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FDA wants drug companies to look at potential for abuse

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The Food and Drug Administration is calling on pharmaceutical firms to give more attention to the potential for abuse of new drugs when subjecting them to pre-market testing.

The agency this week released a draft of new voluntary guidelines to assist drugmakers in figuring out which compounds should be placed under the Controlled Substances Act, which regulates the handling, record-keeping and dispensing of controlled substances -- in some cases imposing criminal penalties for misuse.

The guidelines urge researchers to look beyond traditional indicators such as whether a compound is addictive to other characteristics that could lead to abuse. Advances in chemistry and biochemistry have created new properties in drugs that may include previously unrecognized abuse potential in humans, according to the FDA.

While officials said no specific event triggered the FDAs guidance, Michael Klein, director of the agency's Controlled Substance Staff, pointed to the anesthetic propofol as an example of a drug that might be flagged for restrictions if subjected to more rigorous consideration of potential abuse.

Propofol is best known as part of the cocktail of drugs that caused the death of pop star Michael Jackson.

It currently is not considered a controlled substance, but that status has

been under review by the Drug Enforcement Administration, which enforces the Controlled Substances Act.

"Until recently, there hadn't been much indication that it was being abused. But we have gotten calls from the (health care) industry telling us, 'You need to take a look at it,' " said DEA spokeswoman Barbara Carreno.

Carreno said DEA initially had not thought propofol was subject to abuse because it required careful administration with a needle and was regarded simply as an anesthetic.

But anesthesiologists, nurses and other medical professionals have found that the drug also induces a mild euphoria and other pleasant side effects and, since it's not a controlled substance, is relatively accessible in medical settings.

Anesthesiologist Scott Fishman said propofol is one of a number of drugs "which were released for one purpose and society, or the street, finds another use."

In urging drug developers to cast a wide net for indicators of abuse potential, FDA is saying, "let's do the testing instead of society doing the testing," said Fishman, who is chief of pain medicine at the University of California, Davis School of Medicine. "They're expanding this idea that abusable drugs aren't just the ones that are addictive."

Fishman predicted that drugmakers may balk at higher costs that may result from following the proposed guidelines.

A spokeswoman for the main industry trade group, Pharmaceutical Research and Manufacturers of America, said her organization had no comment because it has not had a chance to study the FDA document.

The FDA will collect industry and public comment for two months before issuing final guidelines.

The new guidelines dovetail with two other ongoing FDA drug-safety initiatives, one to improve medication labeling and use instructions and another to require risk-management plans for selected prescription drugs to ensure that hazards associated with them are minimized.