1SUPPORTING STATEMENT A
FOR PAPERWORK REDUCTION ACT SUBMISSION

Administration of U.S. Fish and Wildlife Service
Investigational New Animal Drug (INAD) Program
OMB Control Number 1018-New

Terms of Clearance: None. This is a request for OMB approval of a new information collection in use without a control number.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The Aquatic Animal Drug Approval Partnership (AADAP) Program, operating under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA; 21 U.S.C. 360b(j)) which permits the use of an investigational new animal drug to generate data to support a new animal drug approval (NADA), is part of the Fish and Aquatic Conservation fish health network. It is the only program in the United States singularly dedicated to obtaining U. S. Food and Drug Administration (FDA) approval of new medications needed for use in fish culture and fisheries management. Ultimately, the AADAP program allows fisheries professionals to more effectively and efficiently rear and manage a variety of fish species to meet production goals, stock healthy fish, and maintain a healthy environment. In order for participants (U.S. aquaculture facilities or researchers) to be able to use an unapproved drug under AADAP's National Investigational New Animal Drug (INAD) Program, they need to follow the FDA-approved study protocol(s) and submit the required data forms, including the INAD treatment data, to AADAP's INAD Program. Data collection is required by the FDA under the following regulations:

- 21 CFR part 511 (New Animal Drugs for Investigational Use) and
- 21 CFR part 514, Subpart A (New Animal Drug Applications, General Provisions).

Additional information for the INAD Program and how to participate can be found at the following link: https://www.fws.gov/service/investigational-new-animal-drugs. This webpage describes frequently asked questions regarding how to participate in the INAD Program and what is expected of the participants. We have also developed additional study templates for the INADs for use as a guide for filling out the forms. These templates will provide study participants with helpful information to correctly complete each form. We also created a user manual for the online INAD database used to enter the data that also describes each step of the database for the INAD participants.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection. Be specific. If this collection is a form or a questionnaire, every question needs to be justified.

We collect the following information in conjunction with the AADAP:

COOPERATIVE AGREEMENT

A cooperative agreement is needed between the participating companies/agencies and the Service's AADAP Program. The goal of this agreement is to consolidate the INAD process; eliminate duplication of effort; reduce workloads and costs; and ensure needed drugs are made available to aquaculture and fisheries management facilities in the U.S. in compliance with FDA regulations.

This agreement establishes obligations to be met and procedures to be followed by the Service and participant to establish and maintain cooperative INADs to enable the use of certain drugs and chemicals under the INAD process as set forth by the FDA. In addition to clarifying roles and responsibilities, the cooperative agreement collects the following:

- Agency/organization name;
- Statutes authorizing the agency/organization to enter into the agreement (if applicable);
  - Information for the National INAD Program Officer for the cooperator, to include:
  - Name and title of cooperator,
  - Agency/organization,
  - Address of facility,
  - Phone number, and
  - Email address.
- Signature, title, and date of authorized signer.

APPROVED INADS

There are 19 approved INADs approved for use within the Service's INAD Program (see https://www.fws.gov/find-inad) described as follows:

Medicated Feeds

Florfenicol (Aquaflor®) INAD #10-697 - Aquaflor® is an aquaculture premix containing florfenicol and is only available through Merck Animal Health. The primary goal of field studies conducted under INAD #10-697 is to evaluate the efficacy of florfenicol-medicated feed for controlling mortality in a variety of fish species diagnosed with a variety of diseases that are caused by pathogens susceptible to florfenicol.

Slice® (Emamectin Benzoate) INAD #11-370 - SLICE® is an aquaculture premix containing emamectin benzoate and is only available through Merck Animal Health. SLICE® premix can be purchased through Merck Animal Health and sent to an aquaculture feed mill for top coating. The primary goal of field studies conducted under INAD #11-370 is to evaluate the efficacy of SLICE®-medicated feed and safety of SLICE® to control mortality caused by external parasites in a variety of freshwater and marine fish species.

