



**Missouri Department of Health and Senior Services**

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**INFORMATIONAL RELEASE F1-11**

To: Regional EPHS V's  
Local Public Health Administrators  
Local Environmental Public Health Specialists

From: Mary Glassburner, Chief,  
Bureau of Environmental Health Services

Subject: Distressed or Adulterated Drugs

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Missouri's laws are based on the federal food, drug and cosmetic act. RSMo 196.015, prohibits the manufacture, sale or delivery, holding or offering for sale any food, drug, device or cosmetic that is adulterated or misbranded. Like food, drugs involved in fires, floods, transportation accidents or other conditions that could cause them to be adulterated have the potential to cause harm to the public. It is the responsibility of the Health Department to evaluate these goods for adulteration.

The purpose of this informational release is to discuss the handling of adulterated or distressed drugs. For the purposes of this document, drugs include over-the-counter (OTC) drugs, prescription drugs, and controlled substances. Many of the processes and procedures used to evaluate and handle adulterated drugs are similar to those used for adulterated foods. The differences in handling are caused by the type of drug being evaluated.

**Definitions**

Drugs fall into three classes: OTC, prescription drugs or controlled substances. OTC drugs are purchased directly by the consumer from the store shelves and do not require a prescription. Aspirin, cold remedies, vitamins, etc. are common examples of OTC drugs. A prescription drug is a medication that can be purchased or given out only with a written instruction from a licensed health care provider. Examples of prescription drugs include birth control pills, blood pressure medicines, and antibiotics. A controlled substance is a drug or other substance that comes under the jurisdiction of the Federal Controlled Substances Act of 1970. Narcotics, depressants, stimulants, hallucinogens and anabolic steroids are regulated by the Controlled Substances Act (CSA) and are listed in one of five schedules. Schedule I substances have a high potential for abuse and no accepted medical use in the U.S. Schedule II drugs also have a high abuse potential with a severe liability for psychic or physical dependence, but in general are substances that are approved by the FDA for a therapeutic use. Schedules III-V includes drugs with decreasing levels of abuse potential.

**Determination of Adulteration**

When evaluating drugs, use the same criteria used to evaluate food. Exposure to fire (smoke and/or soot), floodwater, diesel fuel, hazardous chemicals or physical damage should be considered adulteration. The manufacturer may include temperature and humidity as criteria when they evaluate drugs since many drugs must be held at a prescribed temperature and humidity; however, our evaluation for adulteration will not include these factors. Our documentation should indicate that the product was not evaluated for those parameters. When possible, we should document temperature and humidity conditions at the scene to help the owner of the products make responsible decisions.

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## Evaluating Over-the-Counter Drugs

Your initial action is to embargo the product until evaluated. Gather pertinent information about the incident and the owner of the product. Taking pictures to document conditions is encouraged. For incidents involving OTC drugs, the evaluation for adulteration should be done on scene or at the facility. If they are determined to be adulterated, the owner must determine the disposal method to be used and arrange for secure holding and transport to the disposal site. If the product leaves your jurisdiction for disposal, a copy of the paperwork needs to accompany the load and notification to the receiving jurisdiction is required. If the product is destroyed in your jurisdiction, you will need to witness the destruction.

## Evaluating Prescription Drugs and Controlled Substances

The first action is to embargo the product either at the scene or in the facility. Gather pertinent information about the incident and the owner of the product. **There is a higher level of security when dealing with these substances and for that reason a representative of the owner must be on scene prior to any evaluation of the product. This is a critical procedure to follow. Responsibility for the product is the owner's and their representative must be on site.** Before any product is moved, environmental conditions that exist at the site of the incident should be documented; this includes factors like spilled diesel fuel, soot or smoke damage, floodwater damage, impact damage, the presence of hazardous chemicals and weather parameters like temperature, humidity or precipitation. Taking pictures to document conditions is encouraged.

In a fixed facility like a pharmacy, these products are behind the counter (in a restricted area not accessible to the general public) and sometimes in locked cabinets or storage. Trucks transporting prescription drugs or controlled substances normally carry these in sealed totes. These totes should not be opened on the scene of a transportation accident as adequate security and control cannot be assured. If conditions at the scene indicate, these drugs may have been adulterated and arrangements should be made with the owner of the product for you to evaluate the products after they have been moved to a secure site. The company may want to move the product out of the county (or perhaps even the state) where the incident occurred. Our embargo authority gives us the ability to deny these requests until an evaluation is completed. Individual circumstances will dictate the best course of action. The bottom line is that an evaluation must be made by health authorities to determine if product may be salvaged and released or if the product has been adulterated is unsafe and must be destroyed. If the product is to be transported to another jurisdiction, it must be transported under embargo and the receiving agency needs to be notified. Past experience has shown that companies may decide to dispose of the products without an evaluation to determine if it is adulterated. If so, we need to have this decision adequately documented. Keep in mind that it is still our responsibility to oversee the disposal of the product.

## Final Disposition of Adulterated Drugs

Remind the owner of the product of their responsibility to maintain the product in a secure location. As always, environmental health professionals should not take possession of any product or accept responsibility for the security of any goods.

Our responsibility is to assure that adulterated product is removed from commerce. Often when dealing with adulterated food, it is taken to the nearest landfill for disposal. In most instances, this will not be an acceptable alternative for drugs. Many drugs pose a groundwater contamination hazard and should not be put in landfills or flushed into wastewater treatment systems. Often the drugs are sent to a "reverse distributor" or company that specializes in drug disposal. It is the responsibility of the owner of the product to assure that proper drug disposal methods are used. This will apply to all quantities of all classes of drugs. When a reverse distributor or drug disposal company is used, the product must be transported under embargo and we must be provided with written assurance that all of the drugs were received and disposed of appropriately.