DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

Food and Drug Administration

21 CFR Parts 510 and 529

New Animal Drugs; Hydrogen Peroxide

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 new animal drug application (NADA) filed by Eka Chemicals, Inc. The NADA provides for immersion use of hydrogen peroxide solution for control of mortality in certain freshwater-reared finfish species in several life stages due to various fungal and bacterial diseases.

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

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov.*

SUPPLEMENTARY INFORMATION: Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062–2254, filed NADA 141–255 for 35% PEROX–AID (hydrogen peroxide) for control of mortality in freshwater-reared finfish eggs due to saprolegniasis, for control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and for control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*). The NADA is approved as of January 11,

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2007, and the regulations are amended in part 529 (21 CFR part 529) by adding § 529.1150 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Eka Chemicals, Inc., 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 this firm.

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.

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2), this approval qualifies for 7 years of exclusive marketing rights beginning January 11, 2007, because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 529

Animal drugs.

■ 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 529 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 "Eka Chemicals, Inc."; and in the table in paragraph (c)(2) numerically add an entry for "061088" 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
. . . . .	
Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062–2254.	061088
. . . . .	

(2) * * *

Drug labeler code	Firm name and address
. . . . .	
061088	Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062–2254
. . . . .	

PART 529—OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Add § 529.1150 to read as follows:

§ 529.1150 Hydrogen peroxide.

(a) *Specifications.* Each milliliter of solution contains 396.1 milligrams (mg) hydrogen peroxide (a 35% w/w solution).

(b) *Sponsor.* See No. 061088 in § 510.600(c) of this chapter.

(c) *Conditions of use in finfish*—(1) *Amount*—(i) Freshwater-reared finfish eggs: 500 to 1,000 mg per liter (/L) of culture water for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all coldwater and coolwater species of freshwater-reared finfish eggs or 750 to 1,000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch for all warmwater species of freshwater-reared finfish eggs.

(ii) Freshwater-reared salmonids: 100 mg/L for 30 minutes or 50 to 100 mg/L for 60 minutes once per day on alternate days for three treatments in a continuous flow water supply or as a static bath.

(iii) Coolwater species of freshwater-reared finfish fingerlings and adults (except northern pike & paddlefish) and channel catfish fingerlings and adults: 50 to 75 mg/L for 60 minutes once per day on alternate days for three treatments in continuous flow water supply or as a static bath. Coolwater species of freshwater-reared finfish fry (except northern pike, pallid sturgeon & paddlefish) and channel catfish fry: 50 mg/L for 60 minutes once per day on alternate days for three treatments in continuous flow water supply or as a static bath.

(2) *Indications for use.* For control of mortality in freshwater-reared finfish eggs due to saprolegniasis; for control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*; and for control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*).

(3) *Limitations.* Initial bioassay on a small number is recommended before treating the entire group. Eggs: Some strains of rainbow trout eggs are sensitive to hydrogen peroxide treatment at a time during incubation concurrent with blastopore formation through closure, about 70 to 140 Daily Temperature Units, °C. Consider withholding treatment or using an alternate therapeutant during that sensitive time to reduce egg mortalities due to drug toxicity. Finfish: Use with caution on walleye. Preharvest withdrawal time: zero days.

Dated: 1/26/07
January 26, 2007.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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Dawn P. Hawkins