Abuse-Deterrent Opioid Analgesics

Postmarket Drug Safety Information for Patients and Providers

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Content current as of:
03/08/2021

Regulated Product(s)
Drugs

The FDA is encouraging the development of prescription opioids with abuse-deterrent formulations (ADFs) to help combat the opioid crisis. The agency recognizes that abuse-deterrent opioids are not abuse- or addiction-proof but are a step toward products that may help reduce abuse. The FDA fully supports efforts to better understand the impact of these products in the real-world setting and convened a public workshop on July 10-11, 2017, to discuss the current data and methods for evaluating ADF products postmarketing and what can be done to improve national data and methods moving forward.

The FDA also supports the development of innovative formulations that have the potential to make abuse of these products more difficult or less rewarding. This does not mean a product is impossible to abuse or that abuse-deterrent properties necessarily prevent addiction, overdose, and death. Notably, currently marketed technologies do not effectively deter one of the most common forms of opioid abuse -- swallowing the tablet or capsule. Because opioid medications must in the end be able to deliver the opioid to the patient, there may always be some potential for addiction and abuse of these products.

What does abuse-deterrent really mean?

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. 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. The FDA is working with many drug makers to support advancements in this area and helping drug makers navigate the regulatory path to market as quickly as possible. In working with industry, the FDA is taking a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products.

Opioids with FDA-Approved Labeling Describing Abuse-Deterrent Properties

FDA has approved these opioids with labeling describing abuse-deterrent properties consistent with the FDA's Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling:

- OxyContin
- Hysingla ER
- Xtampza ER
- RoxyBond

Generic Opioids with FDA-Approved Labeling Describing Abuse-Deterrent Properties

FDA has approved the following generic opioid(s) with abuse-deterrent properties consistent with the FDA's Guidance for Industry: General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products:

- Hydrocodone bitartrate (reference listed drug: Hysingla ER)

How does the FDA decide what drugs are considered abuse-deterrent?

To meet the FDA's standards, it is essential that every opioid with labeling describing its abuse-deterrent properties be grounded in science and supported by evidence. Any claims regarding abuse-deterrent properties must be truthful and not misleading based on a product's labeling, and supported by sound science taking into consideration the totality of the data for the particular drug. Absent sufficient science, there can be no claim of abuse deterrence. Permitting insufficiently proven claims does not serve the public health.

The FDA has issued two guidances to help industry understand how the agency currently is evaluating these innovative products.

- "Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling" (final guidance) explains the FDA's current thinking about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties. It also makes recommendations about how those studies should be performed and evaluated, and discusses what labeling claims may be approved based on the results of those studies.
- "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products" (final guidance) includes recommendations about the studies that should be conducted to demonstrate that a generic opioid is no less abuse-deterrent than the brand name product, with respect to all potential routes of abuse.

How will abuse-deterrent opioids help with the opioid crisis?

Because abuse-deterrent products are expected to reduce abuse compared to non-abuse-deterrent products, the agency is very interested in exploring new methods for analyzing and evaluating abuse-deterrent features; evaluating the nomenclature use to describe abuse-deterrent features; facilitating development of science for generic versions of these drugs; and taking new steps to encourage the conversion of the market to effective ADFs as part of the FDA's Opioid Policy Work Plan. The FDA looks forward to a future in which part of the FDA's Opioid Policy Work Plan. The FDA looks forward to a future in which most or all opioid medications are available in formulations that are less susceptible to abuse than the formulations that are on the market today. To achieve this goal, FDA is taking steps to incentivize and support the development of opioid medications with progressively better abuse-deterrent properties. These steps include working with individual sponsors on promising abuse-deterrent technologies; developing appropriate testing methodologies for both innovator and generic products; and publishing guidance on the development and labeling of abuse-deterrent opioids.

We continue to encourage the development of innovative abuse-deterrent technologies, and we are also prioritizing the need for data that will help determine the impact of products incorporating abuse-deterrent technology on misuse and abuse. To collect this important information, all the companies that have brand name opioids with abuse-deterrent labeling claims are being required to conduct post-market studies to determine the impact those products are having in the real world. Having that information is critical and will allow us to take the next important steps in this area.

In addition, FDA supports the development of assessment tools to evaluate packaging, storage, delivery, and disposal solutions, as well as product formulations, designed to prevent and deter misuse and abuse of opioids. To further this effort, the agency held a public workshop on December 11-12, 2017, regarding the role of packaging, storage, and disposal options within the larger landscape of activities aimed at addressing abuse, misuse, or inappropriate access of prescription opioid drug products. A Broad Agency Agreement was amended to add this additional area of research to those previously noted to be of interest to FDA to address our current knowledge gap in this area.