

**GUIDE TO DRUG, VACCINE, AND PESTICIDE USE IN AQUACULTURE
(January 2004)**

Appendix A - Table 2. Unapproved New Animal Drugs of Low Regulatory Priority for FDA (* See NOTE at bottom of table.)

Common Name	Permitted Use
Acetic acid	Used as a dip at a concentration of 1,000-2,000 milligrams per liter (mg/L) for 1-10 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 10-20 mg/L calcium carbonate. Also used to increase water hardness up to 150 mg/L to aid in maintenance of osmotic balance in fish by preventing electrolyte loss.
Calcium oxide	Used as an external protozoacide for fingerling to adult fish at a concentration of 2,000 mg/L for 5 seconds.
Carbon dioxide gas	Used for anesthetic purposes in cold, cool, and warmwater fish.
Fuller's earth	Used to reduce the adhesiveness of fish eggs in order to improve hatchability.
Garlic (whole)	Used for control of helminth and sea lice infestations in marine salmonids at all life stages.
Ice	Used to reduce metabolic rate of fish during transport.
Magnesium sulfate (Epsom salts)	Used to treat external monogenic trematode infestations and external crustacean infestations in fish at all life stages. Used in freshwater species. Fish are immersed in a solution of 30,000 mg/L magnesium sulfate and 7,000 mg/L sodium chloride for 5-10 minutes.
Onion (whole)	Used to treat external crustacean parasites and to deter sea lice from infesting external

	surface of fish at all life stages.
Papain	Used as a 0.2% solution in removing the gelatinous matrix of fish egg masses in order to improve hatchability and decrease the incidence of disease.
Potassium chloride	Used as an aid in osmoregulation to relieve stress and prevent shock. Dosages used would be those necessary to increase chloride ion concentration to 10-2,000 mg/L.
Povidone iodine compounds	Used as a fish egg disinfectant at rates of 50 mg/L for 30 minutes during water hardening and 100 mg/L solution for 10 minutes after water hardening.
Sodium bicarbonate (baking soda)	Used at 142-642 mg/L for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.
Sodium chloride (salt)	Used as a 0.5-1% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock. Used as a 3% solution for 10-30 minutes as a parasiticide.
Sodium sulfite	Used as a 15% solution for 5-8 minutes to treat eggs in order to improve hatchability.
Urea and tannic acid	Used to denature the adhesive component of fish eggs at concentrations of 15 g urea and 20 g NaCl/5 L of water for approximately 6 minutes, followed by a separate solution of 0.75 g tannic acid/5 L of water for an additional 6 minutes. These amounts will treat approximately 400,000 eggs.

* Labeling and GMPs for Low-Priority Drugs

1. Labeling for low-priority use will not be required for a chemical that is commonly used for non-drug purposes even if the manufacturer or distributor promotes the chemical for the permitted low priority use.
2. However, a chemical that has significant animal or human drug uses in addition to low priority aquaculture use will be required to be labeled for the low-priority uses if the manufacturer or distributor establishes the intended low priority use for its product by promotion or other means. Where labeling is required, all other provisions of the Act pertaining to drugs except the approval requirement will

apply. This includes registration, drug listing, and Current Good Manufacturing Practices (CGMP) etc.

Low regulatory priority compounds may be marketed for aquaculture use with drug claims (the claims permitted for such compounds) but must be of an appropriate quality for use in food animals.

If the drug claims appear on the product label, in product catalogs, or in promotional material, the following conditions must be met:

1. The product must have been manufactured according to Current Good Manufacturing Practices (CGMPs) as defined in the Code of Federal Regulations
2. The product manufacturer must be registered with FDA
3. The product must be drug listed with FDA

Material deviations in labeling or promotion from the permitted low priority claims might cause a particular product to be removed from the low priority category.

NOTE: FDA is unlikely to object at present to the use of these low regulatory priority substances if the following conditions are met:

1. The drugs are used for the prescribed indications, including species and life stage where specified.
2. The drugs are used at the prescribed dosages.
3. The drugs are used according to good management practices.
4. The product is of an appropriate grade for use in food animals.
5. An adverse effect on the environment is unlikely.

FDA's enforcement position on the use of these substances should be considered neither an approval nor an affirmation of their safety and effectiveness. Based on information available in the future, FDA may take a different position on their use.

Classification of substances as new animal drugs of low regulatory priority does not exempt facilities from complying with other federal, state, and local environmental requirements. For example, facilities using these substances would still be required to comply with National Pollutant Discharge Elimination System requirements.