Oxytetracycline dihydrate (Terramycin® 200 for Fish) INAD #9332 - Terramycin 200® for fish is an aquaculture premix containing oxytetracycline dehydrate (OTC) and is available through Syndel USA. Feed medicated with OTC can be purchased from aquaculture feed mills and used to treat bacterial diseases or to apply a skeletal mark on the fish. The primary goal of field studies conducted under INAD #9332 is to generate additional OTC-medicated feed efficacy data which can be used to expand the existing OTC label claims. Five treatment options are allowed, and disposition of investigational animals (including withdrawal times) varies with treatment regimen.

17α-methyltestosterone INAD #11-236 - 17α-methyltestosterone (MET) is an

aquaculture premix and is only available through Rangen, Inc. The primary goal of studies conducted under INAD #11-236 is to generate data evaluating the efficacy of MET administered in feed to larval tilapia to produce populations comprised of >90% male fish.

17α-methyltestosterone INAD #8557 - 17α-methyltestosterone (MET) is an aquaculture premix and is only available through Rangen Inc. The primary goal of studies conducted under INAD #8557 is to generate data evaluating the efficacy of MET administered in feed to larval rainbow trout and Atlantic salmon to produce masculinized female fish that produce sperm.

17β-Estradiol INAD #12-671 - 17β-estradiol (E2) will be administered as a medicated feed and is only available to FDA-approved facilities. The primary goal of studies conducted under INAD #12-671 is to generate data evaluating the efficacy of E2 administered in feed to larval brook trout to produce feminized male fish that produce eggs.

Immersion

Chloramine-T INAD #9321 - Chloramine-T (CLT) is a powder that is applied as an immersion bath treatment. CLT is only available for purchase through Syndel USA or B.L. Mitchell, Inc. The primary goal of field studies conducted under INAD #9321 is to evaluate the efficacy of CLT for controlling mortality in a variety of freshwater fish species for bacterial diseases not currently listed on the approved label. Approval of INAD #9321 is for non-labeled use only, and its use must comply with the approved label directions.

Hydrogen peroxide (35% Perox Aid®) INAD #11-669 - 35% Perox-Aid® (H2O2) is a liquid solution containing hydrogen peroxide that is applied as an immersion bath treatment. H2O2 is only available for purchase through Syndel USA. The primary goal of field studies conducted under INAD #11-669 is to evaluate the efficacy of H2O2 for controlling mortality caused by specific ectoparasites in freshwater or marine finfish species. It is also expected that the additional data will be used to expand the current H2O2 label claim. Approval of INAD #11-669 is for non-labeled use only, and its use must comply with the approved label directions.

Oxytetracycline hydrochloride INAD #9033 - Oxytetracycline hydrochloride (OTIMM) is an aquaculture premix containing oxytetracycline hydrochloride, available through Pharmgate. OTIMM is available for purchase through many local farm and ranch stores or veterinarian supply outlets. The primary goal of field studies conducted under INAD #9033 is to evaluate the efficacy of OTIMM for controlling mortality in a variety of freshwater and marine finfish species for bacterial diseases. Immersion therapy is often the only option when treating young fish not yet accustomed to feeding on man-made fish diets.

Diquat® INAD #10-969 - Reward® (DQT) is a liquid concentrate containing diquat dibromide, which is applied as an immersion bath treatment. DQT is available for purchase through many local farm and ranch stores or through Syngenta Crop Protection, LLC. The primary goal of field studies conducted under INAD #10-969 is to evaluate the efficacy of DQT for controlling mortality in all freshwater-reared finfish diagnosed with bacterial gill disease or external flavobacteriosis.

Sedatives

AQUI-S®20E INAD #11-741 - Aqui-S®20E is a liquid containing 10% eugenol that is applied as an immersion bath treatment. Aqui-S®20E is only available for purchase through Merck Animal Health. The primary goal of field studies conducted under INAD #11-741 is to evaluate the efficacy of Aqui-S®20E for use as an anesthetic/sedative in all freshwater-reared finfish, freshwater prawn, all saltwater-reared finfish, and sharks.

