# REMS DOCUMENT
# TECHNICAL CONFORMANCE GUIDE

*Technical Specifications Document*

This document is incorporated by reference into the following Guidance Document:

***Format and Content of a REMS Document***

For questions regarding this technical specifications document, contact CDER at OSE.PMKTREGS@fda.hhs.gov or CBER at the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010, ocod@fda.hhs.gov.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**

**January 2023**

# REMS DOCUMENT
# TECHNICAL CONFORMANCE GUIDE

**January 2023**

## Revision History

| Date | Version | Summary of Revisions |
|---|---|---|
| January 2023 | 1.0 | Initial Version |
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# Table of Contents

*Contains Nonbinding Recommendations*

# REMS DOCUMENT
# TECHNICAL CONFORMANCE GUIDE[1]

This document represents the current thinking of the Food and Drug Administration (FDA or Agency). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for implementing this guidance at OSE.PMKTREGS@fda.hhs.gov or CBER at the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010, ocod@fda.hhs.gov.

## 1. INTRODUCTION

### 1.1. Background

This Risk Evaluation and Mitigation Strategy (REMS) Document Technical Conformance Guide (Guide) provides updated, detailed instructions on the format of a REMS Document, along with standardized language that describes common REMS requirements[2] for applicants to use whenever possible, to help ensure consistency and facilitate efficient review of the REMS Document. This Guide supports submission of a REMS Document in Structured Product Labeling (SPL) format. In addition, this Guide provides an outline to assist applicants in drafting a Bifurcated[3] REMS Document.

This Guide supplements the guidance for industry *Format and Content of a REMS Document* (Month YEAR).

A REMS Document establishes the goals and requirements of the REMS as they relate to the required REMS elements.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

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[1] This guidance has been prepared by the Division of Risk Management in the Center for Drug Evaluation and Research in cooperation with Center for Biologics Evaluation and Research at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2018-D-1216 (available at https://www.regulations.gov/docket?D=FDA-2018-D-1216) (see the instructions for submitting comments in the docket). *[Note: The docket number in this footnote is intended for general comments related to technical specifications. It is not for comments specific to documents or issues that are the subject of other dockets, or for comments specific to electronic submission guidances.]*

[2] Section 505-1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1)

[3] A Bifurcated REMS Document is used when the approval of a shared system REMS may coincide with tentative approval of an ANDA or section 505(b)(2) application. For more information, refer to the revised draft guidance for industry *Development of a Shared System REMS (June 2018).* When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

## 1.2. Purpose

This Guide provides technical recommendations to applicants for the purposes of drafting a REMS Document.

This Guide is intended to complement and promote interactions between applicants and the FDA. However, it is not intended to replace the need for applicants to communicate directly with review staff regarding implementation approaches or issues relating to their REMS. The use of these templates is expected to improve efficiency of the review process for REMS.

## 1.3. Document Revision Control

In the *Federal Register* of October 12, 2017 (82 FR 47529), FDA issued notice announcing the availability of the revised draft guidance for industry *Format and Content of a REMS Document*, which included a template for the REMS Document as an appendix for public comment on its contents. The REMS Document template is now part of this Guide. Future revisions will be posted directly on FDA's REMS website (https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems), and the revision history page of this document will contain information to indicate which sections of the Guide have been revised.

## 1.4. Relationship to Other Documents

This Guide should be considered a companion document to the following:

- Guidance for industry *Format and Content of a REMS Document* (*January 2023*)
- Guidance for industry *Development of a Shared System REMS (June 2018)*
- Guidance for industry *Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling Format* (December 2020)
- Guidance for industry *Risk Evaluation and Mitigation Strategies: Modifications and Revisions* (June 2020)
- Draft Guidance for industry *Use of a Drug Master File (DMF) for Shared System REMS Submissions* (November 2017)[4]
- Technical Conformance Guide for Shared System REMS Drug Master File Submissions (the SSR DMF Technical Conformance Guide)
- Technical Specifications Document, *Structured Product Labeling (SPL) Implementation Guide with Validation Procedures* (May 2018)
- REMS SPL Sample (accessible at https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources)
- Related REMS SPL Terminology web pages:
    - Document Type including Content of Labeling Type (available at https://www.fda.gov/industry/structured-product-labeling-resources/document-type-including-content-labeling-type)
    - REMS Approval (accessible at https://www.fda.gov/industry/structured-product-labeling-resources/rems-approval)

[4] When final, this guidance will represent FDA's current thinking on this topic.

- REMS Protocol (accessible at https://www.fda.gov/industry/structured-product-labeling-resources/rems-protocol)
- REMS Requirements (accessible at https://www.fda.gov/industry/structured-product-labeling-resources/rems-requirements)
- REMS Stakeholder (accessible at https://www.fda.gov/industry/structured-product-labeling-resources/rems-stakeholder)

### 1.5. Document Organization

This Guide contains instructions that are specific to the REMS Document as well as instructions that are specific to a Bifurcated REMS Document.

Section 2: General instructions for drafting a REMS Document

Section 3: General instructions for drafting a Bifurcated REMS Document

Appendices: Detailed template and outline for drafting a REMS Document and Bifurcated REMS Document

## 2. GENERAL INSTRUCTIONS FOR DRAFTING A REMS DOCUMENT

The REMS Document template includes six sections: (I) Administrative Information, (II) REMS Goals, (III) REMS Requirements, (IV) REMS Assessment Timetable, (V) REMS Materials, and (VI) Statutory Elements. Depending on the REMS requirements, an approved REMS Document will include the appropriate sections and text, as applicable, and can include up to six sections.

The margins of the document should be set at "narrow" providing a half inch margin at the top, bottom, and sides. The header should be Verdana font size 14, bold. The body text style should be Verdana font size 10.

## 3. GENERAL INSTRUCTIONS FOR DRAFTING A BIFURCATED REMS DOCUMENT

A Bifurcated REMS Document is used when the approval of a shared system REMS may coincide with tentative approval of an ANDA or section 505(b)(2) application. *Tentative approval* for an ANDA or section 505(b)(2) application is a notification to an applicant that an application meets the requirements for approval, but cannot be approved because of unexpired patents or exclusivity.[5] In such cases, it would not be appropriate for the shared system REMS to be operational yet, because the product proposed in the ANDA or section 505(b)(2) application could not yet be on the market.[6] For more information, refer to the guidance for industry *Development of a Shared System REMS* (June 2018).

A Bifurcated REMS is a single REMS Document consisting of two parts:

[5] Section 505(j)(5)(B)(iv)(II)(dd)(AA) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)(II)(dd)(AA)); 21 CFR 314.3(b) and 314.107.

[6] Bifurcated REMS for a biosimilar product and reference product will be handled on an individual case basis.

**Part A:** The currently approved REMS for the applicable listed drug, which remains in effect until the first ANDA that references the reference listed drug or section 505(b)(2) application that relies upon the listed drug receives full approval, and

**Part B:** The Shared System REMS, which is implemented upon full approval of the first ANDA that references the reference listed drug or section 505(b)(2) application that relies upon the listed drug.

The Bifurcated REMS Document Outline provides the framework for the format, structure, and main headings that should be included in a Bifurcated REMS Document. The outline should be used in conjunction with the REMS Document Template which provides more detailed information about the specific requirements and templated text.

