Actions	Compliance	Procedures
(2) As an alternative method of compliance to the replacements in paragraph (d)(1) of this AD, you may repetitively inspect each front fuselage strut, as follows:. (i) perform a detailed inspection of each front fuselage strut and all fittings attached to the frame for damage (corrosion, cracks, dents). When fatigue damage is found, you must replace the damaged strut. After each inspection, clean the drain holes around the bottom end fitting and protect the tube with an appropriate corrosion preventive spray. Part numbers for existing and replacement front fuselage struts parts are presented in paragraph (e) of this AD. (ii) perform an ultrasonic thickness measurement of all surface on each front fuselage strut. When minimum thickness is below 0.030 inches, you must replace the affected strut. Part numbers for existing and replacement front fuselage struts parts are presented in paragraph (e) of this AD.	Initially inspect upon accumulating 15 years on each front fuselage strut or within the next 12 calendar months after September 6, 2002 (the effective date of this AD), whichever occurs later. Accomplish the repetitive detailed inspection thereafter at intervals not to exceed 12 months and the ultrasonic thickness measurement at intervals not to exceed 5 years. Accomplish the corrosion prevention work prior to further flight after each inspection. Accomplish the replacement prior to further flight after damage is found or the thickness is found below 0.030 inches. Then, after replacement either replace with a new strut at 15-year intervals thereafter or repetitively inspect as prescribed above beginning at 15 years after each replacement.	For the detailed inspection, use an inspection light, inspection mirror, and 10X magnifying glass. For the ultrasonic inspection, use FAA-approved procedures that follow a similar calibration and measures strut thickness to that detailed in Bombardier Service Bulletin 2/49, Revision C.
(3) Do not install, on any affected airplane, any front fuselage strut unless it has a part number specified in the Replacement Part Number column of the chart presented in paragraph (e) of this AD.	As of September 6, 2002 (the effective date of this AD.	Not Applicable.

(e) *What part number front fuselage struts should I use for replacements?* The following charts presents the part numbers for existing parts and replacement parts for the front fuselage strut replacements:

Installed part No.	Replacement part No.	Description
C2FS209 or C2FS3281A	C2FS3281A	Strut Assembly Front Fuselage, Left.
C2FS210 or C2FS3282A	C2FS3282A	Strut Assembly Front Fuselage, Right.

(f) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, New York Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(g) *Where can I get information about any already-approved alternative methods of compliance?* Contact Jon Hjelm, Aerospace Engineer, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone: (516) 256–7523; facsimile: (516) 256–2716.

(h) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(i) *How do I get copies of the documents referenced in this AD?* You may direct technical questions to or get copies of the documents referenced in this AD from Bombardier Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario, Canada M3K 1Y5; telephone: (416) 633–7310. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in Canadian AD CF–98–37R1, dated August 20, 1999.

(j) *When does this amendment become effective?* This amendment becomes effective on September 6, 2002.

Issued in Kansas City, Missouri, on July 15, 2002.

Dorenda D. Baker,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–18334 Filed 7–19–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Melengestrol

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 several supplemental applications filed by Pharmacia and Upjohn Co. to their new animal drug applications (NADAs) for the use of single-ingredient Type A medicated

articles containing melengestrol acetate, monensin, and tylosin to make two-way and (with tylosin) three-way, dry and liquid, combination drug Type C medicated feeds for heifers fed in confinement for slaughter. Some of the supplemental NADAs add the single-ingredient monensin claim for prevention and control of coccidiosis in feedlot heifers to the indications for combinations of melengestrol acetate and monensin with and without tylosin. Other supplemental NADAs extend the dose of tylosin to the single-ingredient range of 60 to 90 milligrams (mg) per head per day to reduce the incidence of liver abscesses in feedlot heifers and provide for use of liquid Type C medicated feeds containing melengestrol acetate and tylosin with and without monensin.

