Section	Field Name	Type	Description
	rems_released rems_released_date document_id	string string string	The refease status of the document. The refease date of the document Unique identifier for the entire document.
	document_link rems_spl_file_link	string string	Link to the document.
	document_title effective_time	string	There is a title with the 'Risk Evaluation and Mitigation Strategy (REMS)' followed by [Drug/Class Name] REMS Program.  Date reference to the particular version of the labeling document.
	set_id wroten	string string string	Date reference to the particular version of the labeling document.  The Set ID, A globally unique identifier (GUID) for the labeling, stable across all versions or revisions.  The version of the file.
	rems_website sponsor_name	string string array of strings	Interestination of the real.  Interestination of the real for the third of the state of the second of the real for the second of the real for the re
	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 settid
products manufactured_product products manufactured_product	brand_name package_type generic_name	string string	
products.manufactured_product products.manketing_info	marketing_category	string string	Inter package type or the only Generic namely of the drug product.  Product types are broken down into several potential Marketing Categories, such as NON/ANDA/BLA, OTC Monograph, or Unapproved Drug.
products.marketing_info	application_number	string	NOSA/ANDA/BLA, OTC Monograph, or Unapproved Drug. This corresponds to the NDA, ANDA, or ELA number reported by the labeler for products which have the corresponding Marketing Calegory dissignated. If the designated Marketing Calegory is indicated. If the designated Marketing Calegory is indicated. If the designated Marketing Calegory is indicated.
products.marketing_info rems_stabutory_elements	approval_holder_org Stile	string string	The organization that noise the orug approval.  The title of this section.
rems_stabutory_elements rems_stabutory_elements rems_stabutory_elements rems_stabutory_elements	sext effective_time medication_guide communication_plan	string string	inclusion air the raw was consent for this section.  The code for this activity in substance administration.  Indicates whether a medication guide is included.  Indicates whether a communication plan is included.
rems_statutory_elements rems_statutory_elements rems_statutory_elements	communication_plan packaging_and_disposal implementation_system	string string string	Indicates whether a communication plan is included. Indicates whether packaging and disposal instructions are included. Indicates whether implementation system instructions are included.
rems_statutory_elements rems_statutory_elements_elements_to_ensure_safe_use	timetable_for_submissions_assessment rems_etasu_A	string string	Indicates whether a timetable for submission of assessments is included.  Elements to Assure Safe Use A.
rems_statutory_elements.elements_to_ensure_safe_use rems_statutory_elements.elements_to_ensure_safe_use rems_statutory_elements.elements_to_ensure_safe_use	rems_etasu_E rems_etasu_C rems_etasu_D	string string string	Elements to Assure Safe Use B. Elements to Assure Safe Use C. Elements to Assure Safe Use D.
eems_stabutory_elements.elements_to_ensure_safe_use rems_stabutory_elements.elements_to_ensure_safe_use rems_stabutory_elements.spl_unclassified_section	rems_etasu_F	string string	Elements to Assure Safe Use E. Elements to Assure Safe Use F.
rems_statutory_elements.apl_unclassified_section rems_statutory_elements.apl_unclassified_section	text effective_time	string	Includes all the raw test content for this section.  Date reference to the particular version of the labeling document.
spl_unclassified_section spl_unclassified_section spl_unclassified_section	title bext effective_time	string string string	The title of this section.  Includes all the raw test content for this section.  Date reference to the particular version of the labeling document.  The title of this section.
rems_administrative_information rems_administrative_information	title text	string string	Includes all the raw text content for this section.
rems_administrative_information rems_administrative_information rems_administrative_information	effective_time rems_released_date initial_rems_approval	string string string	This is the date the product will no longer be available on the market. The release date of the document The intial EXEMS approval.
rems_administrative_information rems_administrative_information	most recent nems update risks	string string	The initial REMS approval.  Date of the most recent REMS update.  The risks indicated.
rems_administrative_information.approval rems_administrative_information.approval rems_administrative_information.approval	code code_system name	string string string	the riss indicated. The risis indicated. The risis of this protocol in substance administration.
rems_administrative_information.approval rems_goals	effective_time title	string string	The same of use product as younger and the same and the s
rems_goals rems_requirements	content effective_time effective_time	string string	includes all the raw test content for this section.  Date reference to the particular version of the labeling document.  Date reference to the particular version of the labeling document.
