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