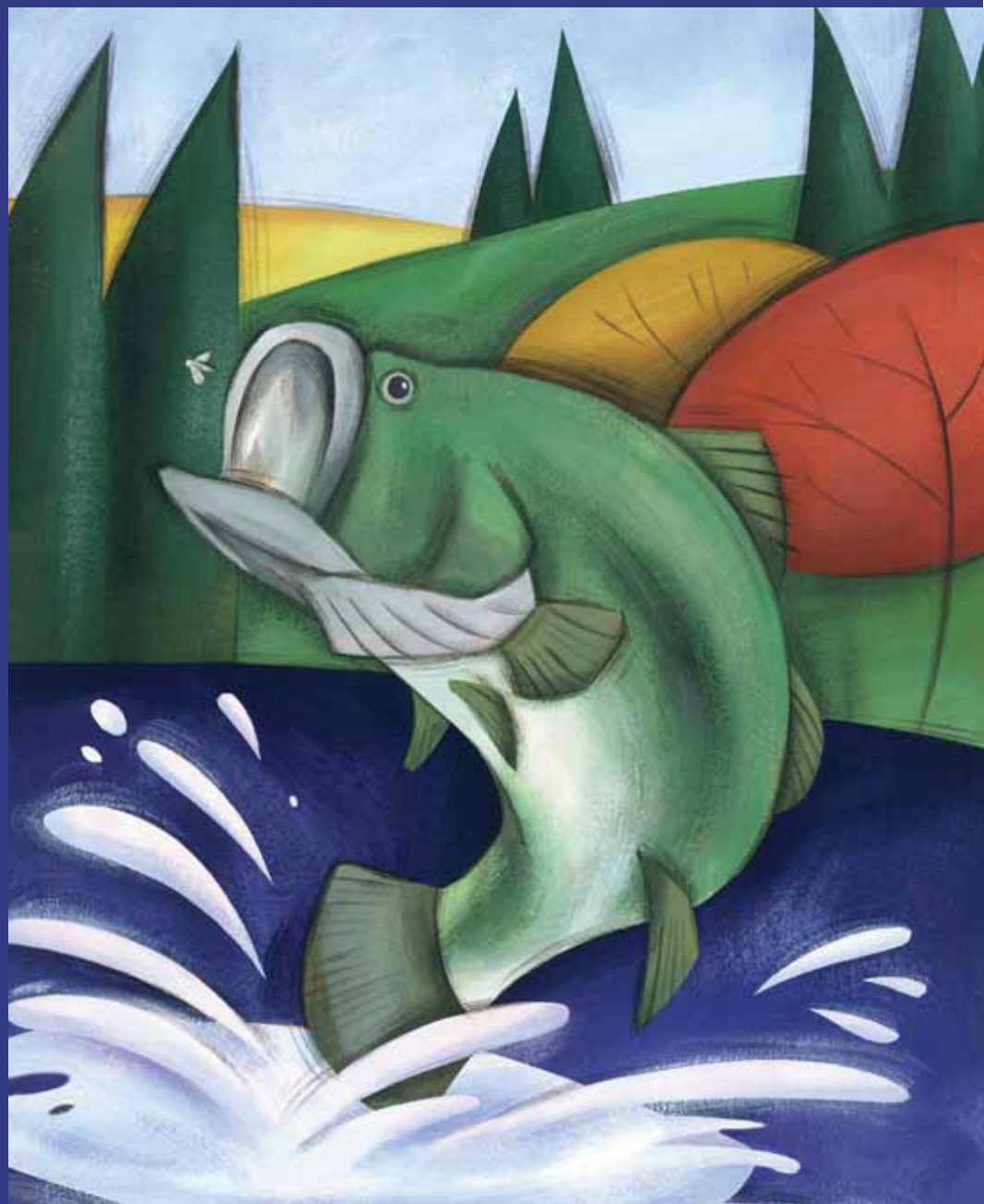
Center for
Veterinary
Medicine

U.S. Department of Health and Human Services
Food and Drug Administration

2/09

ADE Reporting for Fish Drugs

Information for Fisheries on How to Report Adverse Drug Events



ADE Reporting for Fish Drugs

Information for Fisheries on How to Report Adverse Drug Events

What is an ADE?

An adverse drug experience (ADE) or event is either an undesired side effect or the lack of a desired effect, i.e. the drug fails to do what it's supposed to do. The Center for Veterinary Medicine (CVM) defines an ADE as "any side effect, injury, toxicity, or sensitivity reaction (or failure to perform as expected) associated with use of an animal drug, whether or not determined to be attributable to the drug."

Pre-testing by the manufacturer and review of the data by the government does not guarantee absolute safety and effectiveness of approved new animal drugs due to the inherent limitations imposed by testing the product on a limited population of animals.

Veterinarians and other fish health specialists, fishery biologists, hatchery managers, researchers and animal owners are encouraged to report ADEs to FDA using the following instructions:

How Do I Report an ADE?

There are three ways an ADE can be reported.

1. **Call the drug company** if you suspect an ADE. Drug company phone numbers are usually listed on the product labeling. Inform the drug company that you want to report an ADE. The company representative should ask a series of questions about the event, complete an FDA 1932 form, and forward the report to CVM.

   If the drug is not FDA-approved for animal administration, or if it is approved but you do not wish to contact the manufacturer, the report may be submitted directly to the FDA on Form 1932a (see #2).

   Reports for adverse drug events in fish should include a good medical history, all other drugs the animal has been given at the same time, water quality measurements and any recent changes in water quality, and all clinical findings. Clinical findings would include unexpected death and observation of abnormal behavior or appearance (including appetite), as well as necropsy, bacterial or viral culture, and histopathology results. If possible, please indicate whether the system used is flow-through, recirculating, a pond, etc., and any life support that is on the system (e.g., ozone, filtration. etc.)

2. **Fill out and submit FORM FDA 1932a**, Veterinary Adverse Experience, Lack of Effectiveness or Product Defect Report, http://www.fda.gov/opacom/morechoices/fdaforms/fdaforms.html. The postage paid, pre-addressed form can also be obtained by writing to:

   ADE Reporting System
   Center for Veterinary Medicine
   U.S. Food & Drug Administration
   7500 Standish Place
   Rockville, MD 20855-2773

   The Center may occasionally need more detailed information about an incident and the reporter may be called by a CVM staff veterinarian.

3. **Call the Center for Veterinary Medicine at 1-888-FDA-VETS.**

   Leave your name, address, phone number and the brand name of the drug involved. Ask to have a 1932a form sent or ask for the phone number of the drug company you should call to report the problem.

IMPORTANT: The identities of all persons and animals are held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer or distributor unless requested otherwise. However, FDA will not disclose the reporter's identity to a request from the public, pursuant to the Freedom of Information Act.