Risk Evaluation and Mitigation Strategies | REMS

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS.

REMS are not designed to mitigate all the adverse events of a medication, these are communicated to health care providers in the medication's prescribing information. Rather, REMS focus on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event.

REMS in Action: An Example

Here is one example of a product that has a serious risk and a REMS. The set of REMS requirements were designed to make sure all patients receive special monitoring during the period when a side effect is most likely to occur so it can be detected and treated:

Zyprexa Relprevv REMS (https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=74)

Zyprexa Relprevv is a long-acting injectable anti-psychotic medication used to treat schizophrenia in adults. Zyprexa Relprevv can cause serious reactions following injection called post-injection delirium sedation syndrome. Symptoms, including feeling sleepier than usual (sedation), coma, and feeling confused or disoriented (delirium) occurred in clinical studies within 3 hours after treatment with Zyprexa Relprevv. The risk of post-injection delirium sedation syndrome is present with every injection, although it is a small risk - less than 1 percent.

To reduce the risk of post-injection delirium sedation syndrome, FDA required the manufacturer of Zyprexa Relprevv to develop a REMS. The purpose of the REMS is to ensure that the drug is administered only in certified health care facilities that can observe patients for at least three hours and provide the medical care necessary in case of an adverse event.

Currently Approved REMS

- REMS@FDA (https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm)

FDA at a GLANCE

From the OFFICE OF THE COMMISSIONER | January 2024

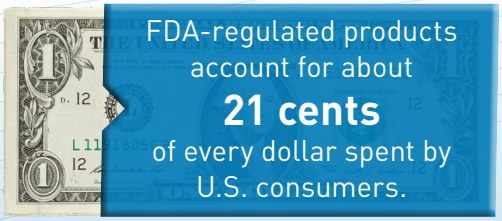
U.S. FOOD & DRUG ADMINISTRATION

FDA REGULATED PRODUCTS AND FACILITIES

FDA oversees the safety of more than

$3.6 trillion

worth of food, tobacco, and medical products produced in the U.S. and abroad.



FDA-regulated products account for about **21 cents** of every dollar spent by U.S. consumers.

There are over 20,000 prescription drug products approved for marketing.

About 82% of active pharmaceutical ingredient manufacturers are located outside of the U.S.

FDA oversees over 6,500 different medical device products.

About 47% of medical devices used in the U.S. are imports.

There are about 1,600 FDA-approved animal products.

About 8% of animal product sales are imports.

There are about 896 FDA-licensed biologics products.

About 80% of biologics sales are imports.

FDA regulates about 78% of the U.S. food supply; except meat, poultry, and some egg products.

About 60% of fresh fruit, 39% of vegetables, and 92% of seafood consumption by volume are imports.

FDA regulations cover about:

- **35,000 produce farms**
- **300,000 restaurant food establishments**
- **10,500 vending machine operators**

FDA oversees over 100,000 tobacco products, not including ENDS.

About 4% of tobacco product sales are imports.

FDA-regulated products are manufactured or handled at nearly 280,000 registered facilities, more than half of which are outside of the U.S.

FDA-Registered Facilities

Program	Domestic	Foreign	Total
Animal Drugs	985	720	1,705
Animal Food	17,969	8,204	26,173
Biologics	5,226	649	5,875
Human Drugs	4,577	3,843	8,420
Human Food	84,886	122,678	207,564
Medical Devices	13,010	12,891	25,901
Tobacco	1,559	0	1,559
Total	**128,212**	**148,985**	**277,197**

FDA-regulated products account for 14% of U.S. imports and 17% of exports.

U.S. Imports and Exports by FDA Program

Program	Imports *(Billions)*	Exports *(Billions)*
Animal Food	$4.50	$7.24
Biologics	$46.91	$34.85
Human & Animal Drugs	$107.90	$34.26
Human Food & Cosmetics	$217.10	$151.20
Medical Devices	$83.04	$49.27
Tobacco	$1.82	$0.23
FDA Total	**$461.27**	**$277.05**
USA Total	**$3,254.27**	**$1,747.05**

Approved Risk Evaluation and Mitigation Strategies (REMS)

REMS@FDA (index.cfm)

Contact Us (https://www.accessdata.fda.gov/scripts/email/cder/comment-rems.cfm) | REMS Resources (https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems) | (https://public.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_342) Get REMS Email Alerts (https://public.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_342) | Reports & Data Files (/scripts/cder/rems/index.cfm?event=RemsData.page) | REMS Public Dashboard (https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/6840df68-c772-45f1-bc4f-39d8b04cbfc1/state/analysis)

Persons with disabilities having problems accessing the PDF file(s) below may call (301) 796-3634 for assistance.

