

Form sGnRHa/Ovaplant-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 sGnRHa/Ovaplant-1 **immediately** upon receipt of sGnRHa.
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 sGnRHa/Ovaplant-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. The following information is submitted in triplicate:

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|--|---|--|---------------|
| Name of Drug | sGnRHa (Ovaplant®) | INAD Number | 11-375 |
| Proposed Use of Drug | To induce gamete maturation in a variety of fish species. | | |
| Date of CVM Authorization Letter | December 15, 2005 | | |
| Source of Drug | Syndel International, Inc. | | |
| Date of Drug Receipt | <i>2/25/08</i> | Amount of Drug Received | <i>30 mg</i> |
| Drug Lot Number | <i>111000</i> | Study Worksheet Number | <i>08-XXX</i> |
| Name of Investigator | <i>John Doe</i> | | |
| Address of Investigator | <i>123 Hatchery Rd; Anywhere, USA 55555</i> | | |
| Location of Trial | <i>Fish Hatchery A</i> | | |
| Pivotal Study (yes/no) | <i>no</i> | Non-pivotal Study (yes/no) | <i>yes</i> |
| Approximate Number of Treated Animals | <i>75</i> | Approximate Number of Control Animals | <i>60</i> |
| Number of Animals Used Previously¹ | | | |
| Study Protocol Number | 11-375 | | |
| Approximate dates of trial (start/end) | <i>March 2008</i> | | |
| Species, Size, and Type of Animals | <i>Steelhead trout; adult</i> | | |
| Maximum daily dose and duration | 150 ug/Kg body weight | | |
| Methods of Administration | Cholesterol-based pellet implant | | |
| Withdrawal Period | No release of fish treated with pellet implant. | | |

¹ To be filled out by the NIO

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| Date Prepared: | <i>2/25/08</i> | Investigator: | <i>Sign here</i> |
| | | | |
| Date Reviewed: | <i>2/25/08</i> | Study Monitor: | <i>Sign here</i> |
| | | | |
| Date Reviewed: | | Sponsor: | |