BENZOAK VET® #11-740 - BENZOAK VET® is a liquid containing 20% benzocaine that is applied as an immersion bath treatment. BENZOAK VET® is only available for purchase through Riverence Brood LLC. The primary goal of field studies conducted under INAD #11-740 is to evaluate the efficacy of BENZOAK VET® for use as an anesthetic/sedative in all freshwater-reared finfish, freshwater prawn, and all saltwater-reared finfish.

Spawning Aids

Lutenizing Hormone - Releasing Hormone (LHRHa) INAD #8061 - Luteinizing Hormone - Releasing Hormone analogue (LHRHa) is a solution that is applied as either an intraperitoneal (IP) or intramuscular (IM) injection. LHRHa is only available for purchase through Syndel USA. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #8061 is to generate data to help determine appropriate LHRHa treatment regimens for inducing gamete maturation in a variety of cultured and wildstock finfish species.

GnRH IIa Chicken Gonadotropin - Releasing Hormone II analogue INAD #13-345 - GnRH IIa is a synthetic peptide analogue of chicken gonadotropin-releasing hormone (cGnRH IIa). It is presented as a dry powder to be resuspended in saline solution for IP injection, and is only available for purchase through AquaTactics Fish Health. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #13-345 is to generate data to help determine appropriate GnRH IIa treatment regimens for use as a spawning aid for female ictalurids.

Ovaplant® Salmon Gonadotropin - Releasing Hormone analoque (sGnRHa) INAD #11-375 - Ovaplant® is a synthetic peptide analogue of salmon gonadotropin-releasing hormone (sGnRHa). It is presented in a biodegradable cholesterol-based matrix as an IM pellet implant and is only available for purchase through Syndel USA. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #11-375 is to generate data to help determine appropriate Ovaplant® treatment regimens.

Ovaplant®-L Salmon Gonadotropin - Releasing Hormone analoque (sGnRHa) INAD #13-298 - Ovaplant®-L is a synthetic peptide analogue of salmon gonadotropin-releasing hormone (sGnRHa). It is presented in a sustained release gel for injection and is only available for purchase through Syndel USA. The use of hormones to induce spawning

in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #13-298 is to generate data to help determine appropriate Ovaplant-L treatment regimens for inducing gamete maturation in a variety of cultured finfish species.

Common Carp Pituitary (CCP) INAD #8391 - Common carp pituitary (CCP) is a powder (for suspension) that is applied as either an IP or IM injection. CCP is only available for purchase through Argent Aquaculture. The use of hormones to induce spawning in fish is critical to the success of many aquatic programs that need hormone treatment to complete final gamete maturation to ensure spawning. The primary goal of field studies conducted under INAD #8391 is to generate data to help determine appropriate CCP treatment regimens for inducing gamete maturation in a variety of cultured and wildstock finfish species.

Marking

Calcein (Se-Mark®) INAD #10-987 - Calcein (Se-Mark®) is a liquid that contains 1% calcein for bath marking treatments on finfish and select freshwater mussels. Calcein is only available for purchase through Syndel USA. Calcein is a fluorochrome compound that chemically binds with alkaline earth metals such as calcium, and upon binding, shows a marked increase in fluorescence when excited with blue light of about 500 nm wavelength. The primary goal of field studies conducted under INAD #10-987 is to establish the effectiveness of calcein to mark fin rays, scales, otoliths, and other calcified fish, oysters, or selected mussel tissues via immersion baths. This is a non-lethal marking evaluation method.

Injectable

Erythromycin 200 Injectable INAD #12-781 - Erymicin 200 Injection (Erymicin 200) is a solution that contains erythromycin for injection on juvenile and adult Salmonids. Erymicin 200 is only available for purchase through Syndel USA. The primary goal of field studies conducted under INAD #12-781 is to evaluate the efficacy of erythromycin for 1) controlling mortality caused by bacterial kidney disease (BKD) (causative agent: *Renibacterium salmoninarum*) in salmonid species; and 2) control the vertical transmission of *R. salmoninarum* from BKD positive female broodstock to eggs/progeny.