rems_requirements rems_requirements	title bext	string string	The title of this section.  The title of this section.
rems_requirements.rems_participant_requirements rems_requirements.rems_participant_requirements rems_requirements.rems_participant_requirements	title content effective_time	string string string	The title of this section.  Beludian slif the raw test content for this section.  Date reference to the particular version of the labeling document.
rems participant requirements substance administration protocol rems participant requirements substance administration protocol	protocol_text protocol_code	string string	The code for this protocol in substance administration.
rems_participant_requirements.substance_administration.protocol rems_participant_requirements.substance_administration.protocol rems_participant_requirements.substance_administration.protocol	protocol_name code_system requirement	string string string	The name of this protocol in substance administration.  The code system used for this protocol in substance administration.  The requirement of the drug being a component of a REMS protocol described in the REMS.
protocol requirement	protocol_text	string	Summary. Includes all the raw test content for this section.
protocol requirement protocol requirement	protocol_code protocol_name protocol_timing_code_name	string string	The code for this protocol in substance administration.  The name of this protocol in substance administration.  The name for the timing in substance administration.  The code for the timing in substance administration.
protocol requirement protocol requirement	protocol_timing_code requirement_code	string string	The code for this requirement in substance administration.
protocol requirement protocol requirement	requirement_code_name requirement_text_number requirement_text	uning string string	The name of the appended RRMS material that are part of the program. The number associated with the requirement test content for this section. Includes all the requirement test content for this section.
protocol requirement protocol requirement	reference_id stakeholder_code	string string	References the procedural step the healthcare provider or the patient should undertake.  The code of the stakeholder for the requirement in substance administration.
protocol requirement rems_requirements rems_application_requirements	document_reference_root sitle	string string	The name or the usoemology for the requirement in substance administration.  Reference id for the document root.  The title of this section.
rems_requirements.rems_application_requirements rems_requirements.rems_application_requirements	content effective_time	string string	The title of this section.  Includes all the raw test content for this section.  Date reference to the particular version of the labeling document.
rems_requirements.rems_application_requirements rems_requirements.rems_application_requirements .rems_application_requirements.substance_administration.protocol	effective_time protocol_text	string string string	Includes all the raw test content for this section.  Date reference to the particular version of the labeling document.  Includes all the raw test content for this section.  The code for this protocol is substance administration.
rens, application, requirements substance, administration protocol rens, application, requirements substance, administration protocol rens, application, requirements substance, administration protocol	protocol_text protocol_code protocol_name	string	The code for this protocol in substance administration. The name of this protocol in substance administration.
rems_application_requirements.substance_administration.protocol .rems_application_requirements.substance_administration.protocol	code_system requirement	string	The name of this protocol in substance administration.  The code system used for this protocol in substance administration.  The requirement of the drug being a component of a REMS protocol described in the REMS farmary.
protocol requirement protocol requirement protocol requirement	protocol_text protocol_code	string string	Includes all the raw text content for this section. The code for this protocol in substance administration. The page of this protocol in substance administration.
protocol requirement protocol requirement	protocol timing code name protocol timing code	string string	The name for the timing in substance administration.  The code for the timing in substance administration.
protocol requirement protocol requirement	requirement_code requirement_code_name requirement_text_number	string string string	The code for this requisement in subtance administration.  The rame of the appended REMS material that are part of the program.  The number associated with the requirement test content for this section.
protocol requirement protocol requirement	requirement_text reference_id	string string	includes all the requirement text content for this section.  References the procedural step the healthcare provider or the patient should undertake.
protocol requirement protocol requirement protocol requirement	stakeholder_code stakeholder_code_name document_reference_root	string string string	The code of the stakeholder for the requirement in substance administration.  The rame of the stakeholder for the requirement in substance administration.  Reference if for the document root.
rems_requirements.rems_communication rems_requirements.rems_communication	text effective_time	string string	Reference is for the document root. Includes all the raw lest content for this section.  Date reference to the particular version of the labeling document. Includes all the raw lest content for this section.
rems_submission_assessments_timetable rems_submission_assessments_timetable rems_material	effective_time title	string string string	lectudes all the raw test content for this section.  Date reference to the particular version of the labeling document.  The title of this section.