## 4. RELATED REFERENCES

1. Guidance for industry *Formant and Content of a REMS Document* (Month Year)

2. Guidance for industry *Development of a Shared System REMS* (June 2018)

3. Guidance for industry *Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling Format* (December 2020)

4. Guidance for industry *Risk Evaluation and Mitigation Strategies: Modifications and Revisions* (June 2020)

5. Draft guidance for industry *Use of a Drug Master File for Shared System REMS Submissions* (November 2017)

6. *Technical Conformance Guide for Shared System REMS Drug Master File Submissions* (the SSR DMF Technical Conformance Guide) (November 2017)

7. Technical Specifications Document, *Structured Product Labeling (SPL) Implementation Guide with Validation Procedures* (May 2018)

8. REMS SPL Sample (accessible at https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources))

9. REMS SPL Resources (accessible at https://www.fda.gov/industry/structured-product-labeling-resources/risk-evaluation-and-mitigation-strategies-rems-spl-resources)

## 5. APPENDICES

**Appendix A:** REMS Document Template
**Appendix B:** Bifurcated REMS Document Outline

# Appendix A: REMS Document Template

## Risk Evaluation and Mitigation Strategy (REMS) Document

## [PROPRIETARY[7] (established/proper name)] or [Established/Proper/Class Name] [Shared System] REMS

The REMS Document template has six sections: (I) Administrative Information, (II) REMS Goals, (III) REMS Requirements, (IV) REMS Assessment Timetable, (V) REMS Materials, and (VI) Statutory Elements. Depending on the REMS requirements, the REMS Document will include sections and text, as applicable.

**Template Key**
Red Text = Instructions
Black Text = Standardized text
Blue text with hyperlink = Name of REMS Material(s)
[Bracketed (blue or black) text] = Information that needs to be entered

**Formatting and Style Key**
Document margins = "Narrow" (0.5" top, bottom, left, and right)
Header Style = Verdana font size 14, bold
Body Text Style = Verdana font size 10

Additional style and formatting instructions, as applicable, are included in sections below

## I. Administrative Information

Retain the text that apply to your REMS and delete the text that does not apply.
Risk: [risk REMS is designed to address. Use the term consistent with how the risk is described in labeling. If this REMS addresses more than one risk, list the risks in the same order that they appear in the Goals section.]
Application Number(s): NDA/BLA [application number(s)] Use this only for single-applicant REMS. Add (and Authorized Generic) after the corresponding NDA number.
Application Holder: [applicant name] Use this only for single-applicant REMS.
Initial [Shared System] REMS Approval: [MM/YYYY]
Most Recent REMS Update: [MM/YYYY] Enter the date of the most recent REMS Revision or approved Modification. If there are no updates since the initial approval, delete the text.

## II. REMS Goal(s)

This section describes the overall, safety-related health outcome that the REMS is designed to achieve (e.g., mitigate the risk of a particular serious adverse event) and the specific,

[7] [PROPRIETARY NAME] includes [list the dosage forms] and applicable authorized generics.

measurable objectives. In many cases, it is not possible to measure a risk mitigation goal directly; therefore, it is important to include one or more specific, measurable objectives that, if achieved, indicate that the REMS is meeting its goal(s).

[Overall REMS goal]

1. [REMS objective]
2. [Other REMS objectives, as needed]

## III. REMS Requirements

This section describes the REMS requirements for the applicant, including requirements that the applicant must undertake directly and requirements that the applicant must ensure that REMS participants undertake. REMS participants can include prescribers, dispensers, health care settings, patients (or their guardians), and wholesalers/distributors.

The REMS Requirements section is divided into two subsections. These subsections are labeled A and B in the template.

A. REMS Participant Requirements describes the requirements that REMS Participants must undertake.

B. REMS Applicant Requirements describes requirements for applicants to develop training, communications, systems, and processes to support REMS operations and compliance.

Standardized text for the most commonly used REMS requirements is included in each subsection in black text. Whenever possible, use the standardized text provided in the template. If you modify from the template text, you should provide a justification for doing so to facilitate FDA review.

Retain the subsections that apply to your REMS and delete the subsections that do not apply.

The participants should appear in the order that they interact with the REMS. Because the patient does not initiate involvement in the REMS, the patient section should not be the first participant section.

If there are different requirements for different patient populations (e.g., pediatric), repeat this subsection for each population, and modify the header accordingly. With-in each subsection:

- Select the REMS requirements that apply to your REMS and delete the REMS requirements that do not apply
- If a particular REMS requirement applies only to a subset of patients (e.g., patients who can get pregnant), use the following format for the requirement:

  For [subset to which the requirement applies]: [Requirement]

  *Example:* For patients who can get pregnant: Counsel the patient on pregnancy prevention

- Some REMS requirements have multiple versions to describe the different ways the requirement can be carried out (e.g., with or without using a REMS material). The different versions of the requirement appear in black text, separated by the word "OR" in red text. Select the appropriate version from the choices provided and delete the version(s) that does not apply to your REMS.

**----------Start Subsection A----------**

REMS Participant Requirements
This subsection describes the requirements that each REMS participant needs to undertake and that the applicant must ensure REMS participants comply with.

The information in this subsection is organized by REMS participant. There is a separate table for each participant that includes the following information:

| **1. [REMS Participant]** | |
|---|---|
| [Timing Category] | 1. [REMS Requirement] using [REMS Material]<br>2. [REMS Requirement] |
| [Timing Category] | 3. [REMS Requirement] |

[REMS Participant] = who (which participant) needs to complete the REMS Requirement(s)

[REMS Requirement] = what the REMS participant is required to do

[Timing Category] = when the participant must carry out the requirement

[REMS Material] = with what REMS material the participants need to use to carry out a requirement. Titles of REMS materials are included as a hyperlink within the requirement text.

Style and Formatting Instructions for REMS Participant tables:

- Gray border lines:
  - Add gray horizontal border lines to the REMS Participant header to begin each table
  - Add a gray horizontal border line to separate each time category to ensure requirements are aligned with the appropriate time category
- Numbering throughout the section:
  - Restart numbering when beginning a new REMS Participant Table
  - Use continuous numbering throughout all the timing categories for each REMS Participant Table

When listing the REMS materials, do not include the name of the REMS in the title of the material. For example, use "Prescriber Enrollment Form" instead of "Drug X REMS Prescriber Enrollment Form."

If there are no requirements that a particular REMS participant has to carry out to comply with the REMS, delete the table for that participant.

If there are no requirements that REMS participants have to carry out to comply with the REMS, delete subsection A. For example, if the REMS only includes requirements that the applicant has to carry out, such as developing and disseminating REMS communications to health care providers, delete subsection A.

**[Applicant] must ensure that [**List the participants who have requirements under this REMS in the order they appear in this section e.g., **health care providers/health care settings/patients/pharmacies/wholesalers-distributors] comply with the following requirements:**

**1. Health care providers who prescribe [proprietary/established/proper/class name] must:**

| | |
|---|---|
| To become certified to prescribe<br>Include this timing category if there are requirements that the health care provider must complete to be able to prescribe | 1. Be able to [clinical activity to be performed].<br>Include this requirement if the prescriber has to have the ability to carry out a particular activity, such as administer a particular treatment, diagnose a particular disease, or recognize a particular adverse event.<br>2. Review the drug's Prescribing Information.<br>Note that the Prescribing Information is not a REMS Material.<br>3. Review the following: [List the Prescriber Educational Material(s)].<br>Include this requirement if the health care provider is required to review certain educational materials that are provided as part of the REMS.<br>4. Take training provided by [entity providing the training, e.g., a CE provider, live or instructor led training by the REMS].<br>**OR**<br>Take the [REMS Material] training provided by the [entity providing the training, e.g., live or instructor led training by the REMS].<br>5. Successfully complete the [Knowledge Assessment] and submit it to the REMS.<br>6. Enroll by completing and submitting the [Enrollment Form] to the REMS. |
| Before treatment initiation ([at specified interval] or [first dose])<br>Include this timing category if there are requirements that the health care provider must complete with a patient, before the patient initiates treatment | 7. Counsel the patient on [topic(s)].<br>Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g., counseling tool, Medication Guide), or both.<br>**OR**<br>Counsel the patient using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient.<br>8. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)]. |

**1. Health care providers who prescribe [proprietary/established/proper/class name] must:**

**OR**
Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].
**OR**
Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].

