



FOOD & DRUG ADMINISTRATION

User Manual for Risk Evaluation and
Mitigation Strategies (REMS) Public
Dashboard

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Summary

Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS focus on preventing, monitoring, and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to mitigate the frequency and/or severity of an adverse event. A REMS may require one or more strategies to mitigate risk of medication use such as Medication Guides (MGs), Elements to Assure Safe Use (ETASU), Communication Plan (CP), and/or Implementation System.

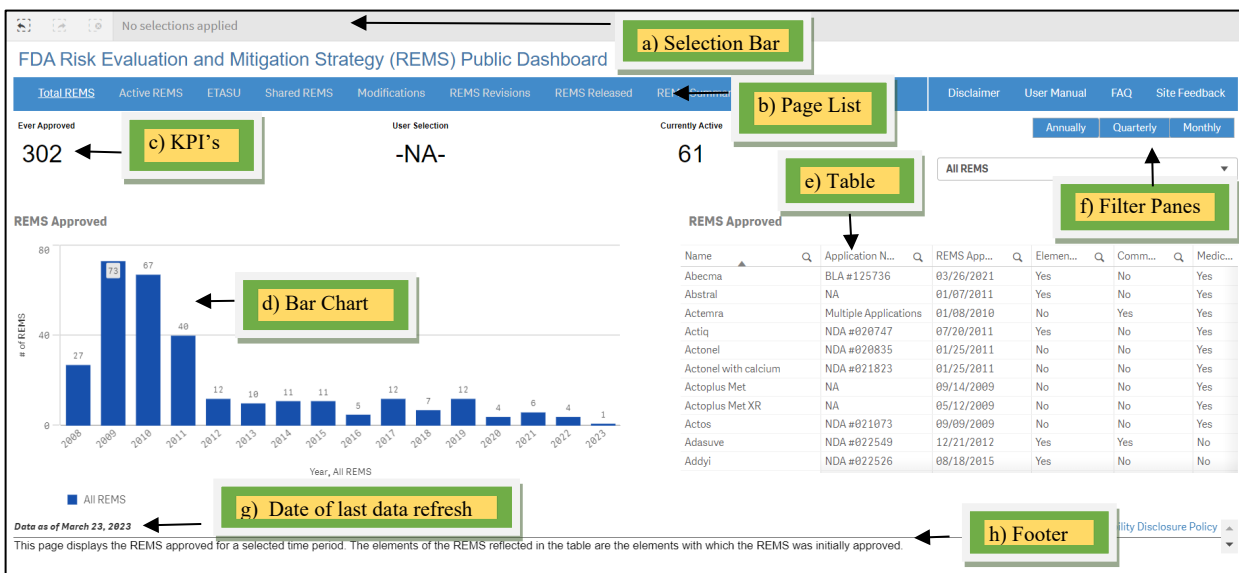
REMS Data are currently available through REMS@FDA for public access. To enhance communication of the FDA REMS Program to the public, FDA has developed a secure and user-friendly dashboard for REMS-related data retrieval and analysis as well as efficient report-generating capabilities. The REMS Dashboard is updated weekly.

The REMS Public Dashboard has the capability to generate eight pages including:

- Page 1 → Total REMS
- Page 2 → Active REMS
- Page 3 → ETASU
- Page 4 → Shared System REMS
- Page 5 → REMS Modifications
- Page 6 → REMS Revisions
- Page 7 → REMS Released
- Page 8 → REMS Summary

Section A: Overview of the REMS Public Dashboard

Microsoft Edge and Chrome are recommended to access the dashboard. When user accepts the disclaimer, the following screen (screenshot #1) should appear:

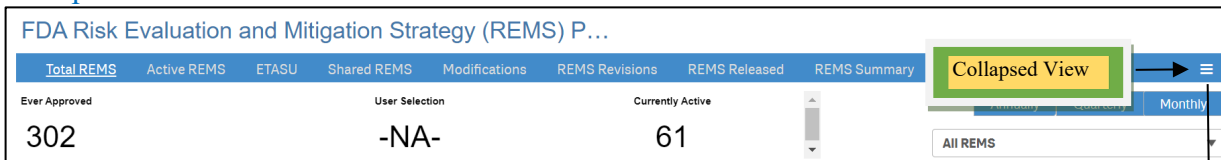


Screenshot 1: REMS Public Dashboard *

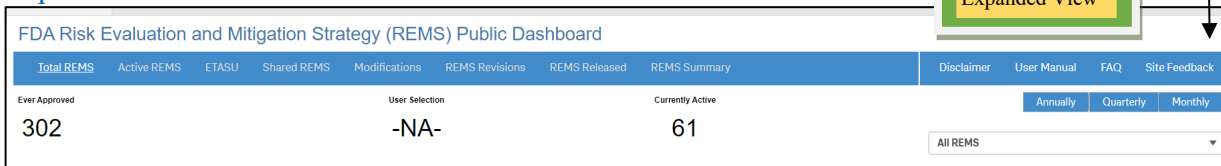
- a) **Selection Bar**- This section shows when user select any selection.
- b) **Page List**- The blue ribbon has the list of page titles which is designed to help users quickly find the page.
- c) **Key Performance Indicators (KPIs)** – KPIs are the measure values used as performance trackers. Dashboard uses KPIs to get an overview of performance values that are central to an organization.
- d) **Bar Chart** – The bar chart consists of multiple rectangles aligned to a common baseline. In the bar chart, the horizontal (X) axis shows the year, and the vertical (Y) axis shows the number of REMS.
- e) **Table** – The table summarizes descriptive information about REMS data (shown in the bar chart). It contains the drug name, application number, REMS approval date, latest version date, REMS Elements at time of approval (ETASU/MG/CP), Approved by REMS, etc. All columns have a search icon in the header. When users change the set of filtered columns, the table automatically updates the values displayed to reflect the current selection. Users may reorder the columns in the table as preferred while viewing the dashboard.
- f) **Filter Panes** –The filter pane to the right contains the elements list (in total, active, Mods and Mods Measure page). Each of these elements can be filtered annually, quarterly, or monthly.
- g) **Date** – The date when the dashboard was last updated.
- h) **Footer** – The footer provides information about the graph on the page. The footer changes depending on the selection from the drop-down menu.

* Note: Based on individual screen resolution, user screen may appear slightly different when viewing REMS Dashboard. See example screen shots below of expanded and collapsed versions of the blue-ribbon menu bar.

Collapsed View:



Expanded View:

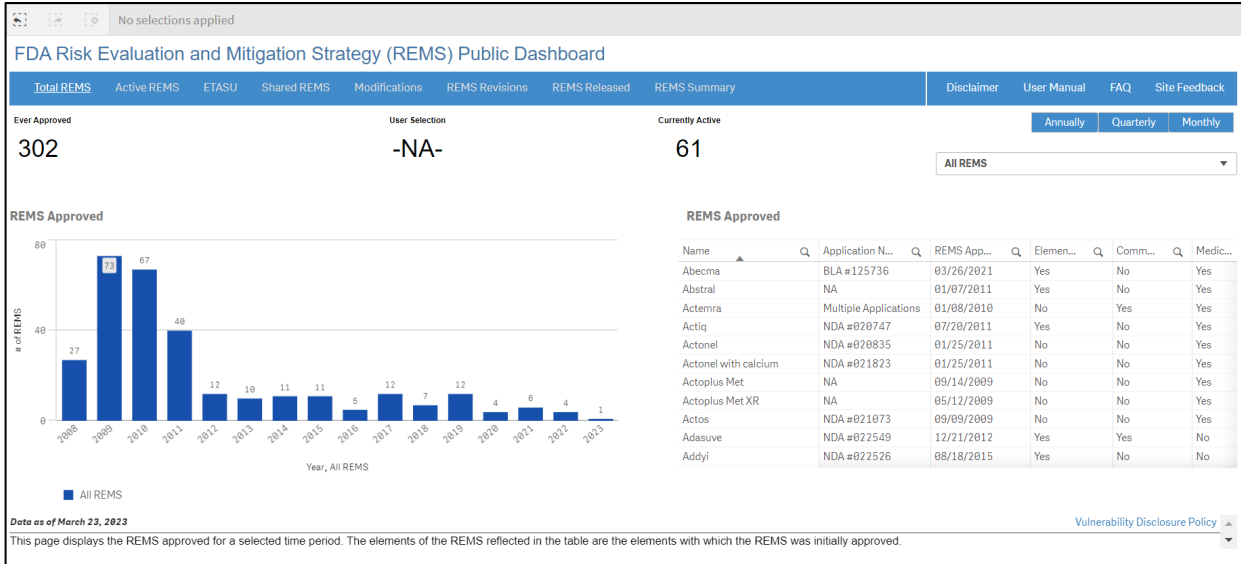


Screenshot 2: Collapsed and Expanded View of REMS dashboard

Section B: Summary of Page

1. Total REMS

Total REMS page contains approved REMS for a selected time.



Screenshot 3: Total Page

The Total REMS has the following KPIs:

- *Ever Approved* represents the total REMS programs that have been approved.
- *User selection* represents how many REMS programs have been approved with the selections. Selection options include choice of one or multiple years from the bar chart or option to select any entity from the table.
- *Currently Active* represents how many REMS are currently active and remains N/A when making any selection(s).

The filter pane on the right contains four dimensions - All REMS, by application type, elements, and elements detailed. The elements of the REMS reflected in the table are the elements with which the REMS was initially approved.

- *All REMS* displays the REMS approved for a selected time.
- *By Application Type* displays the number of applications approved with a REMS by year. The graph and table display the application type (BLA/NDA/ANDA) and the number of applications associated with the approved REMS at time of approval.
- *By Elements* displays the REMS approved for a selected time by high-level REMS elements (CP-Only, ETASU, MG-CP-Only, MG-Only).
- *By Elements-Detailed* displays the REMS approved for a selected time by REMS elements (CP-Only, ETASU-CP-Only, ETASU-MG-CP, ETASU-Only, MG-Only, ETASU-MG-Only, MG-CP-Only).
‘Elements-Detailed’ represents each mutually exclusive element in more detail.

Total REMS table contains the Drug Name, Application Number, REMS Approval Date, ETASU, Communication Plan (CP), Medication Guide (MG), REMS ID, and Approved REMS. The REMS elements reflected in this table are the REMS elements initially approved.

2. **Active REMS**

Active REMS page displays *currently approved REMS*. Active REMS include the following KPIs:

- *Ever Approved* represents the total REMS programs that have been approved.
- *User selection* represents how many REMS programs are currently active with the selections. Selection options include choice of one or multiple years from the bar chart or option to select any entity from the table.
- *Currently Active* represents how many REMS are currently active; and remains N/A when making any selections.

The filter pane on the right contains four dimensions - *All REMS, by application type, elements and elements detailed*. The graph and table display the number of REMS approved in each time period that are still active.