DATES: This rule is effective July 22, 2002.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, dbenz@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental applications to NADAs 124–309 and 125–476 that provide for use of MGA (melengestrol acetate) Premixes and RUMENSIN (monensin sodium) Premixes to make two-way, dry and liquid, combination drug Type C medicated feeds and to NADAs 138–792 and 138–870 that provide for use of MGA Premixes, RUMENSIN Premixes, and TYLAN (tylosin phosphate) Premixes to make three-way, dry and liquid, combination drug Type C medicated feeds for heifers fed in confinement for slaughter. These supplemental NADAs add the claim for use of 50 to 360 mg of monensin per head per day for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*. Pharmacia and Upjohn Co. also filed supplemental applications to NADAs 138–995 and 139–192 that provide for combination use of MGA Premixes and TYLAN Premixes, and to NADAs 138–792 and 138–870, described previously. These supplemental NADAs extend the dose of tylosin to a range of 60 to 90 mg per head per day to reduce the incidence of liver abscesses caused by *Fusobacterium necrophorum and Actinomyces (Corynebacterium) pyogenes* and provide for use of liquid Type C medicated feeds in combinations of melengestrol acetate and tylosin with and without monensin in heifers fed in confinement for slaughter. The supplemental applications are approved as of February 26, 2002, and the regulations are amended in § 558.342 (21 CFR 558.342) to reflect the approvals. Where appropriate, the basis of approval is discussed in freedom of information summaries.

Section 558.342 is also being revised to include a table format and to correct drug labeler codes to reflect recent changes of sponsorship for single-ingredient lasalocid (66 FR 46705, September 7, 2001) and oxytetracycline (66 FR 47962, September 17, 2001) Type A medicated articles. Section 558.355 is also being revised to delete a redundant entry and to add a cross-reference.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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)(2) and (a)(6) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are 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 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.

2. Section 558.342 is amended by revising the section heading and paragraph (a); by redesignating paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e), respectively; by adding a new paragraph (b) and paragraphs (d)(3) through (d)(8); and by revising newly redesignated paragraph (e) to read as follows:

§ 558.342 Melengestrol.

(a) *Specifications.* (1) Dry Type A medicated articles containing 100 or 200 milligrams (mg) melengestrol acetate per pound.

(2) Liquid Type A medicated article containing 500 mg melengestrol acetate per pound.

(b) *Approvals.* See No. 000009 in § 510.600(c) of this chapter.

* * * * *

(d) * * *

(3) Combination Type B or C medicated feeds containing lasalocid must be labeled in accordance with § 558.311(d)(5) of this chapter.

(4) Liquid combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be manufactured in accordance with § 558.311(d) of this chapter.

(5) Combination Type B or C medicated feeds containing monensin must be labeled in accordance with § 558.355(d) of this chapter.

(6) Liquid combination Type B or C medicated feeds containing melengestrol acetate and monensin must be manufactured in accordance with § 558.355(f)(3)(i) of this chapter.

(7) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(c) of this chapter.

(8) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

(e) *Conditions of use*—(1) *Cattle.*

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(i) 0.25 to 0.5		Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day.	000009

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(ii) 0.5		Heifers intended for breeding: For suppression of estrus (heat).	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding.	000009
(iii) 0.25 to 0.5	Lasalocid 100 to 360	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 30 grams (g) of lasalocid per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to a ration of nonmedicated feed to provide 0.25 to 0.5 mg melengestrol acetate and 100 to 360 mg lasalocid/head/day. Lasalocid provided by No. 046573 in § 510.600(c) of this chapter.	000009
(iv) 0.25 to 0.5	Lasalocid 100 to 360 plus tylosin 90	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses.	To administer 0.25 to 0.5 mg melengestrol acetate plus 100 to 360 mg lasalocid plus 90 mg tylosin/head/day: 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 10 to 30 g lasalocid and 8 to 10 g tylosin per ton; or 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to 4.5 to 18 lb of a dry medicated feed containing 10 to 40 g tylosin per ton; or 3. Add 0.5 to 2.0 lb/head/day of a dry pelleted medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article), 50 to 720 mg lasalocid, and 45 to 180 mg tylosin/lb to a ration of nonmedicated feed. Lasalocid provided by No. 046573 and tylosin as tylosin phosphate by No. 000986 in § 510.600(c) of this chapter.	000009
(v) 0.25 to 0.4	Monensin 50 to 360	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate/lb to a feed containing 5 to 30 g monensin per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate plus 25 to 720 mg monensin/lb to a nonmedicated feed to provide 0.25 to 0.40 mg melengestrol acetate and 50 to 360 mg monensin/head/day. Monensin provided by No. 000986 in § 510.600(c) of this chapter.	000009