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

The table below provides links to currently approved individual and shared system REMS.

Information on historical and released REMS is available in downloadable: **data files (https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsData.page)**.

Filter by Keyword (e.g. REMS name, active ingredient, eleme

Excel CSV Print

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Abecma (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=406) (*Idecabtagene vicleucel*), suspension, for intravenous infusion BLA #125736	03/26/2021	04/04/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=406#tabs-2)**	IS
Adasuve (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=2) (*loxapine*), aerosol, powder NDA #022549	12/21/2012	01/27/2022			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=2#tabs-2)**	IS
Addyi (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=350) (*flibanserin*), tablet NDA #022526	08/18/2015	10/09/2019	MG			
Alvimopan Shared System REMS (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=397) Shared System REMS	12/19/2019	06/12/2023			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=397#tabs-3)**	IS
Ambrisentan Shared System (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=396) Shared System REMS	03/28/2019	08/19/2024			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=396#tabs-3)**	IS
Aveed (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=313) (*testosterone undecanoate*), injection NDA #022219	03/05/2014	05/26/2022			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=313#tabs-2)**	IS
BKEMV (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=431) (*eculizumab-aeeb*), injection BLA #761333	05/28/2024	05/28/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=431#tabs-2)**	IS
Bosentan (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=395) Shared System REMS	04/26/2019	09/17/2024			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=395#tabs-3)**	IS

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Breyanzi (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=405) (*lisocabtagene maraleucel*), suspension, for intravenous infusion BLA #125714	02/05/2021	05/30/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=405#tabs-2)**	IS
Brixadi (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=418) (*buprenorphine*), injection NDA #210136	05/23/2023	05/23/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=418#tabs-2)**	IS
Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=9) Shared System REMS		03/20/2024	MG		**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=9#tabs-3)**	IS
Camzyos (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=413) (*mavacamten*), capsule NDA #214998	04/28/2022	12/19/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=413#tabs-2)**	IS
Caprelsa (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=11) (*vandetanib*), tablet NDA #022405	04/06/2011	01/05/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=11#tabs-2)**	IS
Carvykti (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=412) (*ciltacabtagene autoleucel*), suspension, for intravenous infusion BLA #125746	02/28/2022	04/05/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=412#tabs-2)**	IS
Clozapine (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=351) Shared System REMS		09/29/2023			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=351#tabs-3)**	IS
Copiktra (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=382) (*duvelisib*), capsule NDA #211155	09/24/2018	02/02/2022		**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=382#tabs-2)**		
Dsuvia (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=384) (*sufentanil*), tablet, sublingual NDA #209128	11/02/2018	12/19/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=384#tabs-2)**	IS
Elrexfio (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=421) (*elranatamab-bcmm*), injection BLA #761345	08/14/2023	09/10/2024		**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=421#tabs-2)**	**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=421#tabs-2)**	IS
Empaveli (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=409) (*Pegcetacoplan*), injection NDA #215014	05/14/2021	05/14/2021			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=409#tabs-2)**	IS
Epysqli (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=434) (*eculizumab-aagh*), injection BLA #761340	07/19/2024	07/19/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=434#tabs-2)**	IS
Fabhalta (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=425) (*iptacopan*), capsule NDA #218276	12/05/2023	08/07/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=425#tabs-2)**	IS
Filspari (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=416) (*sparsentan*), tablet NDA #216403	02/17/2023	09/24/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=416#tabs-2)**	IS
Fintepla (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=400) (*fenfluramine hydrochloride*), solution NDA #212102	06/25/2020	05/24/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=400#tabs-2)**	IS

