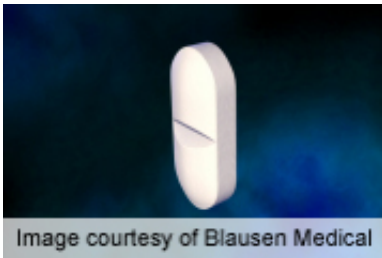


# FDA: Draft guidance issued on abuse-deterrent opioids

January 10 2013

---



The U.S. Food and Drug Administration has issued a draft guidance document to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties.

(HealthDay)—The U.S. Food and Drug Administration has issued a draft guidance document to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties.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This draft guidance fulfills mandates under the [Food and Drug](#)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 "This draft guidance is an important part of a larger effort by [the] FDA aimed at preventing prescription drug abuse and misuse."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](#)

Copyright © 2012 [HealthDay](#). All rights reserved.

Citation: FDA: Draft guidance issued on abuse-deterrent opioids (2013, January 10) retrieved 5 May 2024 from <https://medicalxpress.com/news/2013-01-fda-guidance-issued-abuse-deterrent-opioids.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.
---