Section	Field Name	Type	Description
	effective_time	string	Date reference to the particular version of the labeling document.
	related_spl_document_set_id	array of strings	REMS append the related document(s) with more detail on how to evaluate and manage risks regarding the product described in the related document(s). The related document(s) SPL document is referred to by its setId
	set_id	string	The Set ID, A globally unique identifier (GUID) for the labeling, stable across all versions or revisions.
	sponsor_name	string	The name of the sponsor for the drug.
	document_id	string	Unique identifier for the entire document.
	document_title	string	There is a title with the 'Risk Evaluation and Mitigation Strategy (REMS)' followed by [Drug/Class Name] REMS Program.
openfda	application_number	array of strings	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the application number will be the CFR citation corresponding to the appropriate Monograph (e.g. “part 341”). For unapproved drugs, this field will be null.
openfda	brand_name	array of strings	Brand or trade name of the drug product.
openfda	generic_name	array of strings	Generic name(s) of the drug product.
openfda	manufacturer_name	array of strings	Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC.
openfda	nui	array of strings	Unique identifier applied to a drug concept within the National Drug File Reference Terminology (NDF-RT).
openfda	pharm_class_cs	array of strings	Chemical structure classification of the drug product’s pharmacologic class. Takes the form of the classification, followed by `[Chemical/Ingredient]` (such as `Thiazides [Chemical/Ingredient]` or `Antibodies, Monoclonal [Chemical/Ingredient].
openfda	pharm_class_epc	array of strings	Established pharmacologic class associated with an approved indication of an active moiety (generic drug) that the FDA has determined to be scientifically valid and clinically meaningful. Takes the form of the pharmacologic class, followed by `[EPC]` (such as `Thiazide Diuretic [EPC]` or `Tumor Necrosis Factor Blocker [EPC]`.
openfda	pharm_class_moa	array of strings	Mechanism of action of the drug—molecular, subcellular, or cellular functional activity—of the drug’s established pharmacologic class. Takes the form of the mechanism of action, followed by `[MoA]` (such as `Calcium Channel Antagonists [MoA]` or `Tumor Necrosis Factor Receptor Blocking Activity [MoA]`.
openfda	pharm_class_pe	array of strings	Physiologic effect or pharmacodynamic effect—tissue, organ, or organ system level functional activity—of the drug’s established pharmacologic class. Takes the form of the effect, followed by `[PE]` (such as `Increased Diuresis [PE]` or `Decreased Cytokine Activity [PE]`.
openfda	product_ndc	array of strings	The labeler manufacturer code and product code segments of the NDC number, separated by a hyphen.
openfda	product_type	array of strings	Type of drug product
openfda	route	array of strings	The route of administation of the drug product.
openfda	rxcui	array of strings	The RxNorm Concept Unique Identifier. RxCUI is a unique number that describes a semantic concept about the drug product, including its ingredients, strength, and dose forms.
openfda	spl_id	array of strings	Unique identifier for a particular version of a Structured Product Label for a product. Also referred to as the document ID.
openfda	spl_set_id	array of strings	Unique identifier for the Structured Product Label for a product, which is stable across versions of the label. Also referred to as the set ID.
openfda	substance_name	array of strings	The list of active ingredients of a drug product.
openfda	unii	array of strings	Unique Ingredient Identifier, which is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance’s molecular structure and/or descriptive information.
openfda	upc	array of strings	Universal Product Code
products.manufactured_product	generic_name	string	Generic name(s) of the drug product.
products.manufactured_product	brand_name	string	Brand or trade name of the drug product.
products.manufactured_product	package_type	string	The package type of the drug.
products.marketing_info	application_number	string	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the application
products.marketing_info	approval_holder_org	string	The organization that holds the drug approval.
products.marketing_info	marketing_category	string	Product types are broken down into several potential Marketing Categories, such as NDA/ANDA/BLA, OTC Monograph, or Unapproved Drug.
products.manufactured_product	approval_holder_org	string	The organization that holds the drug approval.
rems_elements.medication_guide	effective_time	string	This is the date the product will no longer be available on the market.
rems_elements.medication_guide	title	string	There is a title with the 'Risk Evaluation and Mitigation Strategy (REMS)' followed by [Drug/Class Name] REMS Program.
medication_guide.text	paragraph	array of strings	Information about location of REMS medication guide(s).
rems_elements.elements_to_assure_safe_use	effective_time	string	Date reference to the particular version of the labeling document.
rems_elements.elements_to_assure_safe_use	title	string	There is a title with the 'Risk Evaluation and Mitigation Strategy (REMS)' followed by [Drug/Class Name] REMS Program.