9. Assess the patient for [adverse event].
Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.
**OR**
Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].
**OR**
Assess the patient for [adverse event] by [list lab test(s) or monitoring].
**OR**
Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].
10. Complete the [Patient Form]. Provide a completed copy of the form to the patient.
**OR**
Complete the [Patient Form]. Retain a completed copy in the patient's record.
**OR**
Complete the [Patient Form]. Provide a completed copy of the form to the patient and retain a copy in the patient's record.
Include this requirement if there is a Patient Form that needs to be completed (e.g., a Patient-Provider Agreement Form), but that is not required to be submitted to the REMS (If the patient's information is required to be submitted to the REMS, use requirement #11).
11. Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS.
**OR**
Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS. Provide a completed copy of the form to the patient.
**OR**
Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS. Retain a completed copy in the patient's record.
Include this requirement if the Enrollment Form is required to be submitted to the REMS (If the patient's information is not required to be submitted to the REMS, use requirement #10). List the applicable Enrollment Forms if there are different Enrollment Forms

**1. Health care providers who prescribe [proprietary/established/proper/class name] must:**

for different patient populations (e.g., patients who can get pregnant).

12. Provide the patient [with the [REMS Material(s)].
    Include this requirement if there are materials or an additional medication that must be provided to a patient (e.g., Patient Brochure). Do not repeat materials that are provided to the patient as part of another requirement (e.g., see requirements #7, #10, and #11).
    **OR**
    Provide the patient with [additional medication prescription].
13. Order the prescription using the [Prescription Order Form]. Include this requirement only when there is a separate Prescription Order Form that is not part of another REMS form, such as a Patient Enrollment Form, that the prescriber must use.
14. Prescribe no more than a [# of days] days' supply.
15. Not prescribe refills.

| | |
|---|---|
| During treatment, before each [dose/infusion/prescription]<br>Include this timing category if there are requirements that the health care provider must complete with the patient, before each dose, infusion, or prescription | 16. Counsel the patient on [topic(s)].<br>Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g., a counseling tool, a Medication Guide), or both.<br>**OR**<br>Counsel the patient using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient.<br>17. Provide the patient with [REMS Material].<br>Include this requirement if there are materials or an additional medication that must be provided to a patient (e.g., Patient Brochure). Materials that are provided to the patient as part of another requirement (e.g., see requirements #7, #10, and #11) do not need to be repeated here.<br>**OR**<br>Provide the patient with [additional medication prescription].<br>18. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>19. Assess the patient for [adverse event].<br>Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.<br>**OR**<br>Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>20. Order the prescription using the [Prescription Order Form]. Include this requirement only when there is a separate Prescription Order |

**1. Health care providers who prescribe [proprietary/established/proper/class name] must:**

Form that is not part of another REMS form, such as a Patient Enrollment Form, that the prescriber must use.

21. Prescribe no more than a [# of days] days' supply.
22. Not prescribe refills.

| | |
|---|---|
| During treatment, [at specified interval]<br>Include this timing category if there are requirements that the health care provider must complete with the patient at specified intervals (i.e., not linked to the time/a visit that a prescription is written) | 23. Counsel the patient on [topic(s)].<br>Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g., a counseling tool, a Medication Guide), or both.<br>**OR**<br>Counsel the patient using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient.<br>24. Provide the patient [with the [REMS Material]<br>Include this requirement if there are materials or an additional medication that must be provided to a patient (e.g., Patient REMS Brochure). Materials that are provided to the patient as part of another requirement (e.g., see requirements #7, #10, and #11) do not need to be repeated here.<br>**OR**<br>Provide the patient with [additional medication prescription].<br>25. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>26. Assess the patient for [adverse event].<br>Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.<br>**OR**<br>Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)]. |

**1. Health care providers who prescribe [proprietary/established/proper/class name] must:**

| | |
|---|---|
| After treatment discontinuation, [at specified interval] Include this timing category if there are requirements that the health care provider must complete after the patient has discontinued treatment | 27. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)]<br>28. Assess the patient for [adverse event].<br>Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.<br>**OR**<br>Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)]. |
| To maintain certification to prescribe, [at specified interval, e.g., every 2 years] Include this timing category if there are requirements that the health care provider must complete to be able to continue prescribing | 29. Review the drug's Prescribing Information.<br>Note that the Prescribing Information is not appended to the REMS.<br>30. Review the following: [List the Educational Material(s)].<br>31. Successfully complete the [Knowledge Assessment] and submit it to the REMS.<br>32. Re-Enroll by completing and submitting the [Re-Enrollment Form] to the REMS. |

**1. Health care providers who prescribe [proprietary/established/proper/class name] must:**

| | |
|---|---|
| At all times<br>Include this timing category if there are requirements that the health care provider must complete on an ongoing basis, as part of complying with the REMS | 33. Report [adverse event(s) of interest] to [the Manufacturer/the REMS/MedWatch].<br>**OR**<br>Report [adverse event(s) of interest] to the REMS using [REMS Material].<br>34. Report [treatment discontinuation or transfer of care] to [the Manufacturer/the REMS].<br>**OR**<br>Report [treatment discontinuation or transfer of care] to the REMS using [REMS Material].<br>Use this requirement if a patient is no longer under the prescriber's care or has discontinued treatment.<br>35. Maintain records of [REMS activity].<br>Include this requirement if there are records of certain REMS activities (e.g., records documenting staff's completion of REMS training) that must be maintained but are not submitted to the REMS. These records may be requested at any time by the applicant or as part of a REMS audit. |

**2. Patients who are prescribed [proprietary/established/proper/class name]:**

| | |
|---|---|
| Before treatment initiation<br>**OR**<br>Before treatment initiation, [at specified interval]<br>Include this timing category if there are requirements that the patient must complete to be able to initiate treatment | 1. Review the [List the Patient Material(s)].<br>2. Complete [Patient Form] with the prescriber.<br>Include this requirement if the patient form is not submitted to the REMS. If the form is submitted to the REMS, use requirement #3.<br>3. Enroll in the REMS by completing the [Enrollment Form] with the [prescriber/health care provider]. Enrollment information will be provided to the REMS.<br>Include this requirement if the form must be submitted to the REMS. Otherwise, use requirement #2.<br>4. Get [description of lab test].<br>**OR**<br>Be monitored for [description of monitoring].<br>Include this requirement if the patient is required to have a lab test completed or to be monitored.<br>5. Receive counseling from the [prescriber/pharmacy/health care provider] on [topic(s)].<br>**OR**<br>Receive counseling from the [prescriber/pharmacy/health care provider] using [REMS Material].<br>**OR**<br>Receive counseling from the [prescriber/pharmacy/health care provider] on [topic(s)] using [REMS Material].<br>6. Complete [Patient Questionnaire].<br>Include this requirement if there are questions that patients need to answer (e.g., monthly questionnaire to assess a patient's understanding of the drug's risks and safe use conditions). |

