

FDA NEWS RELEASE

For Immediate Release: Jan. 9, 2013

Media Inquiries: Morgan Liscinsky, 301-796-0397; morgan.liscinsky@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA issues draft guidance on abuse-deterrent opioids

The U.S. Food and Drug Administration today issued a draft guidance document to assist industry in developing new formulations of opioid drugs with abuse-deterrent properties.

The document “ Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling,” explains the FDA’ s current thinking about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies will be evaluated by the agency, and what labeling claims may be approved based on the results of those studies.

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which is a major public health challenge for our nation,” said FDA Commissioner Margaret A. Hamburg, M.D. “ This draft guidance is an important part of a larger effort by FDA aimed at preventing prescription drug abuse and misuse.”

Opioids can be abused in a number of ways. Abuse-deterrent formulations target the known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject, for the specific opioid drug substance in that formulation. The science of abuse deterrence is relatively new, and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. In working with industry, the FDA will take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products.

“ While prescription opioids are an important component of pain management, abuse and misuse of these products have resulted in too many injuries and deaths across the United States,” said Douglas Throckmorton, M.D., deputy director for regulatory programs in the

FDA's Center for Drug Evaluation and Research. " An important step towards the goal of creating safer opioids is the development of products that are specifically formulated to deter abuse."

The FDA continues to encourage the development of abuse-deterrent formulations of opioids and believes that these products have promise to help reduce prescription drug abuse. At the same time, the FDA remains committed to ensuring that patients with pain have appropriate access to opioid analgesics.

This draft guidance fulfills mandates under the Food and Drug Administration Safety and Innovation Act (FDASIA) and the Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan.

" Our nation is in the midst of a prescription drug abuse epidemic," said Gil Kerlikowske, director of National Drug Control Policy. " While there are no silver bullet solutions to this public health and safety challenge, abuse-deterrent formulations of powerful prescription opioids can make a difference in addressing this epidemic. This guidance is a vital component of the Administration's comprehensive effort to reduce prescription drug abuse in America, and we commend the FDA for its commitment to this challenge."

FDA is seeking public comment on the draft guidance for 60 days and encourages additional scientific and clinical research that will advance the development and assessment of abuse-deterrent technologies. Instructions on how to submit comments will be announced in an upcoming Federal Register notice. The FDA will also hold a public meeting to discuss and receive feedback on the draft guidance. In finalizing the guidance document, the agency will consider the information received from the public.