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(vi) 0.25 to 0.4	Monensin 50 to 360	Heifers fed in confinement for slaughter: As in item paragraph (e)(1)(i) of this section; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate/lb to a feed containing 10 to 30 g monensin per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 0.80 mg melengestrol acetate plus 25 to 720 mg monensin/lb to a nonmedicated feed to provide 0.25 to 0.40 mg melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight, up to 360 mg monensin/head/day. Monensin provided by No. 000986 in § 510.600(c) of this chapter.	000009
(vii) 0.25 to 0.5	Monensin 50 to 360 plus tylosin 60 to 90	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; for the prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and for reduced incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.	To administer 0.25 to 0.50 mg melengestrol acetate to 50 to 360 mg monensin plus 60 to 90 mg tylosin/head/day: 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 5 to 30 g monensin and 8 to 10 g tylosin per ton; or 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 25 to 720 mg monensin per pound to 4.5 to 18 lb of a dry medicated feed containing 10 to 40 g tylosin per ton; or 3. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article), 25 to 600 mg monensin, and 45 to 180 mg tylosin/lb to a ration of nonmedicated feed. Monensin and tylosin as tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter.	000009
(viii) 0.25 to 0.5	Oxytetracycline 75	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduction of liver condemnation due to liver abscesses.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb per pound to a feed containing 6 to 10 g oxytetracycline per ton; or add at the rate of 0.5 to 2.0 lb/head/day a dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 37.5 to 150 mg oxytetracycline/lb to provide 0.25 to 0.5 mg melengestrol acetate and 75 mg oxytetracycline/head/day. Oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter.	000009

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(ix) 0.25 to 0.5	Tylosin 60 to 90	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses caused by *F. necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes*.	To administer 0.25 to 0.5 mg melengestrol acetate with 60 to 90 mg tylosin/head/day: 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 8 to 10 g tylosin per ton; or 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 g tylosin per ton; or 3. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article) plus 45 to 180 mg tylosin/lb to a ration of non-medicated feed. Tylosin as tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter.	000009

(2) [Reserved]

3. Section 558.355 is amended by removing and reserving paragraph (f)(3)(iv) and by revising paragraph (f)(7) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(7) Monensin may also be used in combination with:

(i) Decoquinate alone or with tylosin as in § 558.195.

(ii) Melengestrol acetate alone or with tylosin as in § 558.342.

Dated: July 8, 2002.

Andrew J. Beaulieu,

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

[FR Doc. 02–18367 Filed 7–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Ractopamine

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 reflect approval of two supplemental new animal drug applications (NADAs) filed by Elanco Animal Health for their ractopamine hydrochloride Type A medicated article. The supplemental NADAs provide for use of a 45-gram-per-pound (g/lb) strength Type A medicated article to make Type B and Type C medicated feeds for finishing swine, for amending the assay limits for Type B and Type C medicated feeds containing ractopamine, and for the addition of cautionary statements to labeling.

DATES: This rule is effective July 22, 2002.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600, e-mail: candres@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed two supplemental applications to NADA 140–863 for PAYLEAN (ractopamine hydrochloride), a Type A medicated article used to make Type B and Type C medicated feeds for finishing swine. The first supplemental NADA provides for use of a 45-g/lb strength of PAYLEAN and for amending the assay limits for Type B and Type C medicated feeds containing ractopamine. The second supplemental NADA provides for addition of cautionary statements to labeling. The supplemental NADAs are approved as of February 27 and June 1, 2001, respectively, and the regulations are amended in §§ 558.4 and 558.500 (21 CFR 558.4 and 558.500) to reflect the approval.

In addition, § 558.500 is being revised to correct the wording of the indications for the use of ractopamine alone or in combination with tylosin.

Approval of the first supplemental NADA did not require review of safety or effectiveness data; therefore, a freedom of information summary is not required.

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 submitted to support approval of the second supplemental 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 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