

Status of Abuse-Deterrent Opioid Analgesics

Medical innovations play an important role in improving patient and public health and safety. This table summarizes efforts to provide enhanced safety measures for controlled opioid pain medication through the use of abuse-deterrent formulations (ADFs). An ADF medication possesses chemical or physical properties that render abuse or misuse of a medication more difficult. For example, ADF properties may prevent medication from being crushed and inhaled, or melted and injected, or they may prevent activation of the medication if ingested in a manner other than medically intended. ADF opioid may also be referred to as opioids with abuse-deterrent properties (OADPs).

Help CUSP keep this information current. Email us at info@c4usp.org with developmental updates.

Abuse-Deterrent Labeling

Drug Product	Drug Substance(s)	Sponsor	Approval	Status
Xtampza ER	oxycodone	Collegium	04/26/2016	<u>On Market</u>
MorphaBond (ER)	morphine	Daiichii Sankyo	10/02/2015	<u>On Market</u>
Hysingla ER	hydrocodone	Purdue Pharma	11/20/2014	<u>On Market</u>
Embeda (ER)	morphine + naltrexone (sequestered)	Pfizer	10/17/2014	<u>Discontinued</u>
OxyContin (ER)	oxycodone	Purdue Pharma	04/05/2010	<u>On Market</u>
Arymo ER	morphine	Zyla	01/09/2017	<u>Discontinued</u>

Abuse-Deterrent Labeling cont.

Drug Product	Drug Substance(s)	Sponsor	Approval	Status
RoxyBond IR	oxycodone	Inspirion	04/20/2017	<u>On Market</u>
Vantrela ER	hydrocodone	Teva	01/17/2017	<u>Approved, Not Marketed</u>
Troxyca ER	oxycodone + naltrexone	Pfizer	08/19/2016	<u>Approved, Not Marketed</u>
Targiniq ER	oxycodone + naloxone	Purdue Pharma	07/23/2014	<u>Approved, Not Marketed</u>

Reformulated without Abuse-Deterrent Labeling

Drug Product	Drug Substance(s)	Sponsor	Approval	Status
Oxaydo (IR)	oxycodone	Zyla	01/26/2015	<u>On Market</u>
Xartemis XR	oxycodone + acetaminophen	Mallinckrodt	03/12/2014	<u>On Market</u>
Zohydro ER	hydrocodone	Zogenix	10/25/2013	<u>On Market</u>
Opana ER	oxymorphone	Endo	12/10/2011	<u>Removed</u>
Oxecta (IR)	oxycodone	Pfizer	06/17/2011	<u>On Market</u>
Nucynta ER	tapentadol	Janssen	08/26/2011	<u>On Market</u>
Exalgo (ER)	hydromorphone	Mallinckrodt	03/02/2010	<u>On Market</u>
Apadaz (IR)	benzohydrocodone/acetaminophen	KemPharm	02/23/2018	<u>On Market</u>

Under Review by FDA

CUSP is not aware of any ADFs that are currently under review by FDA.

Not Approved by FDA

Drug Product	Drug Substance(s)	Sponsor	Status
Remoxy (ER)	oxycodone	Pain Therapeutics	<u>Not Approved</u>
MNK-812 (IR)	oxycodone	Mallinckrodt	<u>Not Approved</u>
NKTR-181	oxicodegol	Nektar	<u>Withdrawn</u>

ER: Extended-release formulation
IR: Immediate-release formulation
XR: Extended-release formulation