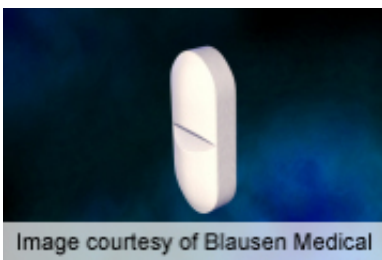


# FDA: Draft guidance issued on abuse-deterrent opioids

January 10 2013

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The U.S. Food and Drug Administration has issued a draft guidance document to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties.

(HealthDay)—The U.S. Food and Drug Administration has issued a draft guidance document to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties.

The document entitled "Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and Labeling," details the FDA's current thinking about the studies that should be done to demonstrate abuse-deterrent properties in a given formulation, how those studies will be evaluated by the FDA, and what labeling claims may be approved based on the study results.

This draft guidance fulfills mandates under the [Food and Drug](#)

[Administration](#) Safety and Innovation Act and the Office of National Drug Control Policy's Prescription [Drug Abuse Prevention](#) Plan, according to information from the FDA.

"The FDA is extremely concerned about the inappropriate use of prescription opioids, which is a major public health challenge for our nation," FDA Commissioner Margaret A. Hamburg, M.D., said in a statement. "This draft guidance is an important part of a larger effort by [the] FDA aimed at preventing prescription drug abuse and misuse."

**More information:** [More Information](#)

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