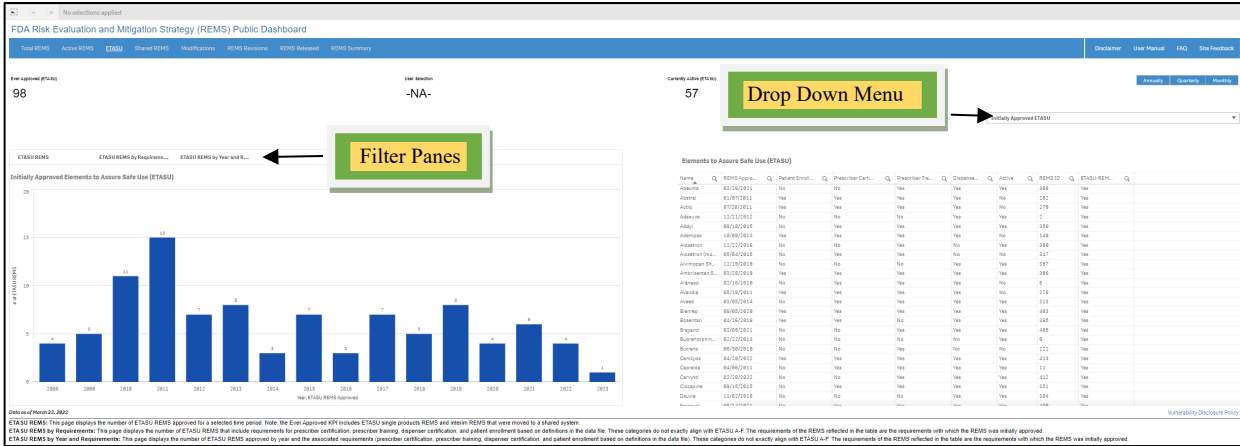
- *All REMS* displays currently approved REMS.
- *By Application Type* displays the REMS approved for a selected time period by application type (ANDA, BLA, NDA). The graph and table display the application type and number of products associated with the approved REMS as of today.
- *By Elements* - The graph and table display the number of REMS approved in a given time period that are still active as of the date last loaded by high-level REMS elements (ETASU, MG-CP-Only, MG-Only, CP-Only).
- *By Elements – Detailed* displays the REMS approved in each time that are still active today by detailed mutually exclusive REMS elements (CP-Only, ETASU-MG-CP, ETASU-Only, MG-Only, ETASU-CP-Only, ETASU-MG-Only, MG-CP-Only).

Active REMS table contains the Drug Name, Application Number, REMS Approval Date, Latest Version Date, ETASU, CP, MG, REMS Materials*, REMS ID, and Currently Approved (REMS). The REMS elements reflected in the table are the latest REMS elements and not the elements which were initially approved with the REMS.

*Note: Access to REMS Materials are available via link through “Active REMS” page only for REMS that are currently approved.

3. **Elements to Assure Safe Use (ETASU)**

ETASU REMS page displays all REMS ever approved with an ETASU. There is a drop-down menu which contains two dimensions: Initially Approved ETASU and Currently Approved ETASU. The filter pane above the bar graph displays three dimensions – ETASU REMS, ETASU REMS by Requirements, and ETASU REMS by Year and Requirements.



Screenshot 4: ETASU Page

i. ETASU by Initial Approval

- *ETASU REMS*: This page displays the number of ETASU REMS approved for a selected time. The ‘Ever Approved KPI’ includes ETASU single products REMS and interim REMS that were moved to a shared system.
- *ETASU REMS by Requirement*: This page displays the number of ETASU REMS with requirements for Prescriber Training, Prescriber Certification, Dispenser Certification, and Patient Enrollment. These categories do not contain all the elements of ETASU A-F. *Please refer to section E- List of Definition.*

ii. ETASU REMS by Year and Requirement: This page displays the number of ETASU REMS Approved by year and the associated requirements (Prescriber Training, Prescriber Certification, Dispenser Certification, and Patient Enrollment). ETASU by Current Approval

- *ETASU*: This page displays the number of active ETASU REMS by year of approval.
- *ETASU REMS by Requirement*: This page displays the number of active ETASU REMS that include requirements for Dispenser Certification, Prescriber Certification, Prescriber Training, and Patient Enrollment. The requirements of the REMS reflected in the table are the current requirements of the REMS.
- *ETASU REMS by Year and Requirement*: This page displays the number of active ETASU REMS approved by year and the associated requirements (prescriber certification, prescriber training, dispenser certification, and patient enrollment based on definitions in the data file).