STUDY PROTOCOLS

Approved INAD study protocols require submission of the following forms associated with the data collection:

- Form-W: Worksheet (all INADs);
- Form-1: Report on Receipt of Drug (all INADs);
- Form-2A or 2B: Chemical Use Log (all INADs);
- Form-3: Diagnosis, Treatment, and Mortality/Spawning/Anesthetic Record (all INADs);
- Form-4: Necropsy Report Form (specific INADs);
- Form-4a: Report on Efficacy Determination Sample (specific INADs); and,
- Form-5: Transfer of Treated Fingerling (specific INADs).

The INAD study protocol forms listed above collect the following information from program

participants (specific information may vary depending on INAD protocol used):

- Study identification number and title;
- Sponsor name and contact information;
- Facility name;
- Study director and contact information;
- Principal clinical field trial coordinator name;
- Study monitor's name and addresses;
- Investigator's name and addresses;
- Proposed study starting and completion dates;
- Background, purpose, and objectives of study;
- Study materials;
- Experimental units;
- Entrance criteria;
- Identification of treatment groups;
- Treatment schedules;
- Treatment response parameters;
- Recordkeeping procedures;
- Disposition of investigational animals;
- Disposition of investigational drug;
- Data handling, quality control, monitoring, and administrative responsibilities;
- Plans for data analysis;
- Protocol and protocol amendments; and,
- Protocol deviations.

The Service's AADAP Program will use the information that is collected on the study forms to ensure the studies are following the guidelines set by the FDA. The study data will be downloaded to a spreadsheet where it will be analyzed for compliance. Summary reports will be created from the data collected from the forms and will be submitted to the FDA, as required. Submission of the data forms is required by the FDA for the facility to participate in the INAD Program.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden and specifically how this collection meets GPEA requirements.

All data will be submitted through an online database (https://aadapinad.com/) that was created to collect the specific INAD data from the paper forms. The database is not publicly accessible without an account on the platform. The participants can only view their information and not anyone else's information since they can only login to their account. The online database has reduced the amount of time it takes to fill out the forms by reducing duplication of information from one form to another (the database automatically fills in necessary information onto the forms such as facility name; study number; and duplicates information from the study worksheet to the Results Report form); ensure accuracy of data; and that the information is legible. The paper forms are no longer submitted to AADAP but instead used as a guide to collect the data that will be entered into the database. Much of this information is already collected by participants on their own hatchery data sheets or research data forms that may be used outside of the INAD.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

There is no duplication. The information collected is specific to the AADAP Program in support of the Service's mission. Due to the unique nature of this program, no other Federal agency collects the same information from the public.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

We collect only the minimum information necessary for participants to be able to use an unapproved drug while it is being evaluated by the FDA. The data collected is required by the FDA in order for participation in the INAD Program. This information collection will not significantly impact small businesses or other small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If we did not collect the information, the Service would be unable to allow non-federal facilities to participate in the INAD Program. This would cause many facilities to be unable to provide the aquaculture medication or drugs they need to keep their fish healthy while the drug is being evaluated for a full approval. Currently there are only nine drug approvals available for aquaculture needs. Without access to the INAD Program some facilities would not be able to stay in business or they would be required to open up their own INAD which would take more time, money, and duplicate effort.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
- **in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secrets, or other confidential information, unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no special circumstances requiring collection of the information in a manner inconsistent with OMB guidelines.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and in response to the PRA statement associated with the collection over the past three years, and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every three years — even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

On July 20, 2021, we published in the *Federal Register* (86 FR 38349) a notice of our intent to request that OMB approve this information collection. In that notice, we solicited comments for 60 days, ending on September 20, 2021. We did not receive any comments in response to that notice.

In addition to the *Federal Register* notice, we consulted with the nine (9) individuals identified in Table 8.1 who familiar with this collection of information in order to validate our time burden estimate and asked for comments on the questions below:

Table 8.1

Organization	Title
Americulture, Inc.	President
The Confederated Tribes of Warm Springs Branch of Natural Resources	Hatchery Manager 1
Walt Disney World	Veterinarian
E.W. Shell Fisheries Center at Auburn University	Associate Director
State of Iowa DNR	Fisheries Technician
Michigan DNR	Natural Resources Manager
Blue Ocean Mariculture, LLC	Broodstock Manager
Makah Tribe	Hatchery Manager
University of Idaho	Assistant Operations Supervisor

"***Whether or not the collection of information is necessary, including whether or not the information will have practical utility; whether there are any questions they felt were unnecessary"***

Comments: The majority of the comments agreed that the information collected was

necessary and appropriate.