**2. Patients who are prescribed [proprietary/established/proper/class name]:**

| | |
|---|---|
| During treatment, before each [dose/infusion/prescription]<br>Include this timing category if there are requirements that the patient must complete before receiving subsequent prescriptions | 7. Receive counseling from the [prescriber/pharmacy/health care provider] on [topic(s)].<br>**OR**<br>Receive counseling from the [prescriber/pharmacy/health care provider] using [REMS Material].<br>**OR**<br>Receive counseling from the [prescriber/pharmacy/health care provider] on [topic(s)] using [REMS Material].<br>8. Get [description of lab test].<br>**OR**<br>Be monitored for [description of monitoring].<br>Include this requirement if the patient is required to have a lab test completed or to be monitored.<br>9. Complete [Patient Questionnaire].<br>Include this requirement if there are questions that patients need to answer (e.g., monthly questionnaire to assess a patient's understanding of the drug's risks and safe use conditions). |
| During treatment<br>Include this timing category if there are requirements that the patient must adhere to during treatment (i.e., not linked to the time a prescription is written) | 10. Adhere to the safe use conditions: [safe use condition(s), e.g., use of contraception].<br>**OR**<br>Adhere to the safe use conditions described in the [Patient Educational Material].<br>**OR**<br>Adhere to the safe use conditions: [safe use condition(s), e.g., use of contraception] described in the [Patient Educational Material].<br>11. Get [description of lab test].<br>**OR**<br>Be monitored for [description of monitoring].<br>Include this requirement if the patient is required to have a lab test completed or to be monitored. |
| During treatment after administration<br>Include this timing category if there are requirements that the patient must complete at after administration during treatment (i.e., not linked to the time a prescription is written) | 12. Get [description of lab test].<br>**OR**<br>Be monitored for [description of monitoring].<br>Include this requirement if the patient is required to have a lab test completed or to be monitored |
| During treatment, [At specified interval]<br>Include this timing category if there are requirements that the patient must complete at specified intervals during treatment (i.e., not linked to the time a prescription is written) | 13. Get [description of lab test].<br>**OR**<br>Be monitored for [description of monitoring].<br>Include this requirement if the patient is required to have a lab test completed or to be monitored. |

**2. Patients who are prescribed [proprietary/established/proper/class name]:**

| | |
|---|---|
| After treatment discontinuation, [at specified interval]<br>Include this timing category if there are requirements that the patient must complete after they have discontinued treatment | 14. Get [description of lab test].<br>**OR**<br>Be monitored for [description of monitoring].<br>Include this requirement if the patient is required to have a lab test completed or to be monitored. |
| At all times<br>Include this timing category if there are requirements that the patient must complete on an ongoing basis under the REMS | 15. Inform [prescriber/healthcare provider] [conditions under which prescriber should be contacted].<br>16. Have [item] with you.<br>Include this requirement if the patient is required to have on hand or carry with them a specific item or intervention (e.g., wallet card, bracelet, emergency treatment). |

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/ proper/class name] must:**

If there are different requirements for different types of pharmacies and/or health care settings (e.g., inpatient pharmacies vs. outpatient pharmacy) repeat this table for each type of pharmacy and/or health care setting.

| | |
|---|---|
| To become certified to dispense<br>Include this timing category if there are requirements that the dispenser must complete to be able to dispense | 1. Be able to [clinical activity to be performed].<br>Include this requirement if the dispenser has to have the ability to carry out a particular activity, such as administer a particular treatment.<br>2. Have [personnel with specific training/experience and/or specific equipment] on-site.<br>**OR**<br>Have the following on-site: [personnel with specific training/experience and/or specific equipment]<br>Include this requirement if the health care setting needs to have personnel with particular training or particular medical equipment on-site.<br>3. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the [health care setting/pharmacy].<br>Include this requirement if the health care setting must designate an authorized representative to act on the health care setting's behalf.<br>4. Have the authorized representative review the [List the Educational Material(s)].<br>Include this requirement if the authorized representative is required to review certain educational materials that are provided as part of the REMS.<br>5. Have the authorized representative take training provided by [entity providing the training, e.g., a continuing education provider, live or instructor led training by the REMS].<br>**OR**<br>Have the authorized representative take the [REMS Material] training provided by the [entity providing the training, e.g., live or instructor led training by the REMS]. |

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/ proper/class name] must:**

6. Have the authorized representative successfully complete the [Knowledge Assessment] and submit it to the REMS.
7. Have the authorized representative enroll by completing and submitting the [Enrollment Form] to the REMS.
   **OR**
   Have the authorized representative enroll by completing and submitting the applicable enrollment form(s) to the REMS: [List all Enrollment Forms].
   Use this version of the requirement if there are different enrollment forms for different types of settings (e.g., inpatient vs. outpatient pharmacy, chain vs. independent pharmacy).
8. Train all relevant staff involved in [activity] on [training topic(s)].
   **OR**
   Train all relevant staff involved in [activity] using [REMS Material(s)].
   **OR**
   Train all relevant staff involved in [activity] on [training topic(s)] using [REMS Material(s)].
9. Establish processes and procedures to verify [safe use conditions to be met].
   Include this requirement if the dispenser is responsible for setting up their own system to verify that safe use conditions have been met. If requirement #9 is included, also include requirement #13 to verify that safe use conditions have been met before dispensing.
10. Establish processes and procedures to [e.g., notify, provide] [safe use conditions to be met].
    Include this requirement if the dispenser is responsible for setting up their own system to carry out safe use conditions beyond verification. If requirement #10 is included, also include a corresponding requirement to carry out the safe use conditions.

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/ proper/class name] must:**

| | |
|---|---|
| Before dispensing<br>Include this timing category if there are requirements that the dispenser must complete before dispensing | 11. Counsel the patient on [topic(s)].<br>Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g., a counseling tool, a Medication Guide), or both.<br>**OR**<br>Counsel the patient using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient.<br>12. Provide the patient with [REMS Material].<br>Include this requirement if there are materials or an additional medication that must be provided to a patient (e.g., Patient REMS Brochure, Medication Guide).<br>**OR**<br>Provide the patient with [additional medication prescription].<br>13. Verify [safe use conditions to be met] through the processes and procedures established as a requirement of the REMS.<br>**OR**<br>Verify and document [safe use conditions to be met] through the processes and procedures established as a requirement of the REMS.<br>Include this requirement if the dispenser must verify that safe use conditions have been met before dispensing and must use systems established through requirement #9.<br>14. Notify [safe use conditions to be met] through the processes and procedures established as a requirement of the REMS.<br>15. Provide [safe use conditions to be met] through the processes and procedures established as a requirement of the REMS.<br>16. Obtain authorization to dispense each prescription by contacting the REMS to verify [safe use condition to be met].<br>Include this requirement if the dispenser must obtain authorization from the REMS to dispense the drug.<br>17. Dispense no more than a [# of days] days' supply.<br>18. Not dispense refills.<br>19. Not dispense [dose(s) e.g., first dose] outside [type of facility]. |

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/ proper/class name] must:**

| | |
|---|---|
| After dispensing<br>Include this timing category if there are requirements that the dispenser must complete after dispensing | 20. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>21. Assess the patient for [adverse event].<br>Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.<br>**OR**<br>Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)]. |

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/proper/class name] must:**

| | |
|---|---|
| Before administering<br>For drugs administered by a health care provider: Include this timing category if there are requirements that the health care provider must complete before the drug is administered | 22. Counsel the patient on [topic(s)].<br>Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g., a counseling tool, a Medication Guide), or both.<br>**OR**<br>Counsel the patient using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material].<br>**OR**<br>Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient.<br>23. Provide the patient with [REMS Material].<br>Include this requirement if there are materials or an additional medication that must be provided to a patient (e.g., Patient Brochure, Medication Guide).<br>**OR**<br>Provide the patient with [additional medication prescription].<br>24. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>25. Assess the patient for [adverse event].<br>Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.<br>**OR**<br>Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)]. |

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/ proper/class name] must:**

