DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use In Animal Feeds; Melengestrol Acetate and Lasalocid; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending and clarifying the animal drug regulations concerning melengestrol acetate (MGA) and the special considerations related to making type B and C feeds and lasalocid type B liquid feed specifications used for making lasalocid/MGA type C heifer feed.

EFFECTIVE DATE: December 1, 1998.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center For Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, is sponsor of NADA's 39–402 and 140–288 that provide for combining separately approved melengestrol acetate (MGA) (dry and liquid) and lasalocid (dry and liquid) type A medicated articles to make lasalocid/MGA (dry and liquid) type B feeds. The type B feeds are used to make dry type C feeds for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat). The sponsor requested that § 558.342 (21 CFR 558.342) be amended to change the special considerations in paragraph (c)(1) to read ''type B or C medicated feeds'' and to change the limitations in paragraph (d)(3)(ii) by adding the specification ''The liquid medicated feeds are required to be manufactured in accordance with § 558.311(d).'' FDA concurs with the sponsor's request and extends the amendments to special considerations to include all type B or C feeds for clarity as originally intended. The regulations are amended in paragraph (c) of § 558.342 as requested.

–FDA 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.

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. Section 558.342 *Melengestrol acetate* is amended in paragraph (c) after the phrase ''Type B'' each place it appears by adding the phrase ''or C'' and in paragraph (d)(3)(ii) by adding a sentence after the first sentence to read ''The liquid medicated feeds are required to be manufactured in accordance with § 558.311(d).''.

Dated: November 10, 1998.

Andrew J. Beaulieu,

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

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–019A]

RIN 1218–AA51

Permit-Required Confined Spaces

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: This final rule amends the Occupational Safety and Health Administration (OSHA) standard on Permit-Required Confined Spaces (permit spaces) (29 CFR 1910.146) to provide for enhanced employee participation in the employer's permit space program, to provide authorized permit space entrants or their authorized representatives with the opportunity to observe any testing or monitoring of permit spaces, and to strengthen and clarify the criteria employers must satisfy when preparing for the timely rescue of incapacitated permit space entrants. The revisions being made to the final rule will substantially enhance the protections being provided to permit space entrants and will additionally clarify a number of issues that have arisen since promulgation of the final Permit-Required Confined Spaces rule in 1993.

Specifically, OSHA is clarifying and strengthening the requirements in revised paragraphs (d), *Permit-required confined space program,* and (e), *Permit system,* to allow for greater employee participation in the permit-space program and for employee access to program information developed under the standard. The Agency is also revising paragraphs (c) and (d) to specify that employers must provide those employees who are authorized permit space entrants, or their authorized representatives, an opportunity to observe any testing of the space that is conducted prior to entry or subsequent to such entry. The Agency believes that these revisions are necessary to ensure that permit space entrants, whose work often requires entry into potentially life-threatening atmospheres, have the information necessary to protect themselves and their co-workers from confined space hazards. Allowing authorized entrants or their authorized representatives to observe the testing of the spaces they are required to enter will help to ensure that the testing has been done properly, that the respirators and other personal protective equipment being worn are appropriate, and that the entrants understand the nature of the hazards present in the space. In addition, paragraph (k) of the final rule, *Rescue and emergency services,* is being revised to clarify the criteria employers must satisfy when selecting a rescue team or service to rescue incapacitated permit space entrants, and a new paragraph (l), *Employee participation,* is being added to the final rule to ensure employee involvement in permit space program development and implementation. A non-mandatory appendix is also being added to the standard to assist employers in selecting appropriately trained and equipped rescuers.

EFFECTIVE DATE: This final rule will become effective February 1, 1999.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), the Agency designates for receipt of petitions for review of the standard the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Ms. Bonnie Friedman, U.S. Department of Labor, Occupational Safety and Health Administration, Office of Information and Consumer Affairs, Room N3647,