There were four additional comments regarding this question which are addressed below:

(1) The first comment was that a fish health person should fill out the efficacy part of the study.
(2) The second comment was that some of the data fields or units of measures were not needed.
(3) The third comment was regarding whether the drug inventory information is necessary.
(4) The fourth comment was regarding the data entry on numbers of fish saved and if this was needed.

Agency Response/Action Taken: Our responses to the four additional comments are as follows:

(1) This is already allowed for the fish health person to review if they are the monitor and recommend changes if necessary.
(2) The response is that the unit of measure needs to be selected since not all participants work in the same unit of measure (i.e. kg vs lb or cm vs in).
(3) The response is this can't be changed as this is a requirement by the FDA to show daily use of an unapproved drug.
(4) The response is this is useful for the AADAP Office and FDA to show efficacy.

"The accuracy of our estimate of the burden for this collection of information"

Comments: The majority of respondents that commented agreed with the estimate of burden for collection of information. There were three comments that said some of the forms took only a few minutes to 5 minutes to fill out.

Agency Response/Action Taken: We do not plan to change the estimate of time as the majority of the responses agreed with the times that were listed. The participants that mentioned it takes less time have been filling out the forms longer then the newer participants that were asked. For them they are more familiar with the data entry process and can better use the time saving features we have incorporated due to their experience.

"Ways to enhance the quality, utility, and clarity of the information to be collected"

Comments: The majority of the respondents that commented said the data entry process was simple and self-explanatory. There was one comment requesting the data entry be more streamlined.

Agency Response/Action Taken: The AADAP will look into streamlining data entry, but it will depend on budget and priority of upgrades for some changes to be made. The data entry is sometimes restricted to a certain format so all data is collected in the same format and can be better analyzed.

"Ways to minimize the burden of the collection of information on respondents"

Comments: Two comments agreed with the current data entry process and had no suggestions for changes.

Four comments had suggestions for changing the data entry to make it easier for them:

(1) Only have a single form to report the data and not a form to show the planned study and then the results.
(2) Entering mortality data as a single entry instead of each raceway.
(3) Waiting until the end of the production season to submit data.
(4) Consolidating the entry of fish marking data into the table.

Agency Response/Action Taken: Our responses to the four additional comments are as follows:

(1) Unfortunately, this can't be done as the AADAP Office needs to review the studies prior to being conducted to make sure they are following the study protocol.
(2) This is already encouraged and the AADAP Office sends out an email each year with helpful hints on how to consolidate the data entry process when possible.
(3) This is an FDA requirement that data be submitted after the completion of the treatment so we can report this information back to the FDA in a timely manner.
(4) This is again an FDA requirement to show efficacy on a certain number of treated fish and can't be changed.

Additional comments received during the outreach:

Comments: Two comments were received for this section and both of them complimented the INAD Team with their help when contacted from the participants with questions. Below are the direct comments:

a. "The team (Bonnie, Paige) has been very helpful and rapid in answering questions, problem solving and support, I really appreciate their efforts to help understand and maneuver the online database. Overall while it takes some learning on how to use the database, it's not very difficult. I think there are ways to make it more efficient and user friendly but not sure what it takes to do that and if the cost/benefit works out."
b. "This was my first year working with these INADs and it went very smooth. I had a couple questions initially but the AADAP staff answered them quickly and effectively."

