

Issued in Washington, DC on November 13, 2009.

John M. Allen,
Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

Effective Upon Publication

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
17-Dec-09	CT	Danielson	Danielson	9/3449	10/9/09	VOR–A, AMDT 6C.
17-Dec-09	IL	Kewanee	Kewanee Muni	9/5179	10/16/09	Takeoff Minimums and Obstacle DP, ORIG.
17-Dec-09	RI	North Kingstown	Quonset State	9/5393	10/21/09	ILS OR LOC RWY 16, AMDT 10.
17-Dec-09	VA	Clarksville	Marks Muni	9/6484	10/23/09	VOR/DME A, ORIG.
17-Dec-09	KY	Mount Sterling	Sterling-Montgomery County.	9/6872	10/23/09	NDB OR GPS RWY 3, AMDT 1C.
17-Dec-09	ND	Devils Lake	Devils Lake RgNL	9/7299	10/28/09	Takeoff Minimums and Obstacle DP, AMDT 1.
17-Dec-09	ME	Auburn/Lewiston	Auburn/Lewiston Muni	9/7617	10/30/09	ILS OR LOC RWY 4, AMDT 10A.
17-Dec-09	ME	Auburn/Lewiston	Auburn/Lewiston Muni	9/7618	10/30/09	RNAV (GPS) RWY 4, ORIG.
17-Dec-09	ME	Auburn/Lewiston	Auburn/Lewiston Muni	9/7620	10/30/09	RNAV (GPS) RWY 22, ORIG.
17-Dec-09	NC	Greenville	Pitt-Greenville	9/8037	10/30/09	RNAV (GPS) RWY 26, AMDT 2.
17-Dec-09	NC	Greenville	Pitt-Greenville	9/8038	10/30/09	RNAV (GPS) RWY 20, AMDT 2.
17-Dec-09	NC	Greenville	Pitt-Greenville	9/8040	10/30/09	RNAV (GPS) RWY 8, AMDT 2.

[FR Doc. E9–27900 Filed 11–20–09; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2009–N–0665]

New Animal Drugs for Use in Animal Feeds; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 10 new animal drug applications (NADAs) from Merial Ltd. to Huvepharma AD.

DATES: This rule is effective November 23, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500,

Duluth, GA 30096–4640, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 10 approved NADAs to Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria: NADA 036–304, 049–179, 049–180, 118–507, 040–264, 041–541, 044–016, 046–209, 049–934, and 099–150. Accordingly, the agency is amending the regulations to reflect the transfer of ownership.

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.

§ 558.55 [Amended]

■ 2. In § 558.55, in paragraph (d)(2)(iv), in the table, in the entry for “Carbarsonne 227 to 340.5”, in the “Sponsor” column, remove “000006” and in its place add “016592”.

■ 3. Amend § 558.58 as follows:

a. Remove paragraphs (a)(3), (b)(1), and (b)(2);

b. In paragraph (e)(1)(i), in the table, in the “Sponsor” column, remove “050604”;

c. In paragraphs (e)(1)(ii) and (e)(1)(iii), in the table, in the “Limitations” column, remove “050604” wherever it occurs and in its place add “016592”; and

d. Revise paragraph (b).

The revisions are to read as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

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§ 558.175 [Amended]

■ 4. In § 558.175, in paragraph (b) and in the table in paragraph (d), in the “Sponsor” column, remove “050604” wherever it occurs and in its place add “016592”.

Dated: November 16, 2009.

Steven D. Vaughn,

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

[FR Doc. E9-28009 Filed 11-20-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2009-N-0665]

New Animal Drugs for Use in Animal Feeds; Melengestrol; Monensin; 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 Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for use of the same dose levels approved for single-ingredient Type C medicated feeds containing melengestrol acetate, monensin, or tylosin phosphate for heifers fed in confinement for slaughter in three-way, combination drug Type C medicated feeds containing melengestrol acetate, monensin, and tylosin phosphate.

DATES: This rule is effective November 23, 2009.

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, e-mail: *suzanne.sechen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 138-870 for use of MGA (melengestrol acetate), RUMENSIN (monensin, USP), and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles to make three-way, combination drug Type C medicated feeds for heifers fed in confinement for slaughter. The supplemental NADA provides for use of the same dose levels approved for single ingredient Type C medicated feeds containing melengestrol acetate, monensin, or tylosin phosphate in the three-way, combination drug Type C medicated feeds. The supplemental application is approved as of October 19, 2009, and the regulations are amended in 21 CFR 558.342 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), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

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 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. In § 558.342, add paragraph (e)(1)(xi) to read as follows:

§ 558.342 Melengestrol.

* * * * *
(e) * * *
(1) * * *

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(xi) 0.25 to 0.5	Monensin 50 to 480, 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 <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium pyogenes</i> .	Feed continuously as sole ration (liquid or dry) at a rate of 0.5 to 2.0 lb/head/day to provide 0.25 to 0.5 mg/head/day melengestrol acetate; 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day; and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into a complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin in the amount of complete feed consumed by an animal per day. Monensin and tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter.	000009