Opioid Analgesic Risk Evaluation and Mitigation Strategy (Document)

Originating Entity
Food and Drug Administration (FDA)

Last Action
Update to REMS

Date of Last Action
Sep 18 2018

Date Introduced
Jul 9 2012

Publication Date
Dec 26 2018

Related News

Do opioid drug-abuse deterrents actually work? FDA wants to know. [7]

The Washington Post [8] – The Food and Drug Administration is ramping up scrutiny of anti-abuse features on opioid painkillers to try to determine if they actually do what they're intended to do.

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Opioid prescriptions dropped for the first time in the modern drug crisis [9]


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Number of Opioid Prescriptions Falls for Fifth Year in a Row [11]

The Hill [12] — Opioid prescriptions issued between 2013 and 2017 have decreased by twenty-two percent, which doctors are touting as progress.

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Related Engagements

July 30, 2019 - 5:00pm

FDA Comment Deadline: Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain [14]

The Food and Drug Administration (FDA) is soliciting public comment on a potential requirement that certain solid, oral dosage forms of immediate-release opioid analgesics commonly prescribed for treatment of acute pain be made available in fixed-quantity unit-of-use blister packaging for outpatient dispensing.

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