4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Ceftiofur Sodium; Lincomycin Powder; Naracin; 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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during March 2012. FDA is also informing the public of the availability of summaries of 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's Center for Veterinary Medicine (CVM) is adopting use of a monthly Federal Register document to codify approval actions for NADAs and abbreviated ANADAs. CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during March 2012, as listed in table 1 of this document. FDA is also informing the public of the availability of environmental review documents required under the National Environmental Policy Act (NEPA), where applicable. For actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA) 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.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During March 2012

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
118-980	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	MONTEBAN (narasin) Type A medicated article	Supplement increasing the upper dose limit for narasin in broiler feed.	558.363	Yes	Environmental assessment (EA)/ Finding of no significant impact (FONSI)
111-636	Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017	LINCOMIX (lincomycin hydrochloride) Soluble Powder	Supplement adding an indication for control of American foulbrood in honey bees.	520.1263c	Yes	Categorically excluded (CE)[1]
200-421	Hospira, Inc., 275 N. Field Dr., Lake Forest, IL 60045	Ceftiofur for Injection (ceftiofur sodium) Sterile Powder	Original approval of generic copy of NADA 140-338.	522.313c	Yes	CE

200-455	Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	TYLOMED-WS (tylosin tartrate) Soluble Powder	Supplement adding an indication for control of porcine proliferative enteropathies.	520.2640	Yes	CE[1]
200-473	Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria	TYLOVET Soluble (tylosin tartrate)	Supplement adding an indication for control of porcine proliferative enteropathies.	520.2640	Yes	CE[1]
[1]The Agency has determined under 21 CFR 25.33 that this action is CE from the requirement to submit an 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.						

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 Parts 520 and 522

Animal drugs.

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, 520, 522, 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 "Hospira, Inc."; and in the table in paragraph (c)(2), numerically add an entry for "000409" 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
* * * * *	
Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045	000409
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
000409	Hospira Inc., 275 North Field Dr., Lake Forest, IL 60045
* * * * *	

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

4. In § 520.1263c, revise paragraph (b) and add paragraph (d)(3) to read as follows:

§ 520.1263c Lincomycin powder.

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(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000009 for use as in paragraph (d) of this section.

(2) Nos. 046573, 054925, 061623, and 076475 for use as in paragraphs (d)(1) and (d)(2) of this section.

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(d) * * *

(3) Honey bees--(i) Amount. Mix 100 milligrams lincomycin with 20 grams confectioners'/powdered sugar and dust over the top bars of the brood chamber once weekly for 3 weeks.

(ii) Indications for use. For the control of American foulbrood (Paenibacillus larvae).

(iii) Limitations. The drug should be fed early in the spring or late in the fall and consumed by the bees before the main honey flow begins to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow.

5. In § 520.2640, revise paragraph (b) introductory text to read as follows:

§ 520.2640 Tylosin.

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(b) Sponsors. See Nos. 000986, 016592, and 061623 in § 510.600(c) of this chapter.

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

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

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

7. In § 522.313c, revise paragraphs (b), (e)(2)(ii), (e)(3)(ii), (e)(4)(ii), and (e)(8)(i) to read as follows:

§ 522.313c Ceftiofur sodium.

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(b) Sponsors. See Nos. 000009, 000409, and 068330 in § 510.600(c) of this chapter.

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(e) * * *

(2) * * *

(ii) Indications for use. For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with Fusobacterium necrophorum and Bacteroides melaninogenicus.

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(3) * * *

(ii) Indications for use. For treatment of sheep respiratory disease (sheep pneumonia) associated with Mannheimia haemolytica and Pasteurella multocida.

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(4) * * *

(ii) Indications for use. For treatment of caprine respiratory disease (goat pneumonia) associated with Mannheimia haemolytica and Pasteurella multocida.

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(8) * * *

(i) Amount. 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 5 to 14 days.

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PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

9. In § 558.363, revise paragraph (d)(1)(i) introductory text to read as follows:

§ 558.363 Narasin.

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(d) * * *

(1) * * *

(i) Amount per ton. Narasin, 54 to 90 grams.

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Dated: May 7, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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