

Packaging, Storage, and Disposal Options to Enhance Opioid Safety: Regulatory Considerations

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Overview

- Potentially Applicable Regulatory Pathways and Authorities
- Potential Applicability of FDA's Approach to Regulation of Abuse-Deterrent Opioids



NDA - Benefits Must Outweigh Risks

- FDA will only approve a new drug application (NDA) if the proposed drug product's benefits outweigh its risks
- FDA considers opioid abuse and misuse potential along with all other appropriate factors in making approval decisions
- When part of a drug development program, the packaging, storage, and disposal options that are the focus of this workshop will be evaluated for their impact on both safety and efficacy



NDA – Labeling

- Prescription drug labeling must include a summary of the essential information needed for the safe and effective use of the drug
- Such labeling must be informative and accurate, and may not be false, promotional, or misleading
- FDA may consider information or claims regarding a storage, packaging, and or disposal option of the type discussed in this workshop appropriate for inclusion in FDA-approved physician and patient labeling, depending on the data supporting the item's intended effect



NDA - REMS

- A Risk Evaluation and Mitigation Strategy (REMS) will be required when necessary to ensure a drug product's benefits outweigh its risks
- Potentially, storage, packaging, or disposal options of the type discussed in this workshop could be regulated through our REMS authorities. For example,
 - Info about the option could be required in a REMS-mandated Medication Guide
 - Info about the option could be required in a REMS-mandated communication plan to health care providers



Drug Container Closure Systems

- Many of the storage and packaging options discussed in this workshop are components of the opioid drug product's "container closure system"
 - A container closure system is the sum of packaging components that together contain and protect the dosage form
- CDER approves container closure systems used in the packaging of drugs as part of the new drug application (NDA) or abbreviated new drug application (ANDA) for the drug
- Part of FDA's assessment of container closure systems is whether the container closure system functions in the manner for which it was designed



Device Considerations

- A device is defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is...
 - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes
- Depending on their intended use, certain storage, packaging, or disposal options of the type discussed in this workshop could potentially be considered devices, or, if included as a part of a drug development program, device constituent parts of a drug-led combination product



Abuse-Deterrent Opioids

- Aspects of FDA's regulatory approach towards abuse-deterrent opioid formulations may be potentially applicable to the safety-enhancing options that are the subject of this workshop.
- For example, FDA is considering what data (pre-market and post-market) would support appropriate labeling claims describing safety benefits of packaging, storage, and disposal options (see *Abuse-Deterrent Opioids: Evaluation and Labeling* (April 2015)).

