SPECIAL CONDITIONS

I. DISEASE CONTROL

The permittee must comply with Maine Department of Inland Fisheries and Wildlife (MDIFW) (freshwater facilities) and Maine Department of Marine Resources (MEDMR) (salmon & marine facilities) fish health laws (12 MRS, § 6071 and 12 MRS, §§10051, 10105, 12507 and 12509, as amended). The cited laws include requirements for notification to the appropriate agency within 24-hours of pathogen detection. In addition to the requirements of the MDIFW and MEDMR rules, **the permittee shall notify the Department in writing within 24 hours following pathogen detection**, with information on the disease/pathogen, necessary control measures, and the contact information for the veterinarian(s) involved .

1. **General requirements.** All chemicals used at the facility must be applied in compliance with federal labeling restrictions and in compliance with applicable statute, Board of Pesticides Control rules and best management practices (BMPs). In accordance with Special Condition D of this permit, the permittee must notify the Department of any substantial change in the volume or character of pollutants being introduced into the wastewater collection and treatment system.

2. **FDA-approved drugs.** All drugs used for disease prevention or control must be approved or authorized by the U.S. Food and Drug Administration (FDA), and all applications must comply with applicable FDA requirements and shall only be administered in accordance with label instructions.

   a. Drugs identified in the permittee's application: A list of drugs, chemicals and other compounds proposed for use at the permittee's facility during the term of the permit, was provided by the permittee in its October 19, 2018, General Application for Waste Discharge Permit.

   b. Preventative treatments: The discharge of any approved drug administered as a preventative measure is not authorized by this permit, unless the following conditions are met: the drug must be approved by FDA, and the treatment and route of administration must be consistent with the drug's intended use and according to label instructions. FDA approved drugs in the permittee's October 19, 2018 application are:
      1. Formalin (Parasite-S)
      2. Terramycine® 200 (oxytetracyline dehydrate)
      3. Aquaflor® (florfenicol)
      4. Romet ®30/Romet®TC (sulfadimethoxine/ormetoprim)
      5. Halamid Aqua® (Chloramine-T)
      6. Finquel®/Tricane-S (Tricaine methanesulfonate)
      7. Ovadine® (PVP Iodine)
      8. Potassium permanagante
      9. Hydrogen peroxide

SPECIAL CONDITIONS

I. DISEASE CONTROL (cont'd)

c. Drugs not identified in the permittee's application: When the need to treat or control diseases requires the use of an FDA-approved drug not identified in the application, the permittee must notify the Department orally or by electronic mail prior to initial use of the drug.

1. The notification must include a description of the drug, its intended purpose, the method of application, the amount, the concentration, the duration of the use, and information on aquatic toxicity.

2. **Within seven (7) days of the initial notification,** the permittee must submit a written report that includes all of the information outlined in Section I.2(c)(1) above.

3. The Department may require submission of an application for permit modification, including public notice requirements, if the drug is to be used for more than a 30-consecutive day period.

4. If, upon review of information regarding the use of a drug pursuant to this section, the Department determines that significant adverse effects are likely to occur, it may restrict or limit use of the drug.

3. **Extralabel drug use.** Extralabel drug use is not authorized by this permit, unless in accordance with a specific prescription written for that use by a licensed veterinarian.

a. Notification. The permittee must notify the Department orally or by e-mail prior to initial extralabel use of a drug.

1. The notification must include a description of the drug, its intended purpose, the method of application, the amount, concentration, and duration of the use, information on aquatic toxicity, and a description of how and why the use qualifies as an extralabel drug use under FDA requirements.

2. **Within seven (7) days of the initial notification** the permittee must submit a written report that includes all of the information outlined in Section I.3(a)(1) above. Notice must include documentation that a veterinarian has prescribed the drug for the proposed use. A copy of the veterinarian's prescription must be maintained on-site during treatment for Department review.

3. If, upon review of information regarding the extralabel use of a drug pursuant to this section, the Department determines that significant adverse effects are likely to occur, it may deny, restrict or limit use of the drug.

SPECIAL CONDITIONS

I. DISEASE CONTROL (cont'd)

4. **Investigational New Animal Drug (INAD).** The discharge of drugs authorized by the FDA for use during studies conducted under the INAD program is not authorized by this permit, unless in accordance with specific prior consent given in writing by the Department.

   a. Initial report. The permittee must provide a written report to the Department for the proposed use of an INAD ***within seven (7) days*** of agreeing or signing up to participate in an INAD study. The written report must identify the INAD to be used, method of use, dosage, and disease or condition the INAD is intended to treat.

   b. Evaluation and monitoring. ***At least ninety (90) days prior to initial use*** of an INAD at a facility, the permittee must submit for Department review and approval a study plan for the use of the drug that:

      1. Indicates the date the facility agreed or signed up to participate in the INAD study.
      2. Demonstrates that the minimum amount of drug necessary to evaluate its safety, efficacy, and possible environmental impacts will be used.

      3. Includes an environmental monitoring and evaluation program that at a minimum describes sampling strategies, analytical procedures, evaluation techniques and a timetable for completion of the program. Currently available data or literature that adequately characterizes the environmental fate of the INAD and its metabolite(s) may be proposed for consideration in determinations of environmental monitoring and evaluation programs required by the Department pursuant to this section.

   c. Notification. The permittee must notify the Department orally or by electronic mail ***no more than forty-eight (48) hours after*** beginning the first use of the INAD under the approved plan.

J. SPILLS

In the event of a spill of drugs, chemicals, feed, petroleum and/or hazardous waste products that results in a discharge to waters of the State, the permittee must provide an oral report of the spill to the Department within 24 hours of its occurrence and a written report on a form provided by the Department, within five (5) days to the Department. The report must include the identity and quantity of the material spilled.