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|---|---|
| During and after administering, [at specified interval]<br>Include this timing category if there are requirements that the health care provider must complete during and after the drug is administered | 26. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>27. Assess the patient for [adverse event].<br>Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.<br>**OR**<br>Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)]. |

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/ proper/class name] must:**

| | |
|---|---|
| After administering, [at specified interval]<br>Include this timing category if there are requirements that the health care provider must complete after the drug is administered | 28. Assess the patient's [condition(s) or health status(es)].<br>Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.<br>**OR**<br>Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>29. Assess the patient for [adverse event].<br>Include this requirement if there is monitoring for an adverse event that must take place (e.g., infusion reactions or anaphylaxis). Repeat this requirement, as needed, to address multiple adverse events.<br>**OR**<br>Assess the patient for [adverse event]. Document and submit [the results] to the REMS using [REMS Material(s)].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring].<br>**OR**<br>Assess the patient for [adverse event] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS using [REMS Material(s)]. |
| At discharge<br>Include this timing category if there are requirements that the health care provider must complete when the patient is discharged | 30. Provide the patient with [REMS Material].<br>Include this requirement if there are materials or an additional medication that must be provided to a patient (e.g., Patient REMS Brochure, Medication Guide).<br>**OR**<br>Provide the patient with [additional medication prescription].<br>31. Dispense no more than a [# of days] days' supply. |

**3. [Health care settings/prescribers/pharmacies] that dispense [proprietary/established/ proper/class name] must:**

| | |
|---|---|
| To maintain certification to dispense, [at specified interval, e.g., every 2 years]<br>Include this timing category if there are requirements that the dispenser must complete to be able to continue dispensing | 32. Have the authorized representative review the [List the Educational Material(s)].<br>Include this requirement if the authorized representative is required to review certain educational materials that are provided as part of the REMS.<br>33. Have the authorized representative successfully complete the [Knowledge Assessment] and submit it to the REMS.<br>34. Have the authorized representative re-enroll by completing and submitting the [Re-Enrollment Form] to the REMS.<br>**OR**<br>Have the authorized representative re-enroll by completing and submitting the applicable form(s) to the REMS: [List all Re-Enrollment Forms].<br>Use this version of the requirement if there are different enrollment forms for different types of settings (e.g., inpatient vs. outpatient pharmacy, chain vs. independent pharmacy).<br>35. Have a new authorized representative enroll by completing and submitting the applicable form [Enrollment Form], if the authorized representative changes to the REMS.<br>Include this requirement if the pharmacy designates a new authorized representative. |
| At all times<br>Include this timing category if there are requirements that the dispenser must complete on an ongoing basis as part of complying with the REMS | 36. Report [adverse event(s) of interest] to [the Manufacturer/the REMS /MedWatch].<br>**OR**<br>Report [adverse event(s) of interest] to the REMS using [REMS Form].<br>37. Return unused product to [the manufacturer].<br>38. Not distribute, transfer, loan, or sell [proprietary/established/ proper/class name].<br>**OR**<br>Not distribute, transfer, loan, or sell [proprietary/established/ proper/class name], except to certified dispensers.<br>39. Maintain records of [activity].<br>Include this requirement if there are records of certain REMS activities (e.g., records of staff's completion of REMS training, all processes and procedures and compliance with those processes and procedures) that must be maintained but are not submitted to the REMS. These records may be requested by the applicant or as part of a REMS audit.<br>**OR**<br>Maintain and submit records of [activity] to [the REMS/Manufacturer].<br>40. Comply with audits carried out by [Entity to conduct audit, e.g., applicant or third party acting on behalf of the applicant] to ensure that all processes and procedures are in place and are being followed.<br>Include this requirement if the REMS participant has to agree to be audited. |

**4. Wholesalers-distributors that distribute [proprietary/established/proper/class name] must:**

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|---|---|
| To be able to distribute<br>Include this timing category if there are requirements that the wholesalers-distributors must complete to be able to distribute | 1. Establish processes and procedures to ensure that the drug is distributed only to certified [setting(s)].<br>2. Train all relevant staff involved in [activity] on [topic(s)]. |
| At all times<br>Include this timing category if there are requirements that the wholesalers-distributors must complete on an ongoing basis as part of complying with the REMS | 3. Distribute only to certified [setting(s)].<br>4. Maintain records of [activity].<br>Include this requirement if there are records of certain REMS activities (e.g., records of drug distribution, all processes and procedures and compliance with those processes and procedures) that must be maintained but are not submitted to the REMS. These records may be requested by the applicant or as part of a REMS audit.<br>**OR**<br>Maintain and submit records of [activity] to [the REMS/manufacturer].<br>Include this requirement if there are records of certain REMS activities (e.g., records of drug distribution) that must be maintained and submitted to the REMS.<br>5. Comply with audits carried out by [Entity to conduct audit, e.g., applicant or third party acting on behalf of the applicant] to ensure that all processes and procedures are in place and are being followed.<br>Include this requirement if the wholesaler-distributor is required to comply with audits of their activities under the REMS. |

**----------End Subsection A----------**

**----------Start Subsection B----------**

**REMS Applicant Requirements**

This subsection describes requirements for applicants to develop and make available REMS *training*; develop and provide *packaging and disposal systems*; develop and disseminate REMS *communications materials*; develop systems and processes to support REMS *operations*; and ensure participants' *compliance* with the REMS.

***REMS Training***

The requirements under this header relate to the requirement for the applicant to develop REMS training and provide to health care providers. REMS training requirements might also include the requirement for the applicant to develop a knowledge assessment for health care providers.

The REMS training requirements include information about how the training is being provided (e.g., website, mailing, in-person) and whether the training is being provided by a third party (such as a Continuing Education (CE) provider). The REMS training section may also include whether the applicant is required to provide funding for training.

If there are no requirements for the applicant to develop and make available REMS training, delete the requirements under this heading.

**[Applicant] must provide training to health care providers who prescribe [proprietary/ established/proper/class name].**

The training includes the following educational material(s): [Educational Material(s)]. The training must be [describe how training will be provided, e.g., available on a website, delivered by the applicant or accredited CE providers].

**[Applicant] must provide training to [health care settings/prescribers/pharmacies] that dispense [proprietary/established/proper/class name].**
The training includes the following educational material(s): [Educational Material(s)]. The training must be [describe how training will be provided, e.g., available on a website, delivered by the applicant or accredited CE providers].

***REMS Packaging and Disposal***
The requirements under this header relate to the requirement for the applicant to make a drug available for dispensing in packaging (e.g., unit dose) or implement a requirement that a disposal system be dispensed.
If there are no packaging and/or disposal requirements for the applicant to implement, delete the requirements under this heading.

***REMS Communications***
The requirements under this header support the development and dissemination of REMS communication materials to health care providers and professional organizations or societies. If there are no requirements for the applicant to disseminate REMS communications, delete the requirements under this heading.

The table below describes who should receive the REMS communication materials, what materials they should receive, as well as how, when, and how often they should receive the materials. The table includes the following information:

> **Target Audience**: The target audience is the particular group of health care providers that are the intended recipients of a REMS communication. For each target audience, include a description of the audience. Include an additional row for each distinct audience.
> **Communication Materials:** The communication materials are intended to disseminate information about the REMS (e.g., REMS Letter for Health Care Providers and for Professional Societies, REMS Fact Sheets, Journal information piece, and REMS Slides).
> **Dissemination Plan:** The dissemination plan describes how the communication materials will be distributed (e.g., via e-mail), the timing (e.g., start, end, how frequent), and whether there is any follow-up required. Include additional distribution plans if a given material is distributed in multiple ways.