.elements_to_assure_safe_use.safe_use_conditions.condition	condition_list	array of strings	Safe use conditions for patients, prescribers, sponsor etc
.safe_use_conditions.condition	description	string	Outlines the conditions the patients must meet.
.safe_use_monitoring.monitoring	monitoring_list	array of strings	Describes the steps for patient monitoring and lists the appended materials.
.safe_use_monitoring.monitoring	description	string	Outlines the conditions the patients must meet.
.safe_use_monitoring.appended_materials	item	array of strings	Additional attached documentation.
rems_elements.rems_implementation_system	effective_time	string	Date reference to the particular version of the labeling document.
.rems_implementation_system.implementation	item	array of strings	Describes the safety measures the sponsor will implement.
rems_elements	rems_submission_assessments_timetable	array of strings	Description of the timetable for submissions assessments to FDA by the sponsor.
rems_elements.rems_submission_assessments_timetable	effective_time	string	Date reference to the particular version of the labeling document.
rems_elements.rems_submission_assessments_timetable	text	string	The full text associated with the timetable.
rems_elements.rems_submission_assessments_timetable	title	string	There is a title with the 'Risk Evaluation and Mitigation Strategy (REMS)' followed by [Drug/Class Name] REMS Program.
rems_elements.rems_summary	effective_time	string	Date reference to the particular version of the labeling document.
.rems_summary.substance_administration.protocol	requirement	object	The requirement of the drug being a component of a REMS protocol described in the REMS Summary.
.rems_summary.substance_administration.protocol	code	string	The code for this protocol in substance administration.
.rems_summary.substance_administration.protocol	code_system	string	The code system used for this protocol in substance administration.
.rems_summary.substance_administration.protocol	name	string	The name of this protocol in substance administration.
.protocol.requirement	document_reference_root	string	Reference id for the document root.
.protocol.requirement	name	string	The name of the appended REMS material that are part of the program.
.protocol.requirement	reference_id	string	References the procedural step the healthcare provider or the patient should undertake.
.protocol.requirement	sequence_number	string	Date reference to the particular version of the labeling document.
.protocol.requirement	stakeholder_code	string	The code of the stakeholder for the requirement in substance administration.
.protocol.requirement	stakeholder_name	string	The name of the stakeholder for the requirement in substance administration.
.protocol.requirement	title	string	There is a title with the 'Risk Evaluation and Mitigation Strategy (REMS)' followed by [Drug/Class Name] REMS Program.

.rems_summary.substance_administration.approval	code	string	The code for this protocol in substance administration.
.rems_summary.substance_administration.approval	code_system	string	The code system used for this protocol in substance administration.
.rems_summary.substance_administration.approval	effective_time	string	Date reference to the particular version of the labeling document.
.rems_summary.substance_administration.approval	name	string	The name of this protocol in substance administration.
rems_elements.rems_material	effective_time	string	Date reference to the particular version of the labeling document.
.rems_material.document	name	string	The name of the REMS material document that are part of the program.
.rems_material.document	reference	string	The location of the appended REMS material that are part of the program.
rems_goals	effective_time	string	Date reference to the particular version of the labeling document.
rems_goals	goal	array of strings	Lists the goals of the REMS for SUBOXONE sublingual film, SUBOXONE sublingual tablets and SUBUTEX sublingual tablets.
spl_unclassified_section	record_details	array of strings	Key points of what is covered in the REMS SPL record
spl_unclassified_section	effective_time	string	Date reference to the particular version of the labeling document.