

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; Change of Sponsor

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 a change of sponsor for 25 approved new animal drug applications (NADAs) and 16 approved abbreviated new animal drug applications (ANADAs) for Type A medicated articles and feed use combinations from Intervet, Inc., to Huvepharma AD.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 25 approved NADAs and 16 approved ANADAs for Type A medicated articles and feed use combinations to Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria:

Application No.	Trade Name(s)
NADA 044-759	FLAVOMYCIN (bambermycins) Type A medicated article
NADA 095-543	AMPROL HI-E / FLAVOMYCIN
NADA 095-547	AMPROL HI-E / FLAVOMYCIN / 3-NITRO

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Application No.	Trade Name(s)
NADA 095-548	AMPROL / 3-NITRO / FLAVOMYCIN
NADA 095-549	AMPROL PLUS / 3-NITRO / FLAVOMYCIN
NADA 098-340	FLAVOMYCIN / MONENSIN
NADA 098-341	FLAVOMYCIN / 3-NITRO / COBAN
NADA 101-628	FLAVOMYCIN / 3-NITRO / ZOALENE
NADA 101-629	FLAVOMYCIN / ZOALENE
NADA 130-185	FLAVOMYCIN / AMPROLIUM
NADA 130-661	FLAVOMYCIN / CARB-O-SEP
NADA 130-951	STENOROL (halofuginone hydrobromide)
NADA 137-483	FLAVOMYCIN / STENOROL
NADA 139-473	STENOROL / STAFAC
NADA 140-339	FLAVOMYCIN / NICARB
NADA 140-340	STENOROL / LINCOMIX
NADA 140-533	STENOROL / 3-NITRO / BMD
NADA 140-584	STENOROL / BMD
NADA 140-824	STENOROL Type A medicated article
NADA 140-843	MONTEBAN / FLAVOMYCIN / 3-NITRO
NADA 140-845	FLAVOMYCIN / MONTEBAN
NADA 140-918	STENOROL / FLAVOMYCIN
NADA 140-919	STENOROL / BMD
NADA 141-034	GAINPRO (bambermycins) Type A medicated article
NADA 141-129	AVATEC / FLAVOMYCIN
ANADA 200-075	SACOX (salinomycin sodium) Type A medicated article
ANADA 200-080	SACOX / 3-NITRO / FLAVOMYCIN
ANADA 200-081	SACOX / 3-NITRO / BMD
ANADA 200-082	SACOX / BMD
ANADA 200-083	SACOX / FLAVOMYCIN
ANADA 200-086	SACOX / ALBAC / 3-NITRO
ANADA 200-089	SACOX / BACIFERM
ANADA 200-090	SACOX / LINCOMIX / 3-NITRO
ANADA 200-091	SACOX / 3-NITRO / AUREOMYCIN

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Application No.	Trade Name(s)
ANADA 200-092	SACOX / STAFAC
ANADA 200-093	SACOX / LINCOMIX
ANADA 200-094	SACOX / STAFAC / 3-NITRO
ANADA 200-095	SACOX / AUREOMYCIN
ANADA 200-096	SACOX / TERRAMYCIN
ANADA 200-097	SACOX / 3-NITRO
ANADA 200-143	SACOX / 3-NITRO / BACIFERM

Accordingly, the agency is amending the regulations in 21 CFR 558.55, 558.58, 558.95, 558.120, 558.265, 558.311, 558.355, 558.363, 558.366, 558.450, 558.550, and 558.680 to reflect the transfer of ownership and a current format.

In addition, Huvepharma AD has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

Also, FDA has found that the April 1, 2005, edition of Title 21, parts 500 to 599 of the Code of Federal Regulations (CFR) does not accurately reflect the use limitations for amprolium in single-ingredient, medicated broiler chicken feeds. The existing entry erroneously includes limitations normally associated with the use of arsenicals in feed. At this time, the regulations are being amended in § 558.55 to correct this error. FDA is also taking this opportunity to consolidate entries for similar combination medicated feeds in the same section of part 558, and to eliminate duplicate entries. These actions are being taken to improve the accuracy and readability of the regulations.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) alphabetically add an entry for “Huvepharma AD”; and in the table in paragraph (c)(2) numerically add an entry for “016592” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* *
Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria	016592
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * *
016592	Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria
* * *	* * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

- 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.55 [Amended]

- 4. Amend § 558.55 as follows:

a. In the table in paragraph (d)(2)(ii), in the “Limitations” column in the entry for “Amprolium 72.6 to 113.5 grams per ton”, remove the first sentence;

b. In the table in paragraph (d)(2)(iii), in the “Limitations” column in the entry for “Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%)”, remove “057926” and add in its place “016592”; and in the “Sponsor” column add “016592”; and

c. In the table in paragraph (d)(2)(iii), in the “Limitations” column and “Sponsor” column in the entry for “Bambermycins 1 to 4”, remove “057926” and add in its place “016592”.