**To inform health care providers about the REMS and the risks and safe use of [proprietary/established/proper/class name], [Applicant] must disseminate REMS communication materials according to the table below:**

| Target Audience | Communication Materials & Dissemination Plans |
|---|---|
| [Target Audience] | [Communication Material(s)]<br>• [Dissemination Plan 1]<br>• [Dissemination Plan 2] |
| Health care providers likely to prescribe [proprietary/established/ proper/class name] | Include Communication Materials that apply to this REMS and delete those that do not apply. Under each REMS communication, include dissemination methods that apply to this REMS and delete those that do not apply:<br>REMS Letter(s): [Health care Provider REMS Letter] [with attachment(s) REMS material(s)], [Professional Society REMS Letter] [with attachment(s) REMS material(s)]<br>1. Mail within [X] calendar days of the [date [proprietary/established/ proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]) and again [X] months later. |

| Target Audience | Communication Materials & Dissemination Plans |
|---|---|
| | a. Send by mail within 30 calendar days of the [date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]) if a health care provider's email address is not available or the email is undeliverable.<br>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.<br>c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.<br>2. Email within [X] calendar days of the [date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]) and again [X] months later. If a health care provider's email address is not available, send by mail.<br>a. For emails that are undeliverable: send by mail within [X] calendar days of the [date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]).<br>b. For first emails marked unopened: send a second email within [X] calendar days of the date the first email was sent.<br>c. For second emails marked unopened: send by mail within [X] calendar days of the date the second email was sent.<br>3. Make available via a link from the [proprietary/established/proper/class name] REMS Website.<br>4. Disseminate through [field-based sales and medical representatives] for [X] months from [the [date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]).<br>5. Disseminate within [X] calendar days of the [date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] [(mm/dd/yyyy)] [and again [X] months later] through the following professional societies and request the letter or content be provided to their members:<br>a. [List all professional societies, e.g., professional society 1; Professional society 2; Professional society 3]<br>6. Disseminate at Professional Meetings where [Applicant] has a presence for [duration] from [the [date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]).<br>[Journal Information Piece]<br>1. Publish every [frequency, e.g., quarterly] for [duration] after the [date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]) in the following journals:<br>[Fact Sheet]<br>1. Disseminate and prominently display at Professional Meetings where [Applicant] has a presence for [duration] from the [date [proprietary/established/proper/class name] is first commercially distributed/ approval of the REMS modification] ([mm/dd/yyyy]). |

| Target Audience | Communication Materials & Dissemination Plans |
|---|---|
| | 2. Disseminate through [field-based sales and medical representatives] during [the initial and/or follow-up] discussion with health care providers for [duration] after [[proprietary/established/proper/class name] is first commercially distributed/approval of this REMS modification] ([mm/dd/yyyy]). [Field-based sales and medical representatives] must verbally review the risk messages contained in the REMS Fact Sheet during the visit with the health care provider.<br>[Website]<br>1. Make the REMS website fully operational and all REMS materials available through the website [by the date [proprietary/established/proper/class name] is first commercially distributed /within [30/60/90] calendar days of REMS modification] ([mm/dd/yyyy]).<br>2. Maintain the REMS website for [duration] from [the date [proprietary/established/proper/class name] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]).<br>3. Include a prominent REMS-specific link to the [proprietary/established/proper/class name] REMS website on all product websites for consumers and health care providers. The [proprietary/established/proper/class name] REMS website must not link back to the promotional product website(s). |

***REMS Operations***

The requirements under this header support activities that are described in subsections A, *REMS Training Requirements, and/or the REMS includes a Medication Guide*. Only include these requirements (or the relevant subset) if the REMS Document includes subsection A and/or *REMS Training Requirements*. Use continuous numbering for the Applicant Requirements included in the REMS Operations and Compliance sections.

**To support REMS operations, [Applicant] must:**

1. Authorize dispensing for each [patient] based on verifying [safe use conditions to be met].

   **OR**

   Authorize dispensing for each [patient] based on verifying [safe use conditions to be met], and [receiving the [form/acceptable lab results]. The authorization is valid for [describe terms].

   **OR**

   Authorize dispensing for each [patient] based on verifying [safe use conditions to be met], [and [receiving the [form/acceptable lab results] on the following schedule: [schedule].

   If a completed [form/acceptable lab result] is not received [timeframe], the patient is not authorized to receive the drug until a completed [form/acceptable lab results] is received.

   **OR**

   Authorize dispensing for each [patient] based on verifying [safe use conditions to be met], [and [receiving the [form/acceptable lab results] within [schedule].

   If a completed [form/acceptable lab result] is not received [timeframe], the patient is not authorized to receive the drug until a completed [form/acceptable lab result] is received. Use this requirement when the health care setting must obtain authorization to dispense the drug.

2. Establish and maintain a REMS website, [REMS Website]. The REMS website must include [the capability to complete [prescriber/pharmacy/health care setting setting] certification or enrollment online,] [the capability to enroll and manage patients online], and the option to print the Prescribing Information[, Instructions For Use, Medication Guide], and REMS materials. All product websites for

consumers and health care providers must include prominent REMS-specific links to the REMS website. The REMS website must not link back to the promotional product website(s).

3. Make the REMS Program website fully operational and all REMS materials available through [medium e.g., website or call center] [within [30/60/90] calendar days of REMS modification (mm/dd/yyyy)]. Include implementation dates only if applicable for a REMS modification.
4. Establish and maintain a REMS [coordinating/call] center at [phone number].
5. Establish and maintain a validated, secure database of all REMS participants who are [enrolled and/or certified OR trained] in the [proprietary/established/proper/class name] REMS.
6. Ensure [List REMS participants] are able to [REMS activity(ies), e.g., enrollment, dispensing authorization] by [method(s) through which activity may be completed]. Use this requirement to specify the multiple ways that an applicant must provide for a REMS participant to comply with a particular REMS requirement(s); for example, REMS participants must be able to enroll in the REMS by phone, fax, and online. Repeat this requirement as needed (e.g., to address multiple REMS participants, requirements, or activities).
7. Maintain a process to [describe activity (e.g., to notify the REMS participant of a change in the patient's status, to validate the pharmacy management system configuration is complete, to ensure health care providers who want to become certified have necessary qualifications)].
8. Ensure that a Medication Guide is made available for dispensing with each [proprietary/established/proper/class name] prescription. Use this requirement only if the Medication Guide is an element of the REMS.
9. Provide [List REMS Material(s)], and the Prescribing Information to REMS participants who (1) attempt to [prescribe/dispense/distribute] [proprietary/established/proper/class name] and are not yet certified or (2) inquire about how to become certified.
10. Notify [List REMS participants] within [specific, reasonable amount of time] after they become certified in the REMS. Use this requirement if the REMS requires certification to prescribe and/or dispense the drug.
11. Notify [list of REMS participants] within [specific, reasonable amount of time] before their enrollment expires and the need to re-enroll.
12. Provide [REMS participants] access to the database of [list of REMS participants]. Repeat this requirement as needed.
13. Provide public access to a database of [certified health care settings/certified pharmacies].
14. Establish and maintain a registry which includes a reporting and collection system for [all patients/specific population] to provide information on [e.g., the incidence of AE or interest, outcomes].
15. Ensure that once a report suggestive of [adverse event of interest] is received, [Applicant] follows up with the health care provider to obtain all required data for the registry.
16. Report [AE of interest] as soon as possible to the FDA but no later than 15 calendar days from the initial receipt of the information by the applicant. This requirement does not affect the applicant's other reporting and follow-up requirements under applicable FDA regulations.

