

## 40 C.F.R. § 451.3

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### General reporting requirements.

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(a) *Drugs.* Except as noted below, a permittee subject to this part must notify the permitting authority of the use in a concentrated aquatic animal production facility subject to this part of any investigational new animal drug (INAD) or any extralabel drug use where such a use may lead to a discharge of the drug to waters of the U.S. Reporting is not required for an INAD or extralabel drug use that has been previously approved by FDA for a different species or disease if the INAD or extralabel use is at or below the approved dosage and involves similar conditions of use.

(1) The permittee must provide a written report to the permitting authority of an INAD's impending use within 7 days of agreeing or signing up to participate in an INAD study. The written report must identify the INAD to be used, method of use, the dosage, and the disease or condition the INAD is intended to treat.

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