

FORM CLT-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form CLT-1 **immediately** upon receipt of chloramine-T.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CLT-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act.

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|--|--|--|-------------|
| Name of Drug | Chloramine-T | INAD Number | 9321 |
| Product Name (check one) | ____ Halamid® ____ Actamide | | |
| Proposed Use of Drug | Treatment or control of bacterial gill disease or certain flavobacteriosis that occur in a variety of fish species | | |
| Date of CVM Authorization Letter | December 5, 2007 | | |
| Date of Drug Receipt | | Amount of Drug Received | |
| Drug Lot Number | | Study Worksheet Number | |
| Name of Investigator | | | |
| Address of Investigator | | | |
| Location of Trial | | | |
| Pivotal Study (yes/no) | | Non-pivotal Study (yes/no) | |
| Approximate Number of Treated Animals | | Approximate Number of Control Animals | |
| Number of Animals Used Previously¹ | | | |
| Study Protocol Number | 9321 | | |
| Approximate dates of trial (start/end) | | | |
| Species, Size, and Type of Animals | | | |
| Maximum daily dose and duration | 20 mg/L for 1hour | | |
| Methods(s) of Administration | Immersion (static bath or flow-through treatment) | | |
| Withdrawal Period | Zero | | |

¹ To be filled out by the NIO

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Date Reviewed: _____ **Sponsor:** _____