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Gattex (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=21) (*teduglutide [rDNA origin]*), injection, powder, for solution NDA #203441	12/21/2012	10/21/2022			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=21#tabs-2)**	
Hepzato (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=422) (*melphalan*), injection NDA #201848	08/14/2023	10/01/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=422#tabs-2)**	IS
Isotretinoin iPLEDGE (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=24) Shared System REMS	10/22/2010	10/03/2023			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=24#tabs-3)**	IS
Jubbonti (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=426) (*denosumab-bbdz*), injection BLA #761362	03/05/2024	08/14/2024		**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=426#tabs-2)**		
Juxtapid (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=25) (*lomitapide*), capsule NDA #203858	12/21/2012	04/26/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=25#tabs-2)**	IS
Jynarque (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=380) (*tolvaptan*), tablet NDA #204441	04/23/2018	09/29/2023		**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=380#tabs-2)**	**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=380#tabs-2)**	IS
Kymriah (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=368) (*tisagenlecleucel*), suspension, for intravenous infusion BLA #125646	08/30/2017	08/16/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=368#tabs-2)**	IS
Lemtrada (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=340) (*alemtuzumab*), injection, solution, concentrate BLA #103948	11/14/2014	03/04/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=340#tabs-2)**	IS
Lenalidomide (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=410) Shared System REMS	05/21/2021	03/24/2023			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=410#tabs-3)**	IS
Lumryz (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=401) (*sodium oxybate extended-release*), solution NDA #214755	05/01/2023	09/26/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=401#tabs-2)**	IS
Macitentan-Containing Products (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=407) Shared System REMS	04/06/2021	05/17/2024			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=407#tabs-3)**	IS
Mifepristone (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390) Shared System REMS	04/11/2019	03/23/2023			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390#tabs-3)**	IS
Myalept (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=314) (*metreleptin*), injection, powder, lyophilized, for solution BLA #125390	02/24/2014	03/06/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=314#tabs-2)**	IS
Mycophenolate (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=37) Shared System REMS	09/25/2012	08/13/2024			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=37#tabs-3)**	

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Natpara (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=343) (*parathyroid hormone*), injection, powder, lyophilized, for solution BLA #125511	01/23/2015	09/14/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=343#tabs-2)**	IS
Opioid Analgesic REMS (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17) Shared System REMS	07/09/2012	04/09/2021	MG		**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17#tabs-3)**	
Palforzia (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=398) (*Peanut (Arachis hypogaea) Allergen Powder-dnfp*), powder BLA #125696	01/31/2020	07/26/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=398#tabs-2)**	IS
Palynziq (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=381) (*pegvaliase-pqpz*), injection, solution BLA #761079	05/24/2018	12/09/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=381#tabs-2)**	IS
Phentermine and Topiramate Extended-Release Capsules (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=433) Shared System REMS	06/25/2024	06/25/2024	MG		**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=433#tabs-3)**	IS
Piasky (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=432) (*Crovalimab-akkz*), injection BLA #761388	06/20/2024	06/20/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=432#tabs-2)**	IS
Pomalidomide (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=404) Shared System REMS	10/30/2020	10/30/2020			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=404#tabs-3)**	IS
Pomalyst (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=41) (*pomalidomide*), capsule NDA #204026	02/08/2013	03/24/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=41#tabs-2)**	IS
Probuphine (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=356) (*buprenorphine hydrochloride*), implant NDA #204442	05/26/2016	11/01/2018	MG		**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=356#tabs-2)**	IS
Prolia (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=43) (*denosumab*), injection BLA #125320	06/01/2010	04/09/2024		**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=43#tabs-2)**		
PS-Mycophenolate (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=419) Shared System REMS	06/01/2023	06/01/2023			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=419#tabs-3)**	
Qsymia (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=45) (*phentermine and topiramate*), capsule, extended release NDA #022580	07/17/2012	02/06/2024	MG		**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=45#tabs-2)**	IS
Riociguat Shared System REMS (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=414) Shared System REMS	10/08/2013	09/01/2022			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=414#tabs-3)**	IS
Siliq (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=362) (*brodalumab*), injection BLA #761032	02/15/2017	07/19/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=362#tabs-2)**	IS
Sodium Oxybate (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=361) Shared System REMS	01/17/2017	01/17/2024			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=361#tabs-3)**	IS

