

Compliance Guide for the Concentrated Aquatic Animal Production Point Source Category

Appendix U: FDA Labeling

Full document available at
<http://www.epa.gov/waterscience/guide/aquaculture>

FDA: LABELS FOR NEW ANIMAL DRUGS FOR AQUACULTURE

In some cases as part of the approval process for new animal drugs, FDA may decide to include information on labels for individual aquaculture drugs in order to address the potential environmental impacts associated with the use of the drug. Drug labels may also require the user to inform the appropriate NPDES permitting authority prior to the first use of the drug. This is necessary because FDA must approve drugs for use on a nationwide basis without in-depth consideration of wastewater treatment (e.g., settling ponds) at individual facilities and local site-specific conditions such as dilution and degradation in receiving waters. The reporting requirement insures that there is appropriate oversight to determine whether effluent discharge limits are needed at individual aquaculture facilities when FDA has determined that release of a drug has the potential to cause effects on organisms in receiving waters at some locations.

Label information on aquaculture drugs may include identification of acute and chronic water quality "benchmarks" derived to address and help mitigate potential adverse effects on aquatic life resulting from drug use. These benchmarks are meant to assist NPDES permitting authorities make determinations on whether discharge limits are needed and help them set these limits, if they are needed (see below). In developing such benchmarks, FDA relies on toxicity and environmental fate information collected and generated through an environmental assessment process that is part of the overall drug approval process (Note: Environmental Assessment documents for veterinary drugs are available through the following FDA website: <http://fda.gov/cvm/ea.htm>). FDA's technical process for deriving water quality benchmarks is similar to that used by the U.S. EPA to develop numerical water quality criteria for the protection of aquatic life (<http://www.epa.gov/waterscience/criteria/aqlife.html#guide>).

Under EPA's NPDES regulations, NPDES permits must include limits necessary to achieve water quality standards under section 303 of the Clean Water Act. 40 C.F.R. § 122.44(d)(1). In cases where a State has not established a water quality criterion for a specific chemical pollutant but has established a narrative criterion (i.e., "no toxics, in toxic amounts"), the permitting authority must establish an effluent limit for a new animal drug if it is present in an effluent in concentrations that cause or has a reasonable potential to cause or contribute to an excursion above a narrative criterion. 40 C.F.R. § 122.44(d)(1)(i). In developing such limits, the permitting authority may use a calculated numeric water quality criterion derived by one of several methods, supplemented with other relevant information which may include "information about the pollutant from the Food and Drug Administration" 40 C.F.R. § 122.44(d)(1)(vi)(A). Water quality benchmarks and other information on drug labels will alert users of the potential adverse effects of drug use on aquatic life in receiving waters. This information will also provide a mechanism for alerting permit writers of the potential need to formally establish facility-specific numeric effluent limitations for aquaculture drug products as well as necessary information for complying with § 122.44(d).

Additional Information

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