Agency Response/Action Taken: No response or action is needed

Additional comments received after the outreach:

Comments: One comment was sent directly to the address listed on the "Estimated Burden Statement" listed on the bottom of the online database and forwarded to the AADAP Office. The following is the comment that was sent in by the Hatchery Manager for Little Traverse Bay Bands of Odawa Indians:

> "I was going through my AADAP INAD investigator data entry and saw that there is a note about contacting this address about comments about the forms. Having submitted several studies over the last few years, I would say that the 15 minutes to 2 hours is a HUGE underestimate. The entry of mortality data form is extremely difficult to use, as it takes > 4 hours to enter one study's worth of data. To enter everything into the form within a single day, I am forced to reduce the quality of data entered, which really limits the use of the information gathered. The addition of a "batch" entry would make the site much easier to use. All of my data is stored in a database anyways, so the ability to

create a query for data export would be great."

Agency Response/Action Taken: This is a unique situation that is not common with the majority of the INAD participants where this facility is using an INAD once a week for an extended amount of time. In the past, we have had participants ask to upload their data to the database, but this is not a feature we have available. We need to be able to review their data in a consistent manner as all of the other submitted data. This may be something we can consider for future database edits to see if the programmers have any suggestions on how we could upload data and have it consistent with manually entered data.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

We will not provide any payment or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

We do not provide any assurance of confidentiality. Information may be disclosed according to the Freedom of Information Act (FOIA); the Privacy Act of 1974 and other applicable law or regulation.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

We will not ask any questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here.**

We estimate that we will receive **302 responses** totaling **1,215 burden hours**. We estimate the annual dollar value of the burden hours is **$63,140** (rounded).

We used Table 1 from the of Bureau of Labor Statistics (BLS) News Release USDL-22-1892, March 17, 2023, Employer Costs for Employee Compensation—December 2022, to calculate the cost of the total annual burden hours:

- Private Sector - the hourly rate for all workers is $40.23, including benefits.
- Government - the hourly rate for all workers is $57.60, including benefits.

Requirement	Average Number of Annual Respondents	Average Number of Responses Each	Average Number of Annual Responses	Average Completion Time per Response	Estimated Annual Burden Hours	Hourly Rate	$ Value of Annual Burden Hours
Cooperative Agreement							
Private Sector	15	1	15	2	30	$40.23	$1,206.90
Government	5	1	5	2	10	57.60	576.00
Medicated Feed - Florfenicol (Aquaflor®) INAD #10-697							
Private Sector	4	1	4	4	16	$40.23	$643.68
Government	4	1	4	4	16	57.60	921.60
Medicated Feed - Slice® (Emamectin Benzoate) INAD #11-370							
Private Sector	5	1	5	5	25	$40.23	$1,005.75
Government	4	1	4	5	20	57.60	1,152.00
Medicated Feed - Oxytetracylcine dihydrate (Terramycin® 200 for Fish) INAD #9332							
Private Sector	5	1	5	5	25	$40.23	$1,005.75
Government	16	1	16	5	80	57.60	4,608.00
Medicated Feed - 17α-methyltestosterone INAD #11-236							
Private Sector	4	1	4	5	20	$40.23	$804.60
Government	5	1	5	5	25	57.60	1,440.00
Medicated Feed - 17α-methyltestosterone INAD #8557							
Private Sector	5	1	5	5	25	$40.23	$1,005.75
Government	1	1	1	5	5	57.60	288.00
Medicated Feed - 17β-Estradiol INAD #12-671							
Private Sector	1	1	1	5	5	$40.23	$201.15
Government	1	1	1	5	5	57.60	288.00
Immersion - Chloramine-T INAD #9321							
Private Sector	1	1	1	4	4	$40.23	$160.92
Government	8	1	8	4	32	57.60	1,843.20
Immersion - Hydrogen peroxide (35% Perox Aid®) INAD #11-669							
Private Sector	1	5	5	4	20	$40.23	$804.60
Government	2	2	4	4	16	57.60	921.60
Immersion - Oxytetracycline hydrochloride INAD #9033							
Private Sector	1	1	1	4	4	$40.23	$160.92
Government	2	2	4	4	16	57.60	921.60
Immersion - Diquat® INAD #10-969							
Private Sector	1	1	1	4	4	$40.23	$160.92
Government	7	2	14	4	56	57.60	3,225.60
Sedative - AQUI-S®20E INAD #11-741							
Private Sector	11	1	11	4	44	$40.23	$1,770.12
Government	73	1	73	4	292	57.60	16,819.20
Sedative - BENZOAK VET® INAD #11-740							
Private Sector	1	1	1	4	4	$40.23	$160.92