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Spravato (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=386) (*esketamine*), spray NDA #211243	03/05/2019	01/03/2022			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=386#tabs-2)**	IS
Sublocade (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=376) (*buprenorphine extended-release*), injection NDA #209819	11/30/2017	04/19/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=376#tabs-2)**	IS
Tecvayli and Talvey (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=415) (*talquetamab-tgvs*), injection; injection, solution BLA #761291 BLA #761342 BLA #761291 BLA #761342	10/25/2022	07/02/2024		**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=415#tabs-2)**	**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=415#tabs-2)**	IS
Tegsedi (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=383) (*Inotersen*), injection NDA #211172	10/05/2018	08/24/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=383#tabs-2)**	IS
Thalidomide (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=417) Shared System REMS	04/27/2023	04/27/2023			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=417#tabs-3)**	IS
Thalomid (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=58) (*thalidomide*), capsule NDA #020785	08/03/2010	03/24/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=58#tabs-2)**	IS
Transmucosal Immediate-Release Fentanyl (TIRF) Products (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=60) Shared System REMS	12/28/2011	08/28/2024	MG		**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=60#tabs-3)**	IS
Tryvio (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=427) (*aprocitentan*), tablet NDA #217686	03/19/2024	08/23/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=427#tabs-2)**	IS
Turalio (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=389) (*pexidartinib*), capsule NDA #211810	08/02/2019	04/17/2023		**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=389#tabs-2)**	**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=389#tabs-2)**	IS
Tyruko (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=423) (*natalizumab-sztn*), injection BLA #761322	08/24/2023	08/24/2023	MG		**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=423#tabs-2)**	IS
Tysabri (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=63) (*natalizumab*), injection BLA #125104	10/07/2011	09/01/2023	MG		**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=63#tabs-2)**	IS
Ultomiris and Soliris (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=429) (*eculizumab*), injection; injection, solution, concentrate BLA #125166 BLA #761108 BLA #125166 BLA #761108	06/04/2010	09/03/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=429#tabs-2)**	IS
Vanflyta (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=420) (*quizartinib*), tablet NDA #216993	07/20/2023	07/20/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=420#tabs-2)**	IS

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Vigabatrin (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=364) Shared System REMS	04/27/2017	09/12/2024			**ETASU (/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=364#tabs-3)**	IS
Voydeya (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=430) (*danicopan*), tablet NDA #218037	03/29/2024	08/28/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=430#tabs-2)**	IS
Xiaflex (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=71) (*collagenase clostridium histolyticum*), kit BLA #125338	02/02/2010	11/02/2022			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=71#tabs-2)**	IS
Xywav and Xyrem (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=345) (*calcium, magnesium, potassium, and sodium oxybates*), solution NDA #021196 NDA #212690 NDA #021196 NDA #212690	02/27/2015	05/22/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=345#tabs-2)**	IS
Yescarta and Tecartus (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=375) (*axicabtagene ciloleucel*), suspension, for intravenous infusion BLA #125643 BLA #125703 BLA #125643 BLA #125703	10/18/2017	06/12/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=375#tabs-2)**	IS
Zilbrysq (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=424) (*zilucoplan*), injection NDA #216834	10/17/2023	01/16/2024			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=424#tabs-2)**	IS
Zulresso (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=387) (*brexanolone*), injection NDA #211371	03/19/2019	10/17/2023			**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=387#tabs-2)**	IS
Zyprexa Relprevv (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=74) (*olanzapine*), kit NDA #022173	12/11/2009	04/28/2021	MG	**CP (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=74#tabs-2)**	**ETASU (/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=74#tabs-2)**	IS

Showing 1 to 73 of 73 entries

*Many products within these REMS programs have Medication Guides not part of the REMS program. For a full list of Medication Guides **click here (http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm)**.

Risk Evaluation and Mitigation Strategy (REMS) Document

Opioid Analgesic REMS Program

The Opioid Analgesic REMS Program includes all opioid analgesics used in the outpatient setting and not covered by other REMS programs.

