

## GUIDE TO DRUG, VACCINE, AND PESTICIDE USE IN AQUACULTURE (January 2004)

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### APPENDIX D: GLOSSARY OF COMMON TERMS

**Active ingredient-** In a drug product, the ingredient responsible for the intended effect of the product. In any pesticide product, the chemical or substance that prevents, destroys, repels, or mitigates a pest. (Pesticides are regulated primarily on the basis of their active ingredients.)

**Autogenous bacterin** - A bacterin (see below) made by a firm licensed to produce autogenous bacterins from organisms isolated from a particular farm, to be sold to and used on that farm only, and for a specified, limited time only.

**Bacterin-** A vaccine made from killed bacteria.

**Best management practices-** Husbandry practices that strive to ensure optimal health, production, and economic performance.

**Clinical field trial-** A research study of the effectiveness of a compound under actual commercial production conditions; involves strict adherence to FDA or USDA protocols and recordkeeping requirements.

**Drug-** An article that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; an article (other than food) intended to affect the structure or any function of the body of man or other animals; or an article that is recognized in official drug compendia.

**Drug sponsor-** An individual or firm seeking FDA approval of a drug product.

**Extra-label use-** The actual or intended use of an approved new animal drug in a manner that is not in accordance with the approved label directions. Extra-label use is permitted only by or on the prescription of a licensed veterinarian when a valid veterinarian-client-patient relationship exists.

**Hazard Analysis Critical Control Points (HACCP)-** A systematic approach to hazard identification, assessment, and control that can be used by all concerned to ensure safe, sound, and properly labeled foods.

**Inert ingredient-** Ingredient in a drug or pesticide product that does not contribute to the intended activity of the product.

**Investigational New Animal Drug (INAD) exemption (standard)**- Exemption authorized under the Federal Food, Drug, and Cosmetic Act to permit the shipment of new animal drugs in interstate commerce without an approved new animal drug application. Specifically limits the distribution of unapproved new animal drugs and their use to experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. In order to distribute a new animal drug for clinical investigations, an exemption from the requirements of an approved new animal drug application must be obtained. This is accomplished by the submission of certain information as part of an INAD application. Is typically sponsored by pharmaceutical companies.

**Investigational New Animal Drug (INAD) exemption (emergency compassionate)**- A type of compassionate investigational new animal drug exemption that is used for nonpredictable diseases or conditions and is authorized for one site, one disease, one drug, and one emergency INAD use for present disease outbreak only. Involves specific requirements, including data submission along with other information.

**Low Regulatory Priority (LRP) substance**- Unapproved new animal drug for which FDA has a policy of regulatory discretion that allows the use of such a substance without an approved new animal drug application or INAD exemption.

**New Animal Drug**- Any drug intended for use in animals other than people, the composition of which is not generally recognized among experts qualified by scientific training and experience as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.

**New Animal Drug Application (NADA)**- An application package submitted to FDA for review that requests the approval of a new animal drug. The application includes sufficient data to establish the safety and effectiveness of the drug product, along with other requirements.

**Non-target organisms**- Organisms at which treatment is not aimed but which contact the product and may be affected by it.

**Over-the-counter (OTC) drugs**- Drugs that have adequate written directions for lay use and are permitted to be sold without a veterinary prescription.

**Pest**- An insect, rodent, nematode, or weed or any other form of terrestrial or aquatic plant or animal life or virus, fungus, bacteria, or other microorganism that is considered to be an annoyance and that may be injurious to health or the environment.

**Pesticide**- Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

**Prescription (Rx) drug**- An animal drug for which adequate directions for safe and effective use by a

layperson cannot be written and which therefore must be prescribed by a licensed veterinarian. The label bears the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

**Quality assurance program-** A proactive, industry-driven code of production practices, carefully designed to ensure that producers supply a wholesome, safe product to consumers.

**Registration-** Under the Federal Insecticide, Fungicide, and Rodenticide Act, the formal listing with EPA of a new pesticidal active ingredient prior to its marketing or distribution in intra- or interstate commerce.

**Restricted Use Pesticide (RUP)-** A registered pesticide that has been classified for restricted use under the Federal Insecticide, Fungicide, and Rodenticide Act for some or all of its applications because it is toxic and requires special handling. Restricted use pesticides may be purchased and applied only by trained, certified applicators or by individuals under their direct supervision and may be utilized only for those uses covered by the certified applicator's certification.

**Sponsor (drug)-** An individual or company that applies for an INAD exemption to develop data with the intent of seeking a new animal drug approval for the compound used under the INAD exemption.

**Target organism-** The plant, animal, or microorganism that is treated or at which treatment is aimed.

**Tissue residue-** The drug, pesticide, or toxic breakdown product remaining in edible tissue after natural or technological processes of removal or degradation have occurred.

**Tolerance-** The maximum amount of pesticide or drug residue allowed by law to remain in or on a harvested crop or food animal product. EPA sets tolerances for pesticides and FDA sets tolerances for drugs so that treated crops or animals consumed do not pose an unreasonable risk to consumers (a reasonable certainty of no harm for pesticides). Tolerances are set for food-use crops on a per-crop basis. Tolerances are set for animal products on the basis of individual species and tissue (muscle, liver, etc.).

**Vaccine-** A preparation of killed microorganisms; living attenuated, fully virulent, or related nonvirulent microorganisms; or parts of micro- or macroorganisms that are administered to produce or increase immunity to a particular disease.

**Veterinary biologics-** All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, and live microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

**Veterinarian-client-patient relationship-** Exists when (1) the veterinarian has assumed responsibility for making medical judgments regarding the health of the animals and the need for medical treatment, and the client has agreed to follow the instructions of the veterinarian; (2) there is sufficient knowledge

of the animals by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animals (i.e., the veterinarian has recently seen and is personally acquainted with the keeping and care of the animals by virtue of an examination of the animals and/or by medically appropriate and timely visits to the premises where the animals are kept); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of treatment.

**Veterinary Feed Directive Drugs-** A drug intended for use in or on an animal feed which is limited by an approved NADA application to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.

**Withdrawal time-** The minimum required period of time between the last drug treatment of an animal and the slaughter or release of that animal.