U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program

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www.fws.gov/fisheries/aadap

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National INAD Program Participants:

The USFWS's Aquatic Animal Drug Approval Partnership (AADAP) Program has received your 2018 enrollment in the INAD Program Management System indicating your interest in participating in the National INAD Program. I will email out the invoice to the principle contact person for your agency/company. Please forward this letter to any participant that is not listed in the on-line INAD database; as only the monitors and investigators listed in the database will receive this correspondence.

Important INAD information to note is:

1) All study protocols must be reviewed so you follow the correct treatment regimens. Please go to the following web page (https://www.fws.gov/fisheries/aadap/inads.html); click on the INAD(s) you will participate under; click on the study protocol (green text of the second paragraph under the Summary section); and review the fact sheet(s).

2) A VFD is not needed if you are using an INAD. List the feed manufacturer's fax or email address in the study design section of the study request. I will than send a copy of the approved study request to them for their records.

3) The Study Request form copies data into the Results Report. This was done to help save time for the investigators; however, the copied data is oftentimes no longer correct (things happen/plans change), and the incorrect data is oftentimes overlooked by investigators resulting in a number of inconsistencies in the final report. For any reports that are submitted and found to have errors, they will be sent back to stage 4 for the necessary changes. With respect to all INADs the areas below are where most of the errors are occurring:

    a. Treatment start and end dates
    b. Number of treated fish

c. Number of treatment days (only the number of days treatment was administered)

For Aqui-S 20E INAD participants:

If mixed fish species is selected in the main form then each fish species treated and the number of each one needs to be listed in the Description of Results write up section. Please also note if there were any differences seen between the sedation time for the different species. If different doses are used or different purposes for the anesthetic (spawning, tagging, euthanizing, or surgery) then different study requests are needed.

The final reports are submitted to FDA/CVM for review so it is important that the data is consistent and accurate. Thank you for your help in ensuring these reports are completed correctly.

4) As specified in all INAD authorizations, all INAD drug use must be in compliance with NPDES permitting requirements. Investigators are responsible for contacting their local NPDES permitting offices to ensure they have no objection to the proposed use of any drug under INAD authorization.

5) Several INADs now have approved labels for specific indications. If you are using the drug for an approved label indication then you will not report this information under the INAD Program.

6) A new study number is needed for any of the following reasons:
   a. There is more than 30 days between treatments for non-therapeutic INADs; different treatment days for therapeutic INADs (i.e. pond one has start treatment date of 2/1/18 and pond two has start treatment date of 2/5/18).
   b. There is a different purpose for the treatments - i.e. spawning, tagging, sampling, level of sedation
   c. Different doses are needed - a new study request is needed for each different dose
   d. Treatment crosses into the new year by more than 2 weeks

Please also note that all INADs participants must follow specified treatment regimens (dosage, treatment duration, target species, etc.), withdrawal times, and reporting requirements in order to participate under an INAD. If you have any questions, please do not hesitate to call me at 406-994-9905.

Thank you,

Bonnie Johnson
National INAD Program Administrator