I. Administrative Information

Initial Shared System REMS Approval:07/2012
Most Recent REMS Update: 04/2021

II. REMS Goal

The Opioid Analgesic REMS is an educational effort and one of a number of national efforts that are designed to address the epidemic of prescription opioid abuse.

The goal of the Opioid Analgesic REMS is to educate prescribers and other healthcare providers (including pharmacists and nurses) on the treatment and monitoring of patients with pain. The education provided through the REMS program is based on the Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint"). Through better education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with nonpharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies which is intended to assist healthcare providers in reducing adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse. The REMS will accomplish this goal by:

1. Ensuring that training based on the FDA Blueprint is effective in educating prescribers and other healthcare providers involved in the treatment and monitoring of patients in pain (including pharmacists and nurses) about recommended pain management practices and appropriate use of opioid analgesics.

2. Informing patients about their roles and responsibilities regarding their pain treatment plan, including the risks of opioid analgesics and how to use and store them safely, as outlined in the Medication Guides and Patient Counseling Guide for opioid analgesics.

III. REMS Requirements

Opioid Analgesic Applicants must make training available to healthcare providers who prescribe and healthcare providers involved in the treatment and monitoring of patients who receive opioid analgesics.

The training must include all the elements of the FDA Blueprint. The training must be made available to healthcare providers who prescribe or are involved in the treatment and monitoring (including pharmacists and nurses) of patients who receive opioid analgesics.

Training is compliant with the REMS if it: 1) for training provided by Continuing Education (CE) Providers, is offered by an accredited CE Provider and supported by unrestricted educational grants from the opioid analgesic applicants; 2) includes all elements of the FDA Blueprint; 3) includes a knowledge assessment of

all sections of the FDA Blueprint; and 4) is subject to independent audit to confirm that conditions of the REMS training have been met.

To inform healthcare providers about the REMS Program and the risks and safe use of opioid analgesics, Opioid Analgesic Applicants must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials-& Dissemination Plans
All DEA-registered prescribers, pharmacies, hospitals, and teaching institutions registered to prescribe or dispense Schedule II, III, and IV drugs	REMS Letter: Healthcare Provider Letter 1 or Professional Society/Licensing Board Letter 1 with attachment Patient Counseling Guide 1. Email within 60 calendar days of the approval (09/18/2018) of the REMS. a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened. 2. Disseminate through the following professional societies and request the letter or content be provided to their members: a. The professional societies identified in Appendix A. 3. Disseminate through all dental, medical (allopathic and osteopathic), nursing, and pharmacy licensing boards and request the letter or content be provided to their licensed practitioners. REMS Letter: Healthcare Provider Letter 2 or Professional Society/Licensing Board Letter 2 with attachment Patient Counseling Guide 4. Email within 30 calendar days of 03/31/2019. a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened. 5. Disseminate through the following professional societies and request the letter or content be provided to their members. a. The professional societies identified in Appendix A. 6. Disseminate through all dental, medical (allopathic and osteopathic), nursing, and pharmacy licensing boards and request the letter or content be provided to their licensed practitioners.

Target Audience	Communication Materials-& Dissemination Plans
All newly DEA-registered prescribers, pharmacies, hospitals, and teaching institutions registered to prescribe or dispense Schedule II, III, and IV drugs since the last dissemination	REMS Letter: Healthcare Provider Letter 2 with attachment Patient Counseling Guide 1. Email annually from the date of the approval (09/18/2018) of the REMS. a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.

To support REMS Program operations, Opioid Analgesic Applicants must:

1. Establish and maintain a REMS Program website, www.opioidanalgesicrems.com. The REMS Program website must include a current list of training funded by the Opioid Analgesic Applicants that is REMS-compliant and the option to print the PI, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product websites.

2. Direct CE Providers to the FDA Blueprint on www.fda.gov/OpioidAnalgesicREMSBlueprint.

3. Make the REMS Program website fully operational and all REMS materials available through the website and call center within 60 calendar days of REMS approval (09/18/2018).

4. Establish and maintain a REMS Program call center for healthcare providers at 1-800-503-0784.

5. Ensure healthcare providers who prescribe or are involved in the treatment and monitoring of patients who receive opioid analgesics are able to access training by 3/31/2019

6. Notify accredited CE Providers of REMS-compliant training regarding changes to the FDA Blueprint within 10 calendar days of such changes.