4. Shared System REMS

A Shared System REMS encompasses multiple prescription drug products, which are developed and implemented jointly by two or more applicants. Shared System REMS page contains currently approved and ever approved Shared System REMS for a selected time. Shared System REMS table includes the drug name, REMS approval date, Active, REMS ID, and shared REMS.

5. **REMS Modifications**

REMS Modification page displays the REMS Modifications (major/minor) approved for a selected time. The drop-down menu located above the table allows the user to display # of *All Modifications*, # of *First Modifications*, # of *Shared System Modifications*, # of *Moved to Shared Systems Modifications*, and # of *Released*. REMS revisions are not included in this page.

6. **Revision**

The REMS revisions page contains the number of REMS revisions for a selected time. The revision table contains a list of REMS along with the ID, revision date, and the revision status.

7. **Released REMS**

Released REMS displays REMS which have been released for a selected time. The elements of the REMS reflected in the table are the elements at the time the REMS is released, not the elements with which the REMS was initially approved. The table contains a list of released REMS along with the latest version date, and the REMS elements at time of release. The filter pane contains two dimensions – *Released REMS* and *Released REMS by Elements (MG, CP, ETASU)*. When user selects Released REMS by Elements option, the graph and table display the elements of the REMS at time of release.

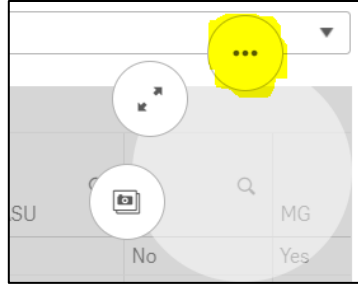
8. **REMS Summary**

This page displays the cumulative number of active REMS at the end of each year (red line) overlaid on the graph showing the number of REMS approved and deactivated by year. The red line represents the cumulative number of REMS. Cumulative Active REMS End of Year (EOY) is calculated by Number of Approved REMS to Date - Number of Deactivated REMS to Date. Deactivated REMS include all REMS that are no longer active or in effect. This includes released REMS (i.e., REMS that are no longer necessary), individual REMS moved to shared systems, and products with REMS that have been withdrawn from the market and published in the Federal Register.

Section C: Download the result from table and bar graph

1. Download Data from table in Excel spreadsheet:

- After selection in any page, right click anywhere on the table which is in the right side. It should show 3 options:
 - Export as an image/PDF/DATA
 - Enlarge table
 - Snapshot Library (currently unavailable)



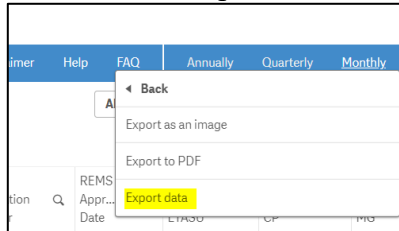
Screenshot 5: Right click from Table (step 1)

- Select ‘Export’ (highlighted) from the three dotted circles



Screenshot 6: Export data from Table (step 2)

- Click ‘Export Data’ option from the three options available



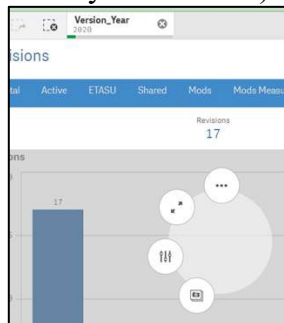
Screenshot 7: Export data from Table (step 3)

- Download the result in Excel spreadsheet

2. Download Data from Bar Graph in excel Spreadsheet

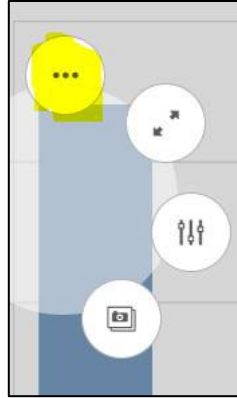
In Total, Active, Shared, MODS, Revision’s page:

- After selection, right click anywhere on Bar graph area. It should show 4 options
 - Export as an image/PDF/DATA
 - Enlarge table
 - Enlarge table in Full screen
 - Snapshot Library (currently unavailable)



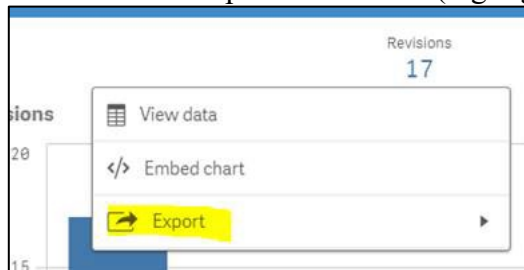
Screenshot 8: Export data from Bar Graph (step 1)

- Select ‘three dotted circles’ icon (highlighted in yellow)



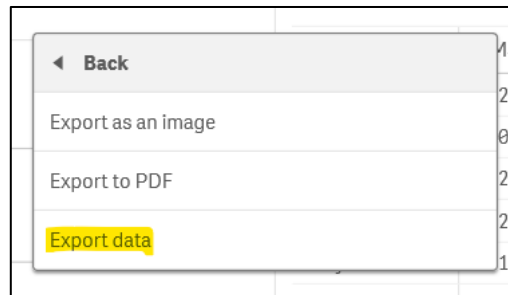
Screenshot 9: Export data from Bar Graph (step 2)

- Select 'Export' from the three format options available (highlighted in yellow)



Screenshot 10: Export data from Bar Graph (step 3)

- From the three options, select 'Export Data' and download the result in Excel spreadsheet.



Screenshot 11: Export data from Bar Graph (step 4)

In ETASU and Released page:

ETASU and Released page contains filter pane on top of the bar graph. User can select and download results from these pages in following steps:

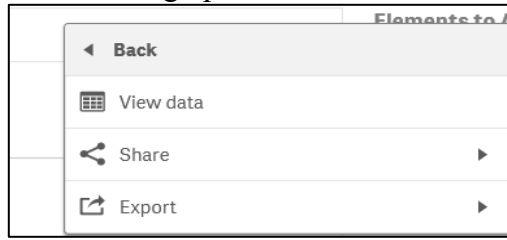
- After selection, right click anywhere on Bar graph area. It should show 2 options: container and bar chart



Screenshot 12: Export data from Bar Graph (step 1)

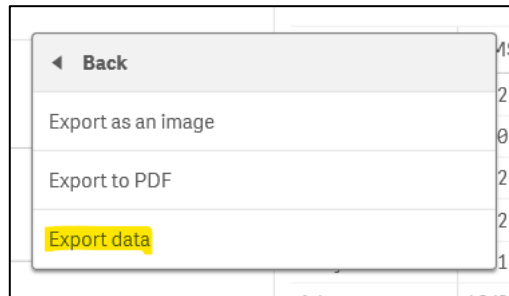
- The container will provide the link to embed in your webpage.

- The bar chart till provides following options:



Screenshot 13: Export data from Bar Graph (step 2)


- From the three options, select ‘Export Data’ and download the result in Excel spreadsheet.

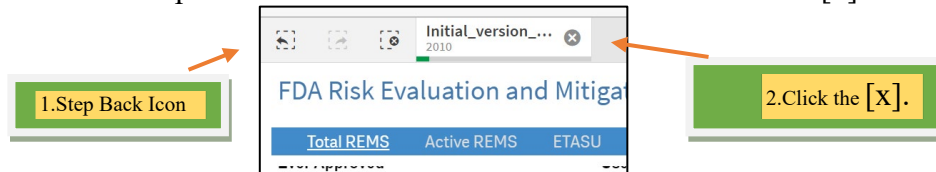


Screenshot 14: Export data from Bar Graph (step 3)

Section D: Remove Filter

REMS dashboard allows one or more filter in both bar graph and table. Before applying new filter(s), make sure to remove the previous selection. There are 2 ways to remove filter/selection:

- Click ‘Step Back’ Icon  located at the top gray selection area.
- Find the tab near the top of the sheet with the name of filter and click the [X].



