4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Dexmedetomidine; Lasalocid; Melengestrol; Monensin; and Tylosin

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 actions for new animal drug applications and abbreviated new animal drug applications during March 2013. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during March 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.

In addition, the animal drug regulations are being amended at 21 CFR 522.558 to add a new strength of dexmedetomidine hydrochloride injectable solution for use in dogs and cats. This change is being made to improve the accuracy 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.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During March 2013

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	F Sun
200-532	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	TYLOVET 100 (tylosin phosphate) and MGA (melegestrone acetate) Type A medicated articles	Original approval as a generic copy of NADA 139-192	558.342	yes
200-533	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str.,	TYLOVET 100 (tylosin phosphate) and RUMENSIN (monensin)	Original approval as a generic copy of NADA	558.195	yes

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FO Sum
	1113 Sophia, Bulgaria	and DECCOX (decoquinate) Type A medicated articles	141-149		
200-535	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	TYLOVET 100 (tylosin phosphate) and BOVATEC (lasalocid) and MGA (melegestrone acetate) Type A medicated articles	Original approval as a generic copy of NADA 138-992	558.342	yes

[1]The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment (EA) or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feed.

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 522 and 558 are amended as follows:

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. In § 522.558, revise paragraph (a) to read as follows:

§ 522.558 Dexmedetomidine.

(a) Specifications. Each milliliter of solution contains 0.5 or 1.0 milligrams dexmedetomidine hydrochloride.

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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.

4. In § 558.195, in the table, in paragraph (e)(2)(v), revise the last sentence in the "Limitations" column and revise the "Sponsor" column to read as follows:

§ 558.195 Decoquinate.

* * * * *

(e) * * *

(2) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(v) * * *	*	*	* * * Monensin as provided by No. 000986, and tylosin as provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	016592, 046573
*	*	*	*	*

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5. In § 558.342, in the table, in paragraphs (e)(1)(iv) and (e)(1)(ix), revise the last sentence in the "Limitations" column and revise the "Sponsor" column 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
*	*	*	*	*
(iv) * * *	*	*	* * * Lasalocid provided by No. 046573, and tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	000009, 000986, 016592
*	*	*	*	*
(ix) * * *	*	*	* * * Tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	000009, 000986, 016592
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Dated: April 25, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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