7. Use independent auditors (accreditation bodies of CE Providers are considered independent and eligible to conduct the audits) to audit the educational materials used by the accredited CE Providers of REMS-compliant training of a random sample of at least 10% of the training funded by the Opioid Analgesic Applicants to evaluate (1) whether the content of the training covers all the components of the FDA Blueprint, (2) whether the knowledge assessment measures knowledge of all sections of the FDA Blueprint, (3) whether the training was conducted in accordance with the standards for CE of the Accreditation Council for Continuing Medication Education or of another CE accrediting body appropriate to the prescribers, dental, pharmacy, nursing, or healthcare profession.

IV. REMS Assessment Timetable

Opioid Analgesic NDA Applicants must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the approval of the REMS (09/18/2018). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date

for that assessment. Opioid Analgesic NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Opioid Analgesic REMS**:**

Training and Educational Materials

Healthcare Provider:

1. Healthcare Provider training available at www.opioidanalgesicrems.com

Patient:

2. Medication Guide (available at www.opioidanalgesicrems.com)
3. Patient Counseling Guide

Communication Materials

4. Healthcare Provider Letter 1
5. Healthcare Provider Letter 2
6. Professional Society/Licensing Board Letter 1
7. Professional Society/Licensing Board Letter 2

Other Materials

8. Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (FDA Blueprint)
9. Opioid Analgesic REMS Program website (www.opioidanalgesicrems.com)

Appendix A: List of Professional Societies

1. American Academy of Addiction Psychiatry
2. Council of Medical Specialty Societies
3. Academy of Integrative Pain Management
4. Academy of Managed Care Pharmacists
5. American Academy of Family Physicians
6. American Academy of Hospice and Palliative Medicine
7. American Academy of Neurology
8. American Academy of Nurse Practitioners
9. American Academy of Nursing
10. American Academy of Orofacial Pain
11. American Academy of Pain Medicine
12. American Academy of Physical Medicine and Rehabilitation
13. American Academy of Physician Assistants
14. American Association of Colleges of Nursing
15. American Association of Colleges of Osteopathic Medicine
16. American Association of Poison Control Centers
17. American Board of Medical Specialties
18. American Board of Orofacial Pain
19. American College of Clinical Pharmacy
20. American College of Nurse Midwives
21. American College of Nurse Practitioners
22. American College of Osteopathic Family Physicians
23. American College of Physicians
24. American College of Rheumatology
25. American Dental Association
26. American Dental Education Association
27. American Medical Association
28. American Medical Directors Association
29. American Nurses Association
30. American Nurses Credentialing Center
31. American Osteopathic Association

32. American Osteopathic Association of Addiction Medicine
33. American Pain Society
34. American Pediatric Association
35. American Pharmacists Association
36. American Psychiatric Nursing Association
37. American Society for Pain Management Nursing
38. American Society of Addiction Medicine
39. American Society of Anesthesiologists
40. American Society of Consultant Pharmacists
41. American Society of Pain Educators
42. Association of American Medical Colleges
43. Doctors of Nursing Practice
44. Gerontological Nursing Association
45. Hospice and Palliative Nurses Association
46. National Association of Managed Care Professionals
47. National Association of Pediatric Nurse Practitioners
48. National Conference of Nurse Practitioners
49. National League of Nursing
50. National Organization of Nurse Practitioner Faculties
51. Nurse Practitioners in Women's Health
52. Oncology Nursing Society
53. Society of Emergency Medicine Physician Assistants

Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of Roe v. Wade

Xavier Becerra
June 28, 2022
Hubert H. Humphrey Building
Washington, D.C.

As Prepared for Delivery

On Friday, June 24th, five Americans decided to use the vast power bestowed upon them by our democracy and our Constitution to unconscionably put at risk the life and health of millions of their fellow Americans. They chose to unconscionably limit Americans' established freedom and autonomy to control their own body — decisions usually made in consultation with their doctor, not a politician. And they chose to unconscionably strip away the fundamental health care protections that every American of child-bearing age has known all their lives.