Screenshot 15: Remove Filter

Section E: Acronym List

ANDA	Abbreviated New Drug Application
BLA	Biologics License Application
CP	Communication Plan
ETASU	Elements to Assure Safe Use
EOY	End of year
FDA	Food and Drug Administration
KPI	Key Performance Indicator
MG	Medication Guide

MODS	Modifications
NDA	New Drug Application
REMS	Risk Evaluation and Mitigation Strategy
REMSID	REMS Identification

Section F: List of Definition

	TERMS	DEFINITIONS
1	REMS	REMS is a risk management plan that uses risk minimization strategies beyond professional labeling. It is designed to achieve specific goals to mitigate risks associated with use of a drug and ensure that the benefits of the drug outweigh the risks
2	Total REMS	Total REMS are the approved REMS (active and inactive) for a selected time.
3	Active REMS	Active REMS are <i>currently approved REMS</i> .
4	Shared REMS	Shared REMS encompasses multiple prescription drug products and is developed and implemented jointly by two or more applicants.
5	REMS Modification	REMS modifications are defined as changes that have a limited effect on the information contained in the REMS document and/or REMS materials about the serious risk or safe use of the drug. Example: Addition of an approved new strength or dosage regimen of the drug.
6	REMS Revisions	REMS revisions are defined as editorial changes that do not affect the information contained in the REMS document and/or REMS materials about the serious risk or safe use of the drug. For example: Changes in the application holder name or address to reflect transfer of application ownership, Changes in the application holder name or address to reflect transfer of application ownership.
7	REMS Released	Release of REMS or components of REMS program after FDA determines that extra measures in a REMS are no longer necessary to ensure a medication's benefits outweigh its risks.
8	Deactivated REMS	Deactivated REMS include all REMS that are no longer active or in effect. This includes released REMS (i.e., REMS that are no longer necessary), individual REMS moved to shared systems, and products with REMS that have been withdrawn from the market and published in the Federal Register.
9	Application Type	The type of marketing approval the drug received. A drug may be marketed under a New Drug Application (NDA), Biologics License Application (BLA), or as a generic drug under an Abbreviated New Drug Application (ANDA).
10	User selections	USER selection represents how many REMS programs have been approved with the selections. Options include choice of one or multiple years from the bar chart or option to select any entity from the table.

11	ETASU	<p>ETASU are medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient. ETASU may have 1 or more elements to mitigate the known serious risks associated with the use of the drug. The following elements are different components of a REMS:</p> <ul style="list-style-type: none"> ❖ Element A: Healthcare Providers ❖ Element B: Pharmacies ❖ Element C: Certain Healthcare Settings ❖ Element D: Documentation of Safe Use Conditions ❖ Element E: Monitoring ❖ Element F: Registry <ul style="list-style-type: none"> • Element A- Health care providers who prescribe the drug have training or experience are specially certified. • Element B -Pharmacies, practitioners or Healthcare setting that dispense the drug are specially certified. • Element C- Drug dispensed to patients only in certain health care settings, such as hospitals. • Element D- Drug dispensed to patient with evidence or other documentation of safe-use conditions, such as laboratory test results (i.e., laboratory test or enrollment forms). • Element E - Each patient using the drug be subject to certain monitoring. • Element F – Each patient using the drug is enrolled in registry.
12	Communication Plan	<p>Communication Plan is FDA approved materials used to aid sponsor’s implementation of a REMS and/or inform healthcare providers about serious risks – Cannot be targeted directly to patient</p>
13	Medication Guide	<p>Patient-friendly handouts that are required for distribution at the time prescription medications (i.e., covered by REMS) are delivered to the patients.</p>