APPENDIX 12: UNAPPROVED ANIMAL DRUGS FOR AQUACULTURE

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

UNAPPROVED ANIMAL DRUGS FOR AQUACULTURE

The following list identifies unapproved new animal drugs of low regulatory priority and provides their indicated use and usage levels (CVM's Policy and Procedures Manual Attachment: "Enforcement Priorities for Drug use in Aquaculture" Guide 1240.4200 https://www.fda.gov/media/70193/download)

- **Acetic acid**

  Used in a 1,000 to 2,000 ppm dip for 1 to 10 minutes as a parasiticide for fish.

- **Calcium chloride**

  Used to increase water calcium concentration to ensure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 10 to 20 ppm CaCO3. Used up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish to enable fish to maintain osmotic balance.

- **Calcium oxide**

  Used as an external protozoacide for fingerlings to adult fish at a concentration of 2,000 mg/L for 5 seconds.

- **Carbon dioxide gas**

  Used for anesthetic purposes in fish.

- **Fuller's earth**

  Used to reduce the adhesiveness of fish eggs to improve hatchability.

- **Garlic (whole form)**

  Used for control of helminth and sea lice infestations in marine salmonids at all life stages.

- **Ice**

  Used to reduce the metabolic rate of fish during transport.

- **Magnesium sulfate**

  Used to treat external monogenic trematode infestations and external crustacean infestations in freshwater fish species at all life stages. Fish are immersed in a 30,000 mg MgSO4/L and 7,000 mg NaCl/L solution for 5 to 10 minutes.

- **Onion (whole form)**

  Used to treat external crustacean parasites and to deter sea lice from infesting the external surface of salmonids at all life stages.

- **Papain**

  Used in a 0.2% solution to remove the gelatinous matrix of fish egg masses to improve hatchability and decrease the incidence of disease.

- **Potassium chloride**

  Used as an aid in osmoregulation, relieves stress, and prevents shock. Dosages used would be those necessary to increase chloride ion concentration to 10 to 2,000 mg/L.

- **Povidone iodine**

  Used in a 100ppm solution for 10 minutes as an egg surface disinfectant during and after water hardening.

- **Sodium bicarbonate**

  Used at 142 to 642 ppm for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.

- **Sodium chloride**

  Used in a 0.5% to 1% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock, and in a 3% solution for 10 to 30 minutes as a parasiticide.

- **Sodium sulfite**

  Used in a 1.5% solution for 5 to 8 minutes to treat eggs to improve their hatchability.

- **Thiamine hydrochloride**

  Used to prevent or treat thiamine deficiency in salmonids. Eggs are immersed in an aqueous solution of up to 100 ppm for up to 4 hours during water hardening. Sac fry are immersed in an aqueous solution of up to 1,000 ppm for up to 1 hour.

- **Urea and tannic acid**

  Used to denature the adhesive component of fish eggs at concentrations of 15 g urea and 20 g NaCl/5 liters of water for approximately 6 minutes, followed by a separate solution of 0.75 g tannic acid/5 liters of water for an additional 6 minutes. These amounts will treat approximately 400,000 eggs.

BIBLIOGRAPHY

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA verified the website addresses for the references it makes available as hyperlinks on the Internet copy of this Guidance. FDA is not responsible for any subsequent changes to Non- FDA Web site references after April 2018.

- U.S. Food and Drug Administration. Implantation or injectable dosage form new animal drugs. In Code of Federal Regulations, 21 CFR 522. U.S. Government Printing Office, Washington, DC. (https://www.ecfr.gov/cgi-bin/text-idx?SID=569e121f743184a034ffff345ce6efab&mc=true&node=pt21.6.522&rgn=div5)

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- U.S. Food and Drug Administration. New animal drugs for use in feed. In Code of Federal Regulations, 21CFR 558 U.S. Government Printing Office, Washington, DC. (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=558%0C)

- World Health Organization. (2017). WHO guidelines on use of medically important antimicrobials in food-producing animals. World Health Organization. (https://apps.who.int/iris/handle/10665/258970) License: CC BY-NC-SA 3.0 IGO

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