Friday's Supreme Court decision was despicable, but it was also predictable. HHS has been preparing for this for some time. That's why, earlier this year, we launched our HHS Reproductive Access Task Force to plan for every action necessary to protect women's access to reproductive health care.

There is no magic bullet. But if there is something we can do, we will find it and we will do it at HHS. Indeed, that was the instruction I received from the President of the United States.

Last Friday, President Biden announced the actions he is taking to ensure medication abortion is available to the fullest extent possible and that women can travel safely from states where abortion is banned to states where abortion is legal. Here is how HHS will support these issues:

- First, HHS will take steps to increase access to medication abortion.
  - Federal law requires our programs to provide medication abortion in limited circumstances, including life of the woman, rape, or incest.
  - Now more than ever it is imperative that all federally-supported programs and services are complying and providing this under the law.
- Second, I am directing the Office for Civil Rights within HHS to ensure patient privacy and nondiscrimination for patients seeking reproductive health care, as well as for providers who offer reproductive health care.
- Third, I am directing the Department to examine its authority under the Emergency Medical Treatment Act (EMTALA) to ensure that clinical judgment of doctors and hospitals is supported in treating pregnant patients, including those experiencing pregnancy loss or complications, and reaffirming that abortion care can be appropriate to stabilize patients.

- Fourth, I am directing all agencies in my Department to work to ensure that all providers – from doctors to pharmacists -- and clinics have appropriate training and resources to handle family planning needs, including administering patient referrals for care, and helping patients navigate this new reality.
- Fifth, I am directing the Centers for Medicare and Medicaid Services (CMS) to take every legally available step to protect family planning care, including emergency contraceptives and long acting reversable contraceptives, such as IUDs. Health care is a matter to be decided by patients and their providers, not politicians. As part of these efforts, we will make clear that family planning providers are able to participate in the Medicaid program. These clinics provide safe care and have a vast expertise in providing reproductive health care.

Let me now tell you a little more about why I think medication abortion is so critical.

- Medication abortion has been approved by the FDA for years and is safe for patients.
- It is the gold standard for care when someone who's pregnant experiences a miscarriage, which is all too real for many expectant mothers across the country.
- The Supreme Court's decision will result in worsened health outcomes and death for some patients. Working to increase access to this drug is a national imperative and in the public interest.
- We will continue to support the FDA and its rigorous scientific review for these safe and effective drugs.
- We will also work with the Attorney General and the Justice Department as they work to ensure that states may not ban medication abortion, based on a disagreement with the FDA's expert judgment about the drug's safety and efficacy.
- And we will issue guidance to providers to ensure they receive accurate and robust information on medication abortion.

The HHS Reproductive Access Task Force will report to me on additional impactful ways to ensure appropriate information about, access to, and coverage for sexual and reproductive health care – as well as coordinate with other federal agencies.

I was at a Planned Parenthood clinic in St. Louis, Missouri, on Friday morning when the Supreme Court overturned Roe v. Wade. I saw in real time the impact of this unconscionable decision. The Clinic Director had to almost immediately start turning away patients as the state's ban went into effect. This clinic has stopped providing safe and legal abortion care. People in the room were visibly shaken, there were tears and an unshakeable sense of sadness.

After my visit to the clinic in St. Louis, I traveled across the state line to another clinic in Fairview Heights, Illinois – a state that, unlike Missouri, still had lawful abortion care. There, I visited a site that helps patients get care by providing assistance – ranging from helping patients find appointments to paying for their travel expenses – and abortion care. It was shocking that, in the United States of America, a short drive can make such a dire and draconian difference in health care outcomes. I saw restrictions that leave women and families on unequal footing and widen maternal health disparities.

The impact was visible and real.

This is a critical moment in history. How we respond will speak to how we view the rights, dignity and wellbeing of women everywhere. This is a moment of crisis in health care. We will leave no stone unturned. All options are on the table. We will do everything within the legal limit of the law to reach patients and support providers.

I know we are all tired and our hearts are broken by this loss of rights and dignity. But now is the time for us to continue on for the many people across the country who live in banned abortion states, who lack voices that represent them.

I stand with you and I have your back.

Content created by Assistant Secretary for Public Affairs (ASPA)
Content last reviewed June 28, 2022