SUPPLEMENTAL POLICIES

USE OF DRUGS IN OUTDOOR AQUATIC RESEARCH FACILITIES

Issues to be addressed: Should aquatic species reared in ponds or other outdoor containment research facilities be considered laboratory animals? If so, when should unapproved new animal drug use in these animals fall under Title 21 Code of Federal Regulations Part 511.1 (a)1 (21 CFR 511.1 (a)[1]), which pertains only to laboratory research and which does not require prior FDA notifications? When should it fall under 21 CFR 511.1 (b)[2], which pertains to clinical studies and which requires prior FDA notification, an environmental assessment or categorical exclusion, and, sometimes, authorization?

Issue 1: Can aquatic species reared in ponds or other outdoor containment research facilities ever be considered laboratory animals?

Position: Aquatic animals reared in outdoor containment research facilities may be considered laboratory animals provided the necessary criteria in 21 CFR 511.1(a) are fully met.

Reasoning: Any species may potentially be used for laboratory studies. Laboratory research animals used for tests of investigational new animal drugs are generally housed according to accepted animal husbandry techniques. For aquatic species, the laboratory research environment may include ponds or other outdoor containment facilities. Conceivably, ponds may be the only feasible way to house some fish (e.g., adult paddlefish) for certain types of laboratory studies. It may be argued that laboratory research generally implies a relatively controlled environment. However, the degree of environmental control needed in a laboratory study varies with the purpose of the study. Although FDA has the authority and ability to determine the acceptability of studies and the procedures used to conduct those studies to support new animal drug approval, it does not have the authority or the ability to declare laboratory research (including preliminary studies) in any species not to be laboratory research simply because the research environment is outdoors. FDA agreement that a particular pond use meets the criteria of a 21 CDR 511(a) research use does not relieve the facility from the requirements to observe local, state, and federal environmental requirements through the appropriate regional authorities.

[1] 21 CFR 511.1(a)refers to the conditions where a new animal drug can be used for test in vitro and in laboratory research animals.
[2] 21 CFR 511.1(b) describes the conditions where a new animal drug can be used for clinical investigation in animals.

Issue 2: When should unapproved new animal drugs used in animals in laboratory research ponds or other outdoor aquatic research facilities fall under 21 CFR 511.1 (a)? 511.1 (b)?

Position: Unapproved new animal drugs used in animals in laboratory research ponds fall under 511.1 (a) when laboratory research is the only intended purpose for the use of the unapproved new animal drug and for the animals. If the use of the unapproved new animal drug is intended for in-vitro use in the regular course of diagnosing or treating disease, or for use in the animal for other than laboratory research, then the use of the drug falls under 21 CFR 511.1(b). If the animals are used for food purposes, livestock (breeding) purposes, commercial sale, or pets, the drug use falls under 511.1 (b), and the following are required: 1) prior notification to CVM, 2) an environmental assessment or claim for categorical exclusion, and 3) if applicable, CVM's authorization for use of the treated animals or their byproducts for food. If there is any question whether particular research falls under 511.1 (a) or 511.1 (b), CVM should be contacted for clarification. Even if laboratory research falls under 511.1 (a), it may be advantageous to establish an INAD file with CVM before study initiation, especially if the research may be important in supporting a new animal drug application (NADA).

The automatic exemption allowed for laboratory research under 511.1 (a) does not exempt a researcher or research facility from compliance with other applicable Federal, State, and local laws and regulations, including those pertaining to environmental and occupational safety.

Reasoning: CFR 511.1 (a) states, "A shipment or other delivery of a new animal drug or animal feed bearing or containing a new animal drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 512 (a) and (m) of the Act . . - "(emphasis added). CVM's Policy & Procedures Manual (1240.3000, New Animal Drugs for Investigational Use) defines animals that fall under CFR 511.1 (a) as follows: "Any species may potentially be used for laboratory studies. Laboratory research however must be the animal's sole intended function."

"Animals used for food purposes or for livestock (breeding) purposes, or animals which are kept as pets, are not considered to be laboratory animals." This definition appears to adequately address concerns about the potential for abuse of the "laboratory research" designation.

The above stated position on outdoor aquatic research facilities is a reflection of current CVM policies and may be subject to change in the future.