- 5. Amend § 558.58 as follows:

a. Revise paragraph (a);

b. Redesignate paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e);

c. Add new paragraph (b);

d. In the table in newly redesignated paragraph (e)(1)(i), add an entry for “Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1”;

e. In the table in newly redesignated paragraph (e)(1)(ii), in the “Limitations” column in the entries for “Bambermycins 2 to 3 plus roxarsone 22.8 to 34.1”, remove “057926” and add in its place “016592”; and in the “Sponsor” column add “016592”; and

f. In the table in newly redesignated paragraph (e)(1)(iii), in the “Limitations” column in the entries for “Bambermycins 1 to 3” and “Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1”, remove “057926” and add in its place “016592”; and in the “Sponsor” column add “016592”.

The revisions and additions read as follows:

§ 558.58 Amprolium and ethopabate.

(a) *Specifications.* Type A medicated articles containing:

(1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;

(2) 25 percent amprolium and 0.8 percent ethopabate or 5 percent amprolium and 0.16 percent ethopabate.

(b) *Approvals.* See No. 050604 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(1) * * *

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) Amprolium 113.5 (0.0125%) and ethopabate 3.6 (0.0004%).	* *	* *	*	*
	Bambermycins, 1 to 3; plus roxarsone, 22.8 to 34.1	Broiler chickens: As an aid in the prevention of coccidiosis; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; withdraw 5 d before slaughter; roxarsone provided by No. 046573, bambermycins by No. 016592 in § 510.600(c) of this chapter.	016592
*	*	*	*	*

* * * * *

■ 6. Amend § 558.95 as follows:

a. In paragraphs (a)(1), (a)(2), and (a)(5), remove “057926” and add in its place “016592”;

b. Remove and reserve paragraph (d)(1)(ii);

c. Remove paragraphs (d)(1)(iii) through (d)(1)(xiv) and paragraphs (d)(3)(iii) and (d)(3)(iv); and

d. Revise paragraph (d)(5).

The revision reads as follows:

§ 558.95 Bambermycins.

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(d) * * *

(5) Bambermycins may also be used in combination with:

(i) Amprolium alone or with roxarsone as in § 558.55.

(ii) Amprolium and ethopabate alone or with roxarsone as in § 558.58.

(iii) Diclazuril as in § 558.198.

(iv) Halofuginone as in § 558.265.

(v) Lasalocid alone or with roxarsone as in § 558.311.

(vi) Monensin alone or with roxarsone as in § 558.355.

(vii) Narasin alone or with nicarbazin or roxarsone as in § 558.363.

(viii) Nicarbazin as in § 558.366.

(ix) Salinomycin alone or with roxarsone as in § 558.550.

(x) Zoalene alone or with roxarsone as in § 558.680.

■ 7. In § 558.120, add paragraph (d)(1)(iv) and remove paragraph (d)(2)(iii) to read as follows:

§ 558.120 Carbarosone (not U.S.P.).

* * * * *

(d) * * *

(1) * * *

(iv) *Grams per ton.* 227 carbarsone, plus 1 or 4 grams per ton bambermycins.

(a) *Indications for use.* As an aid in the prevention of blackhead; and for increased rate of weight gain (4 grams per ton bambermycins) or improved feed efficiency (1 gram per ton bambermycins).

(b) *Limitations.* Feed continuously 2 weeks before blackhead is expected and continue as long as prevention is needed. Withdraw 5 days before slaughter. As sole source of organic arsenic. Bambermycins provided by No. 046573 in § 510.600(c) of this chapter.

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■ 8. In § 558.265, revise paragraph (a); redesignate paragraphs (b) and (c) as paragraphs (c) and (d); and add new paragraph (b) to read as follows:

§ 558.265 Halofuginone hydrobromide.

(a) *Specifications.* Type A medicated articles containing 6 grams of halofuginone hydrobromide per kilogram.

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

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■ 9. Amend § 558.311 as follows:

a. In the table in paragraph (e)(1)(ii) in the entry in the “Combination in grams per ton” column for “Roxarsone 45.4 plus bambermycins 1”, in the “Limitations” column remove “012799” and add in its place “016592”;

b. In the table in paragraph (e)(1)(ii) following the entry in the “Combination in grams per ton” column for “Roxarsone 45.4 plus bambermycins 1”, add an entry for “Bambermycins 1 to 2”; and

c. Remove and reserve paragraph (e)(5)(ii).

The addition reads as follows:

§ 558.311 Lasalocid.

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(e) * * *

(1) * * *

Lasalocid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 68 (0.0075 pct) to 113 (0.0125 pct).	* *	* *	*	
*	*	*	*	*
	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	016592
*	*	*	*	*

* * * * *

■ 10. In § 558.355, in paragraphs (b)(10), (f)(2)(v)(b), and (f)(2)(vi)(b), remove “057926” and add in its place “016592”; and revise paragraphs (f)(1)(vi), (f)(1)(vii), and (f)(1)(xvii) to read as follows:

§ 558.355 Monensin.