Government	1	1	1	4	4	57.60	230.40
Spawning Aid - Lutenizing Hormone - Releasing Hormone (LHRHa) INAD #8061							
Private Sector	19	1	19	4	76	$40.23	$3,057.48
Government	7	2	14	4	56	57.60	3,225.60
Spawning Aid - GnRH IIa Chicken Gonadotropin - Releasing Hormone II analog INAD #13-345							
Private Sector	9	1	9	4	36	$40.23	$1,448.28
Government	1	1	1	4	4	57.60	230.40
Spawning Aid - Ovaplant® Salmon Gonadotropin - Releasing Hormone analoque (sGnRHa) INAD #11-375							
Private Sector	5	1	5	4	20	$40.23	$804.60
Government	12	1	12	4	48	57.60	2,764.80
Spawning Aid - Ovaplant®-L Salmon Gonadotropin - Releasing Hormone analoque (sGnRHa) INAD #13-298							
Private Sector	1	1	1	4	4	$40.23	$160.92
Government	4	1	4	4	16	57.60	921.60
Spawning Aid - Common Carp Pituitary (CCP) INAD #8391							
Private Sector	5	1	5	4	20	$40.23	$804.60
Government	7	2	14	4	56	57.60	3,225.60
Marking - Calcein (Se-Mark®) INAD #10-987							
Private Sector	1	1	1	4	4	$40.23	$160.92
Government	2	1	2	4	8	57.60	460.80
Injectable - Erythromycin 200 Injectable INAD #12-781							
Private Sector	2	1	2	4	8	$40.23	$321.84
Government	14	1	14	4	56	57.60	3,225.60
Totals:	***273***		***302***		***1,215***		***$63,140.22***

13. Provide an estimate of the total annual non-hour cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected in item 12.)

- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information (including filing fees paid for form processing). Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3)**

for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

The total estimated annual non-hour burden cost is **$289,232**. The facility is responsible for purchasing the INAD from the appropriate drug supplier (costs per INAD listed below). All equipment that would be used for the INAD studies is typically standard equipment already used by the facilities. Each INAD facility also pays a $700 enrollment fee each year as an average between INAD years 2019 and 2020) for a total of $197,400 in enrollment fees (282 INADS x $700.

Requirement	Average Number of Annual Responses	Average Cost per INAD	Enrollment Fee ($700 per Facility)	Cost per Response	Total Nonhour Cost Burden
Medicated Feed - Florfenicol (Aquaflor®) INAD #10-697					
Private Sector	4	$ 1,130	$ 700	$ 1,830	$7,320
Government	4	1,130	700	1,830	7,320
Medicated Feed - Slice® (Emamectin Benzoate) INAD #11-370					
Private Sector	5	$ 900	$ 700	$ 1,600	$8,000
Government	4	900	700	1,600	6,400
Medicated Feed - Oxytetracylcine dihydrate (Terramycin® 200 for Fish) INAD #9332					
Private Sector	5	$ 155	$ 700	$ 855	$4,275
Government	16	155	700	855	13,680
Medicated Feed - 17α-methyltestosterone INAD #11-236					
Private Sector	4	$ 415	$ 700	$ 1,115	$4,460
Government	5	415	700	1,115	5,575
Medicated Feed - 17α-methyltestosterone INAD #8557					
Private Sector	5	$ 1,031	$ 700	$ 1,731	$8,655
Government	1	1,031	700	1,731	1,731
Medicated Feed - 17β-Estradiol INAD #12-671					
Private Sector	1	$ 119	$ 700	$ 819	$819
Government	1	119	700	819	819
Immersion - Chloramine-T INAD #9321					
Private Sector	1	$ 265	$ 700	$ 965	$965
Government	8	265	700	965	7,720
Immersion - Hydrogen peroxide (35% Perox Aid®) INAD #11-669					
Private Sector	5	$ 695	$ 700	$ 1,395	$6,975
Government	4	695	700	1,395	5,580
Immersion - Oxytetracycline hydrochloride INAD #9033					
Private Sector	1	$ 41	$ 700	$ 741	$741
Government	4	41	700	741	2,964
Immersion - Diquat® INAD #10-969					
Private Sector	1	$ 330	$ 700	$ 1,030	$1,030
Government	14	330	700	1,030	14,420
Sedative - AQUI-S®20E INAD #11-741					
Private Sector	11	$ 242	$ 700	$ 942	$10,362
Government	73	242	700	942	68,766
Sedative - BENZOAK VET® INAD #11-740					
Private Sector	1	$ 550	$ 700	$ 1,250	$1,250
Government	1	550	700	1,250	1,250
Spawning Aid - Lutenizing Hormone - Releasing Hormone (LHRHa) INAD #8061					
Private Sector	19	$ 23	$ 700	$ 723	$13,737
Government	14	23	700	723	10,122
Spawning Aid - GnRH IIa Chicken Gonadotropin - Releasing Hormone II analog INAD #13-345					
Private Sector	9	$ 387	$ 700	$ 1,087	$9,783
Government	1	387	700	1,087	1,087
Spawning Aid - Ovaplant® Salmon Gonadotropin - Releasing Hormone analoque (sGnRHa) INAD #11-375					
Private Sector	5	$ 548	$ 700	$ 1,248	$6,240

