 12, 1994.

Additional regulations were proposed on January 4, 1995 (60 FR 397) (hereinafter sometimes referred to as the 1995 proposed regulations), and on June 20, 1996 (61 FR 31474) (hereinafter sometimes referred to as the 1996 proposed regulations). The 1995 and 1996 proposed regulations supplemented, and in a few cases revised, the 1993 proposed regulations. Hearings on the 1995 and 1996 proposed regulations were held on May 3, 1995, and October 15, 1996, respectively.

The final regulations in this document generally adopt the 1993 proposed regulations, as revised by the 1995 and 1996 proposed regulations, with certain changes reflecting comments that were received. These final regulations also adopt additional portions of the 1995 proposed regulations. The sections that are not adopted at this time remain proposed.

The provisions governing mark to market of debt instruments, which were proposed in January 1995, attracted substantial comment. The IRS and Treasury intend to finalize those regulations in a substantially revised form in response to those taxpayer comments.

Explanation of Provisions

Acquisition by a Dealer of a Security With a Substituted Basis

The final regulations adopt without change the provisions in the 1995 proposed regulations that provide rules for situations where a dealer in securities receives a security with a basis in its hands that is determined, in whole or in part, either by reference to the basis of the security in the hands of the transferor or by reference to other property held at any time by the dealer. In these cases, section 475(a) applies only to post-acquisition gain and loss with respect to the security. That is, section 475(a) applies only to changes in value of the security occurring after its acquisition. See section 475(b)(3).

The character of the mark-to-market gain or loss is determined as provided under section 475(d)(3). The character of pre-acquisition gain or loss (that is, the built-in gain or loss at the date the dealer acquires the security) and the time for taking that gain or loss into account are determined without regard to section 475. The fact that a security has a substituted basis in the dealer's hands does not affect the security's date of acquisition for purposes of