***REMS Compliance***

The requirements under this header support activities that are described in subsections A. Only include these requirements (or the relevant subset) if the REMS Document includes subsection A. Use continuous numbering for the Applicant Requirements included in the REMS Operations and Compliance sections.

**To ensure REMS participants' compliance with the REMS, [Applicant] must:**

17. Ensure [form/acceptable lab result] is received for each patient. If the [form/lab result] is not received [timeframe], [applicant] must contact the [REMS participant] to obtain the [form/lab result]. If the [form/acceptable lab result] is not received [timeframe], the patient is not authorized to receive the drug until the [form/acceptable lab result] is received.

18. Verify [annually] that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the [health care setting and/or pharmacy]. If different, the [health care setting and/or pharmacy] must be required to re-certify with a new authorized representative.

19. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: [proprietary/established/proper/class name] distribution and dispensing; certification of [prescribers, pharmacies, and health care settings; enrollment of patients]; and audits of REMS participants]. These records must be readily available for FDA inspections.

20. Establish and maintain a plan for addressing noncompliance with REMS requirements.

21. Monitor [List REMS participant(s) to be monitored] on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

22. Audit [quantity e.g., all, percentage, number] [REMS participant(s) to be audited] no later than [number of days, e.g., 180 days] after [timepoint e.g., they become certified, commercial distribution, they have ordered [proprietary/established/proper/class name] to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements. Repeat this requirement if the audit approach differs among REMS participants.

23. Take reasonable steps to improve operations of and compliance with the requirements in the [proprietary/established/proper/class name] REMS based on monitoring and evaluation of the [proprietary/established/proper/class name] REMS. Include this requirement for all REMS with a subsection A.

**----------End Subsection B----------**

## IV. REMS Assessment Timetable

This section describes the timetable for the applicant to submit its REMS Assessments.
[NDA/BLA Holder(s)] must submit REMS Assessments at [time intervals/frequency, e.g., 18 months, 3 years, and 7 years from the date of the initial REMS approval **OR** 6 months,12 months, and annually thereafter from the date of the initial approval of the REMS (MM/DD/YYYY)]. 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. [NDA/BLA Holder(s)] must submit each assessment so that it will be received by the FDA on or before the due date.
This section does not apply to ANDAs and should not be included in ANDA-only REMS Document.

## V. REMS Materials

This section should include a consolidated list of all materials mentioned in the *REMS Requirements Section.* The materials listed in this section are part of the REMS.

When listing the REMS materials, do not include the name of the REMS in the title of the material. For example, use "Prescriber Enrollment Form" instead of "Drug X REMS Prescriber Enrollment Form." Delete headings and items from the list of materials that do not apply to your REMS. Use continuous numbering throughout the section.

The following materials are part of the [proprietary/established/proper/class name] REMS**:**

**Enrollment Form(s):**

Prescriber:

1. [Prescriber Enrollment Form]

Patient:

2. [Patient Enrollment Form]
3. If the REMS includes different enrollment forms for different patient populations, include them as follows:
   [Patient Enrollment Form for [type of patient]]

Pharmacy:

4. [Pharmacy Enrollment Form]
5. If the REMS includes specific enrollment forms for different types of pharmacies, include them as follows:
   [[Type of pharmacy] Pharmacy Enrollment Form]
   For example:
   [Independent Pharmacy Enrollment Form]
   [Inpatient Pharmacy Enrollment Form]

Health Care Setting:

6. [Health Care Setting Enrollment Form]
7. [Other setting-specific Enrollment Forms, as needed]

Other Enrollment Form(s): Include the names of other enrollment forms here

**Training and Educational Materials**

Prescriber:

8. [Prescriber Education]
9. [REMS Overview]
10. [Knowledge Assessment]

Patient:

11. [Patient Guide]
12. [Medication Guide]

Pharmacy:

13. [Pharmacy Education]
14. [REMS Overview]
15. [Knowledge Assessment]

**Patient Care Form(s)**

16. [Patient Care Form] Include the names of forms used in patient care (other than enrollment forms), such as forms used to support patient monitoring or to document safe use conditions

**Communication Material(s)**

17. [Health Care Provider REMS Letter]
18. [REMS Letter]
19. [Journal Information Piece]
20. [Fact Sheet]

**Other Material(s)**

21. [REMS website]
22. [Administrative forms and materials] Include any administrative forms or materials here, as well as materials that don't fit into the above categories

# VI. Statutory Elements

This section describes the elements of the REMS as defined by the Food, Drug, and Cosmetic Act.
This REMS is approved under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

Delete the elements that do not apply to this REMS.

1. Medication Guide
2. Packaging and Disposal
3. Communication Plan
4. Elements to Assure Safe Use (ETASU):
    - Health care providers who prescribe [proprietary/established/proper/class name] are specially certified under 505-1(f)(3)(A)(ETASU A)
    - Pharmacies and health care settings that dispense [proprietary/established/proper/class name] are specially certified under 505-1(f)(3)(B)(ETASU B)
    - [proprietary/established/proper/class name] is dispensed to patients only in certain health care settings under 505-1(f)(3)(C)(ETASU C)
    - [proprietary/established/proper/class name] is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)(ETASU D)
    - Each patient using [proprietary/established/proper/class name] is subject to certain monitoring under 505-1(f)(3)(E)(ETASU E)
    - Each patient using [proprietary/established/proper/class name] is enrolled in the [proprietary/established/proper/class name] REMS program/Registry under 505-1(f)(3)(F)(ETASU F)
5. Implementation System Only include if ETASU B, C or D are used
6. Timetable for Submission of Assessments Include if the application is an NDA or BLA

# Appendix B: Bifurcated REMS Document Outline

## Risk Evaluation and Mitigation Strategy (REMS) Document

This is the template for a Bifurcated REMS Document. A Bifurcated REMS Document is used when the approval of a shared system REMS may coincide with tentative approval of an ANDA or section 505(b)(2) application. For more information, refer to the Guidance for Industry, *Development of a Shared System or Separate Comparable REMS,* available at https://www.fda.gov/media/113869/download.

A Bifurcated REMS, is a single REMS consisting of two parts:

**(Part A)** The currently approved REMS for the applicable listed drug, which remains in effect until the first ANDA that references the reference listed drug or section 505(b)(2) application that relies upon the listed drug receives full approval, and

**(Part B)** The Shared System REMS, which is implemented upon full approval of the first ANDA that references the reference listed drug or section 505(b)(2) application that relies upon the listed drug.

## A. [PROPRIETARY NAME][8,9] REMS

### I. Administrative Information

Retain the text that apply to your REMS and delete the text that does not apply.

Risk: [risk REMS is designed to address]
Application Number(s): NDA/BLA [application number(s)] Use this only for single-applicant REMS. Add (and Authorized Generic) after the corresponding NDA number.
Application Holder: [applicant name] Use this only for single-applicant REMS.
Initial REMS Approval: [MM/YYYY] Initial approval of the REMS for the reference listed drug.
Most Recent REMS Update: [MM/YYYY] Enter the date of the most recent REMS Revision or approved Modification. If there are no updates since the initial approval, delete the text.

