
SUPPLEMENTAL POLICIES

DRUG-PESTICIDE ISSUES

I. Introduction:

If a registered pesticide is being used properly (i.e., the labeled conditions in fact exist in the facility at the time the pesticide is used, and the compound is not misused under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)), FDA will not object to that proper use if the pesticide has purported incidental, concurrent therapeutic (drug) benefit. Title 40 of the Code of Federal Regulations contains the regulations under which the pesticide programs operate.

II. Registered Pesticide:

If a registered pesticide is not being used properly under FIFRA and is intended for a drug use, then FDA may consider regulatory action.

- A. Coordination should be effected with EPA since a FIFRA violation likely would have occurred in addition to an FD&C Act violation.
- B. Regulatory action against a vendor should be considered if the vendor is (overtly/subtly) establishing an intended drug use for the pesticide. Regulatory action at the producer level should be considered only in light of the limits discussed in II.A.3. in CVM Program Policy and Procedures Manual 1240.4200.

III. Compound Not Registered as a Pesticide:

If a compound that is not registered as a pesticide (and is not exempted from registration) is promoted or used both as a pesticide and a drug, regulatory action should be considered. Coordination should be effected with EPA since a FIFRA violation would likely have occurred in addition to an FD&C Act violation.