<RULE>

<PREAMB>

<AGENCY TYPE='S'>DEPARTMENT OF HEALTH AND HUMAN SERVICES

<SUBAGY>Food and Drug Administration

<CFR>21 CFR Parts 510, 522, 524, and 529

<DEPDOC>[Docket No. FDA-2013-N-0002]

<SUBJECT>New Animal Drugs; Hyaluronate Sodium; Hydrogen Peroxide; Imidacloprid and Moxidectin; 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 approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October 2013. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of sponsorship of an ANADA.

DATES: This rule is effective December 9, 2013.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October 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, Eka Chemicals, Inc., 1850 Parkway Pl. SE., suite 1200, Marietta, GA 30067 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-255 for PEROX-AID (hydrogen peroxide) 35% Solution to Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248. Following this change of sponsorship, Eka Chemicals, Inc., is no longer a sponsor of an approved NADA. Accordingly, the Agency is amending the regulations to reflect this change of sponsorship and change of sponsor status.

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 October 2013

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-432	Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601	NEXHA (hyaluronate sodium) Injectable Solution	Original approval as a generic copy of NADA 140-883	522.1145	yes	CE[1,2]
141-251	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	ADVANTAGE MULTI for Dogs (imidacloprid and moxidectin) Topical Solution	Supplemental approval for the treatment of Dirofilaria immitis circulating microfilariae in heartworm-positive dogs and the treatment and control of sarcoptic mange caused by Sarcoptes scabiei var. canis	524.1146	yes	CE[1,3]
141-254	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	ADVANTAGE MULTI for Cats (imidacloprid and moxidectin) Topical Solution	Supplemental approval for the prevention of heartworm disease caused by Dirofilaria immitis; kills adult fleas (Ctenocephalides felis) and is indicated for the treatment of flea infestations on ferrets	524.1146	yes	CE[1,3]

[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 or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.
[2]CE granted under 21 CFR 25.33(a)(1).
[3]CE granted under 21 CFR 25.33(d)(1).

<LSTSUB><HED>List of Subjects

<CFR>21 CFR Part 510

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

<CFR>21 CFR Parts 522, 524, and 529

Animal drugs.</LSTSUB>

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, 522, 524, and 529 are amended as follows:<REGTEXT TITLE=' 21 ' PART=' 510 '>

<PART><HED>PART 510--NEW ANIMAL DRUGS

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

<AUTH><HED>Authority:<P> 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "Eka Chemicals, Inc."; and in the table in paragraph (c)(2), remove the entry for "061088".</REGTEXT><REGTEXT TITLE=' 21 ' PART=' 522 '>

<PART><HED>PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

<AUTH><HED>Authority:<P> 21 U.S.C. 360b.

4. In § 522.1145, revise paragraph (e)(2) and the heading of paragraph (e)(3) to read as follows:

§ 522.1145 Hyaluronate sodium.

* * * * *

(e) * * *

(2) Sponsors. See sponsors in § 510.600(c) of this chapter:

(i) No. 000859 for use of products described in paragraph (e)(1) as in paragraph (e)(3) of this section.

(ii) No. 064847 for use of product described in paragraph (e)(1)(i) as in paragraph (e)(3) of this section.

(3) Conditions of use--

* * * * *</REGTEXT><REGTEXT TITLE=' 21 ' PART=' 524 '>

<PART><HED>PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 524 continues to read as follows:

<AUTH><HED>Authority: <P>21 U.S.C. 360b.

6. In § 524.1146, revise paragraphs (a)(2) and (d)(1)(ii); and add paragraph (d)(3) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

(a) * * *

(2) Each milliliter of solution contains 100 mg imidacloprid and 10 mg moxidectin for use as in paragraphs (d)(2) and (d)(3) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) Indications for use--(A) For the prevention of heartworm disease caused by Dirofilaria immitis; and the treatment and control of intestinal roundworms (Toxocara canis and Toxascaris leonina), hookworms (Ancylostoma caninum and Uncinaria stenocephala), and whipworms (Trichuris vulpis); kills adult fleas and treats flea infestations (Ctenocephalides felis).

(B) For treatment of Dirofilaria immitis circulating microfilariae in heartworm-positive dogs and the treatment and control of sarcoptic mange caused by Sarcoptes scabiei var. canis.

* * * * *

(3) Ferrets--(i) Amount. Topically apply 9.0 mg/lb body weight (20 mg/kg) imidacloprid and 0.9 mg/lb (2 mg/kg) moxidectin, once a month.

(ii) Indications for use. For the prevention of heartworm disease caused by Dirofilaria immitis; kills adult fleas (Ctenocephalides felis) and is indicated for the treatment of flea infestations on ferrets.</REGTEXT><REGTEXT TITLE=' 21 ' PART=' 529 '>

<PART><HED>PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

7. The authority citation for 21 CFR part 529 continues to read as follows:

<AUTH><HED>Authority:<P> 21 U.S.C. 360b.

§ 529.1150 [Amended]

8. In paragraph (b) of § 529.1150, remove "061088" and in its place add "050378".</REGTEXT>

<SIG><DATED>Dated: December 2, 2013.

<NAME>Bernadette Dunham,

<TITLE>Director,

Center for Veterinary Medicine.</SIG>

<FRDOC> [FR Doc. 2013–29234 Filed 12–6–13; 8:45 am]

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