### II. REMS Goal(s)

[Add goals here]

### III. REMS Requirements

**[Applicant] must ensure that [**List the participants who have requirements under this REMS in the order they appear in this section e.g., **health care providers/pharmacies/health care settings/patients/wholesalers-distributors] comply with the following requirements:**

[8] [PROPRIETARY NAME] includes [list the dosage forms and applicable authorized generics].
[9] The [PROPRIETARY NAME]-specific requirements contained in this document apply until the date of full approval of the first [abbreviated new drug application (ANDA)/505(b)(2) application] joining a shared system REMS with [PROPRIETARY NAME].

| | |
|---|---|
| **1. Health care Providers who prescribe [PROPRIETARY NAME] must:** | |
| | 1. |
| **2. Patients who are prescribed [PROPRIETARY NAME]:** | |
| | 1. |
| **3. [Health care settings/prescribers/pharmacies] that dispense [PROPRIETARY NAME] must:** | |
| | 1. |
| **4. Wholesalers-distributors that distribute [PROPRIETARY NAME] must:** | |
| | 1. |

Training: **[Applicant] must make training available to health care providers who prescribe [PROPRIETARY NAME].**

The training includes the following educational material(s): [Educational Material(s)]. The training must be [describe how training will be provided, e.g., available on a website, delivered by the applicant or accredited CE providers].

REMS Communications: **To inform health care providers about the REMS Program and the risks and safe use of [PROPRIETARY NAME], [Applicant] must disseminate REMS communication materials according to the table below:**

| Target Audience | Communication Materials & Dissemination Plans |
|---|---|
| [Target Audience] | [Communication Material(s)]<br>• [Dissemination Plan 1]<br>• [Dissemination Plan 2]<br>• [Insert requirements] |

Operations: **To support REMS Program operations, [Applicant] must:**

1. [Insert requirements]

Compliance: **To ensure REMS participants' compliance with the REMS Program, [Applicant] must:**

2. [Insert requirements]

## IV. REMS Assessment Timetable

[NDA/BLA Holder(s)] must submit REMS Assessments at [time intervals/frequency, e.g., 18 months, 3 years, and 7 years from the date of the initial REMS approval **OR** 6 months, 12 months, and annually

thereafter from the date of the initial approval of the REMS (MM/DD/YYYY)]. 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. [NDA/BLA Holder(s)] 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 [PROPRIETARY NAME] REMS:

**Enrollment Forms**

1. form
2. form

**Training and Educational Materials**

3. material
4. material

**Patient Care Form(s)**

5. form
6. form

**Communication Materials**

7. material
8. material

**Other Materials**

9. material
10. material
11. material

## VI. Statutory Elements

This REMS is approved under section 505-1 of the Federal Food, Drug and Cosmetic Act (FD&C Act) and consists of the following elements: Delete the elements that do not apply to this REMS.

1. Medication Guide
2. Communication Plan
3. Packaging and Disposal
4. Elements to Assure Safe Use: (ETASU)
    - Health care providers who prescribe [PROPRIETARY NAME] are specially certified under 505-1(f)(3)(A). (ETASU A)
    - Pharmacies and health care settings that dispense [PROPRIETARY NAME] are specially certified under 505-1(f)(3)(B). (ETASU B)
    - [PROPRIETARY NAME] is dispensed to patients only in certain health care settings under 505-1(f)(3)(C). (ETASU C).

- [PROPRIETARY NAME] is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D). (ETASU D)
- Each patient using [PROPRIETARY NAME] is subject to certain monitoring under 505-1(f)(3)(E). (ETASU E)
- Each patient using [PROPRIETARY NAME] is enrolled in the [PROPRIETARY NAME] REMS program/Registry under 505-1(f)(3)(F). (ETASU F)

5. Implementation System Only include if Elements B, C or D are used.
6. Timetable for Submission of Assessments Include if the application is an NDA or BLA.

The requirements of the shared system REMS for [Drug Class or Established/Proper Name] apply as of the date of full approval of the first Abbreviated New Drug Application (ANDA) joining a shared system with [PROPRIETARY NAME]

## B. [Drug Class or Established/Proper Name] Shared System REMS

### I. Administrative Information

Retain the text that apply to your REMS and delete the text that does not apply.

Risk: [risk REMS is designed to address]
Initial Shared System REMS Approval: [MM/YYYY]
Most Recent REMS Update: [MM/YYYY] Enter the date of the most recent REMS Revision or approved Modification. If there are no updates since the initial approval, delete the text.

### II. REMS Goal(s)

[Add goals here]

### III. REMS Requirements

**[Drug Class or Established/Proper Name] Applicants must ensure that [**List the participants who have requirements under this REMS in the order they appear in this section e.g., **health care providers/pharmacies/health care settings/patients/wholesalers-distributors] comply with the following requirements:**

| **1. Health care Providers who prescribe [Drug Class or Established/Proper Name] must:** |
|---|
| 1. |

| **2. Patients who are prescribed [Drug Class or Established/Proper Name]:** |
|---|
| 1. |

| **3. [Health care settings/prescribers/pharmacies] that dispense [Drug Class or Established/Proper Name] must:** |
|---|
| 1. |

| **4. Wholesalers-distributors that distribute [Drug Class or Established/Proper Name] must:** |
|---|
| 1. |

Training: **[Drug Class or Established/Proper Name] Applicants must make training available to health care providers who prescribe [Drug Class or Established/Proper Name].**

The training includes the following educational material(s): [Educational Material(s)]. The training must be [describe how training will be provided, e.g., available on a website, delivered by the applicants or accredited CE providers].

REMS Communications: **To inform health care providers about the REMS Program and the risks and safe use of [Drug Class or Established/Proper Name], [Drug Class or Established/Proper Name] Applicants must disseminate REMS communication materials according to the table below:**

| **Target Audience** | **Communication Materials & Dissemination Plans** |
|---|---|
| [Target Audience] | [Communication Material(s)]<br>• [Dissemination Plan 1]<br>• [Dissemination Plan 2]<br>• [insert requirements] |

Operations: **To support REMS Program operations, [Drug Class or Established/Proper Name] Applicants must:**

1. [Insert requirements]

Compliance: **To ensure REMS participants' compliance with the REMS Program, [Drug Class or Established/Proper Name] Applicants must:**

2. [Insert requirements]

## IV. REMS Assessment Timetable

[Drug Class or Established/Proper Name] NDA/BLA Applicants(s) must submit REMS Assessments at [time intervals/frequency, e.g., 18 months, 3 years, and 7 years from the date of the initial REMS approval **OR** 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS (MM/DD/YYYY)]. 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. [Drug Class or Established/Proper Name] Applicants(s) 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 [Drug Class or Established/Proper Name] REMS**:**

**Enrollment Forms**

1. form
2. form

**Training and Educational Materials**

3. material
4. material

**Patient Care Form(s)**

5. form
6. form

**Communication Materials**

7. material
8. material

**Other Materials**

9. material
10. material
11. material

## VI. Statutory Elements

This REMS is approved under section 505-1 of the Federal Food, Drug and Cosmetic Act (FD&C Act) and consists of the following elements: Delete the elements that do not apply to this REMS.

1. Medication Guide
2. Communication Plan
3. Packaging and Disposal
4. Elements to Assure Safe Use: (ETASU)
    - Health care providers who prescribe [Drug Class or Established/Proper Name] are specially certified under 505-1(f)(3)(A). (ETASU A)
    - Pharmacies and health care settings that dispense [Drug Class or Established/Proper Name] are specially certified under 505-1(f)(3)(B). (ETASU B)
    - [Drug Class or Established/Proper Name] is dispensed to patients only in certain health care settings under 505-1(f)(3)(C). (ETASU C)
    - [Drug Class or Established/Proper Name] is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D). (ETASU D)
    - Each patient using [Drug Class or Established/Proper Name] is subject to certain monitoring under 505-1(f)(3)(E). (ETASU E)

- Each patient using [Drug Class or Established/Proper Name] is enrolled in the [Drug Class or Established/Proper Name] REMS program/Registry under 505-1(f)(3)(F). (ETASU F)

5. Implementation System Only include if Elements B, C or D are used.
6. Timetable for Submission of Assessments Include if the application is an NDA or BLA.