Why Medical Marijuana Isn't

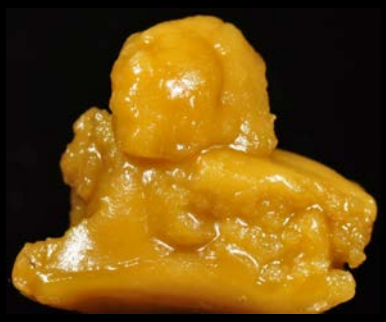
Without FDA Approval, no medicine can be marketed legally to the public.

Congress enacted the Pure Food and Drug Act of 1906 to protect consumers from the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, and medicines. Later, the Food and Drug Administration (FDA) was created to implement the Act's provisions.

Animal Testing

The experimental medicine must be tested in multiple species of animals for toxicity before it can be administered to humans. No marijuana medicine legalized by states has been tested in animals.

FDA requires the manufacturer of an experimental medicine to prove it is safe and effective before it can be marketed to the public. No marijuana medicine legalized by states has been approved by FDA.



Application to Test Medicine in Humans

With proof from animal testing of purity, safety, and potential efficacy a manufacturer can ask FDA for permission to test the medicine in humans. The application also must contain information about the medicine's composition, manufacturing, and plan for clinical trials.

FDA approval involves several steps:

Purity

The experimental medicine must be pure and free of contaminants. Most medicines are developed with pure chemicals and automatically meet the purity test. However, marijuana plants can contain mold, mildew, pesticides, salmonella, E. coli, and other impurities. Few states require marijuana plant material or foods and drinks infused with its extracts to be tested for purity.

Informed Consent

The manufacturer must show FDA that its clinical trials will not hurt humans and explain how it will inform patients of all known harms of the experimental medicine so patients can decide whether to enter the trials. No patient who buys medical marijuana legalized by states has been given informed consent.

Clinical Trials

Phase 1 trials involve 20 to 80 healthy volunteers to further test the experimental medicine for safety, what side-effects it might have, and how it is metabolized and excreted.

Pictured are whole-plant extracts, marijuana concentrates with THC levels of 80% to 90% sold for medical use. They include wax (center), honey oil (right), and shatter (left).

Phase 2 trials involve several hundred patients who have a certain disease or condition to learn if the experimental medicine works. In controlled trials, patients receiving the experimental medicine are compared with similar patients who receive a standard medicine or a placebo.

Phase 3 trials are large-scale studies which enroll thousands of patients. These trials gather more information about safety and effectiveness, study different populations and different dosages, and study how the experimental medicine interacts with other medicines. No marijuana products legalized for medical use have been studied in clinical trials.

Request for Approval

The manufacturer files a second application to FDA for approval to market its new medicine. This includes all animal and human data, analyses of the data, information about how the drug behaves in the body, and how it is manufactured. An FDA team evaluates the manufacturer's safety and effectiveness research. Because no manufacturer of any marijuana medicine legalized by states has conducted safety or effectiveness research, there is none for FDA to review.

Medicine Labeling

FDA reviews the manufacturer's proposed labeling to ensure all appropriate information is included for both health care professionals and patients. No manufacturer of marijuana medicines legalized by states has submitted its product label for FDA review.

Facility Inspection

FDA inspects the facilities where the experimental medicine will be manufactured if approved. No facilities that grow marijuana or extract its cannabinoids and infuse them into foods and drinks have been inspected by FDA.

Post-Approval Monitoring

Not all effects of a new medicine can be detected during clinical trials. Monitoring safety issues is critical once the approved medicine hits the market. The manufacturer submits periodic safety updates to FDA. So do consumers and physicians. Newly uncovered risks are added to the medicine's label. Sometimes the medicine's use must be limited substantially or even removed from the market entirely. No marijuana products legalized for medical use are monitored after these unapproved medicines are sold.

Users inhale whole plant extracts via a rig, top. Extracts are also infused into foods and drinks as shown on the rest of this page. Many appeal to children who are overdosing and being rushed to ERs after eating them accidentally.