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(f) * * *

(1) * * *

(vi) *Amount per ton.* Monensin, 90 to 110 grams; plus bambermycins, 1 to 2 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Monensin, 90 to 110 grams; plus bambermycins, 1 gram; plus roxarsone, 22.7 to 45.4 grams

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 d before slaughter; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter; roxarsone provided by No. 046573.

* * * * *

(xvii) *Amount per ton.* Bambermycins, 1 to 2 grams plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams.

(a) *Indications for use.* For increased rate of weight gain; and as an aid in prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 d before slaughter; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter; roxarsone provided by No. 046573.

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■ 11. Amend § 558.363 as follows:

a. In paragraphs (a)(4), (a)(5), and (d)(1)(vii)(B), remove “057926” and add in its place “016592”;

b. In paragraph (d)(1)(iv)(B) add a new sentence at the end of the paragraph; and

c. Remove paragraph (d)(1)(xii).

The addition reads as follows:

§ 558.363 Narasin.

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(d) * * *

(1) * * *

(iv) * * *

(B) * * * Narasin as provided by No. 000986; bambermycins by No. 016592 in § 510.600(c) of this chapter.

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■ 12. In the table in paragraph (d) of § 558.366, alphabetically add new entries for “Narasin 27 to 45, and bambermycins 1 to 2” and “Bambermycins 1 to 2” to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(d) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
	Narasin 27 to 45, and baci tracin methylene disalicylate 50, and roxarsone 22.7 to 45.4	*	*	*
	Narasin 27 to 45, and bambermycins 1 to 2	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter. Bambermycins provided by No. 016592; nicarbazin and narasin by No. 066104 in § 510.600(c) of this chapter..	000986
*	*	*	*	*
113.5 (0.0125 pct)	*	*	*	*
	Bacitracin zinc 4 to 50	*	*	*
	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	016592
*	*	*	*	*

■ 13. In the table in paragraph (d)(1)(vii) of § 558.450, remove the entry for “Salinomycin 40 to 60 g/ton”; and add paragraph (d)(3)(v) to read as follows:

§ 558.450 Oxytetracycline.

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(d) * * *

(3) * * *

(v) Salinomycin as in § 558.550.

■ 14. In § 558.550, in paragraphs (d)(1)(xv)(c) and (d)(1)(xvi)(c), remove “057926” and add in its place “016592”; add paragraphs (d)(1)(xxiii) and (d)(1)(xxiv); and revise paragraphs (b)(2) and (d)(4) to read as follows:

§ 558.550 Salinomycin.

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(b) * * *

(2) No. 016592 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), (d)(1)(xxiii) and (d)(1)(xxiv), (d)(2)(i), (d)(3)(i), and (d)(4) of this section.

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(d) * * *

(1) * * *

(xxiii) *Amount per ton.* Salinomycin, 40 to 60 grams; plus bambermycins, 1 to 3 grams.

(a) *Indications for use.* Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; and for improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens; not approved for use with pellet binders; may be fatal if accidentally

fed to adult turkeys or horses. Salinomycin as provided by Nos. 046573 and 016592; bambermycins by No. 016592 in § 510.600(c) of this chapter.

(xxiv) *Amount per ton.* Salinomycin, 40 to 60 grams; plus bambermycins, 1 to 2 grams; plus roxarsone, 45.4 grams.

(a) *Indications for use.* Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone; and for improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens; as sole source or organic arsenic; withdraw 5 days before slaughter; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses; Salinomycin as provided by Nos. 046573 and 016592; bambermycins by No. 016592; roxarsone by No. 046573 in § 510.600(c) of this chapter.

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(4) *Chickens:* It is used in chicken feed as follows:

(i) *Amount per ton.* Salinomycin, 40 to 60 grams; plus oxytetracycline, 500 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; and for reduction of mortality due to air sacculitis (air-sac-infection) caused by *Escherichia coli* susceptible to oxytetracycline.

(b) *Limitations.* Feed continuously for 5 days; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter. Salinomycin as provided

by Nos. 046573 and 016592; oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter.

(ii) [Reserved]

■ 15. In § 558.680, alphabetically add two entries to the table in paragraph (d)(1)(ii); and revise paragraph (d)(2) to read as follows:

§ 558.680 Zoalene.

* * * * *

(d) * * *

(1) * * *

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations
(ii) 113.5 (0.0125%).	* *	* *	* * *
	Bacitracin 100 to 500	* * *	* *
	Bambermycins 1	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to chickens over 14 weeks of age. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.
	Bambermycins 1 plus roxarsone 22.7	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to chickens over 14 weeks of age; feed as sole source of organic arsenic; withdraw 5 days before slaughter. Bambermycins as provided by No. 016592, roxarsone by No. 046573 in § 510.600(c) of this chapter.
* *	* *	* *	* *

(2) Zoalene may also be used in combination with roxarsone as in § 558.530.

Dated: May 3, 2006.

Steven D. Vaughn,

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

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