Government	12	548	700	1,248	14,976
Spawning Aid - Ovaplant®-L Salmon Gonadotropin - Releasing Hormone analoque (sGnRHa) INAD #13-298					
Private Sector	1	$ 475	$ 700	$ 1,175	$1,175
Government	4	475	700	1,175	4,700
Spawning Aid - Common Carp Pituitary (CCP) INAD #8391					
Private Sector	5	$ 369	$ 700	$ 1,069	$5,345
Government	14	369	700	1,069	14,966
Marking - Calcein (Se-Mark®) INAD #10-987					
Private Sector	1	$ 188	$ 700	$ 888	$888
Government	2	188	700	888	1,776
Injectable - Erythromycin 200 Injectable INAD #12-781					
Private Sector	2	$ 135	$ 700	$ 835	$1,670
Government	14	135	700	835	11,690
Totals:	***282***				***$ 289,232***

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.

The estimated annual cost to the Federal Government associated with this collection of information is **$339,812** (rounded) ($84,953 for each quarter the INAD fees are not collected).

It should be noted that actual costs are minimal because the employees that are working with the INAD Program are not base funded employees. Instead, their salaries and any costs associated with the INAD Program are typically funded through the contributed funds that are collected from the INAD fees. Costs associated with the INAD Program includes but not limited to: salaries; maintaining and managing the online INAD database; digitizing INAD forms; and travel for meetings and training.

To determine average annual salary costs, we used the Office of Personnel Management Salary Table 2023-RUS as an average nationwide rate. In accordance with BLS News Release USDL-22-1892, we multiplied the annual salary by 1.61 to account for benefits. To determine average annual salary costs, we used the estimated time required to administer the INAD Program:

Position	Grade/ Step	Hr Rate	Hr Rate (with Benefits)	Total Responses	Time per Response (hr)	Total Annual Hours	Annual Cost
Fish Biologist	GS-12/5	$ 44.98	$ 72.42	416	5	2,080	$ 150,633.60
Fish Biologist	GS-11/5	37.53	60.42	416	5	2,080	$ 125,673.60
Branch Chief	GS-14/5	63.21	101.77	208	3	624	$ 63,504.48
						Total:	**$ 339,811.68**

15. Explain the reasons for any program changes or adjustments in hour or cost burden.

This is a request for OMB approval of a new information collection in use without a control number.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of

the collection of information, completion of report, publication dates, and other actions.

We will not publish any of the collected data. However, it may be shared at presentations or summarized and shared with the appropriate drug sponsor and the FDA as needed**.**

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

We will display the expiration date on all forms and protocols.

18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

There are no exceptions to the certification statement.