

FDA Recommends Tighter Regulations for Prescribing Hydrocodone Products



The Food and Drug Administration (FDA) has recommended tighter restrictions for products containing hydrocodone and other painkillers such as acetaminophen or aspirin.

These combination products include Vicodin and Lortab.

Currently, patients can refill prescriptions for hydrocodone products five times over a six-month period before they need a new prescription. Under the new FDA regulations, patients will only be able to receive a 90-day supply of the medication without a new prescription. According to federal data, most patients only take the drugs for about two weeks, creating the potential for extra pills to be sold or taken by teens who find them in the medicine cabinet.

The new rules will also require patients to take a prescription to a pharmacy, instead of having a doctor call it in.

These changes are expected to take place as early as next year, The New York Times reports. They first must be approved by the Department of Health and Human Services and adopted by the Drug Enforcement Administration (DEA), which has long advocated for stronger regulations for prescribing hydrocodone products.

The FDA rules reclassify hydrocodone-containing products from Schedule III drugs to the more restrictive Schedule II drugs, which are medications with the highest potential for abuse that can be legally prescribed, including oxycodone.

Until now, the FDA has said further restricting hydrocodone-containing products would make it more difficult for patients in pain to obtain them. The American Medical Association and other doctors' groups and pharmacy organizations have opposed tighter restrictions.

Dr. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, said while the new rules would affect patients, the agency had to consider the impact of prescription drug abuse. "These are very difficult trade-offs that our society has to make," she told the newspaper.

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"The reason we approve these drugs is for people in pain. But we can't ignore the epidemic on the other side."

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