rems_material rems_material	text effective_time	string string	includes all the raw test content for this section.  Date reference to the particular version of the labeling document.
rems_material.document rems_material.document rems_material.document	title rems_electronic_resource_name developer_of_the_standard	string string string	The title of this section. The name of the REMS electronic resource The developer of the standard.
rems_material.document rems_material.document	version_standard transaction	string string	The version of the standard. Information about the transaction.
rems_material.document rems_material.document	Id_rems_material_document reference	string string	The distraction address. The id of the RRMS Material document. The reference to this document.
rems_elements.medication_guide rems_elements.medication_guide	effective_time content effective_time	string	The reference to this document.  This is the date the product will no longer be available on the market.  Includes all the raw test content for this section.  Date reference to the particular version of the labeling document.
rems_elements.elements_to_assure_safe_use rems_elements.rems_implementation_system	content effective_time	string	Includes all the raw test content for this section.  Date reference to the particular version of the labeling document.
tems_elements.rems_implementation_system tems_elements.rems_summary tems_elements.rems_summary	content title text	string string string	includes all the raw text content for this section. The title of this section. Includes all the raw text content for this section.
terns_elements.rems_summary terns_elements.rems_summary .rems_summary.substance_administration.protocol	effective_time protocol_text	string string	Date reference to the particular version of the labeling document. Includes all the raw test content for this section.
zems_summary.substance_administration.protocol zems_summary.substance_administration.protocol zems_summary.substance_administration.protocol	protocol code protocol name code system	string string string	The code for this protocol in substance administration.  The rame of this protocol in substance administration.  The code system used for this protocol in substance administration.
.rems_summary.substance_administration.protocol .rems_summary.substance_administration.protocol	code_system requirement	string	The code system used for this protocol in substance administration. The requirement of the drug being a component of a REMS protocol described in the REMS summary.
protocol requirement protocol requirement protocol requirement	protocol_text protocol_code protocol_name	string string string	Includes all the raw text content for this section. The code for this protocol in substance administration. The name of this protocol in substance administration.
protocol requirement protocol requirement	protocol timing_code_name protocol timing_code	string string	The name for the timing in substance administration. The code for the timing in substance administration.
protocol requirement protocol requirement protocol requirement	requirement_code requirement_code_name requirement_text_number	string string string	The code for this requisement in substance administration. The name of the appended REMS material that are part of the program. The number associated with the requirement text content for this section.
protocol requirement protocol requirement	requirement_text reference_id	string string	includes all the requirement text content for this section.  References the procedural step the healthcare provider or the patient should undertake.
protocol requirement protocol requirement	stakeholder_code stakeholder_code_name document_reference_root	string string string	The code of the stakeholder for the requirement in substance administration. The name of the stakeholder for the requirement in substance administration. Reference is for the document root.
terns_electronic_resource	effective_time	string string	An extension of the service of the service of the labeling document.  The reference to this document.  The name of the REMS electronic resource
rems_electronic_resource rems_electronic_resource rems_electronic_resource	rems_electronic_resource_name developer_of_the_standard standard_version	string string string	The developer of the standard. The version of the standard.
rems_electronic_resource	transaction destination_address id_news_material_document	string string	Information about the transaction.
openida	Id_rems_material_document application_number	string array of strings	The list of the BERGM Material discusses.  18. It is a BERGM Material discusses.  18. It is extraposable to the NGA ARDA, or BEAL number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category designated, if the designated Marketing Category Colleges of the Category
			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 342"). For unapproved drugs, this field will be mall.
openida openida	brand_name generic_name	array of strings array of strings	this field will be not.!  More of trader among the drug product.  Center's resembly of the drug product.  More of manufacture or company the makes this drug product, corresponding to the labeler code segment of the NDC.  Longia Secretary of the NDC.  Longia Secretary spilled to a drug concept within the National Drug File Reference Terminology, NDC-41).  NDC-41 December spilled to a drug concept within the National Drug File Reference Terminology, NDC-41.
openida enenida	manufacturer_name	array of strings	Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC.  Items inferiting annitiating a drug consequence of the MANUFACTURE
openida	nui pharm_class_cs	array of strings array of strings	(NGF-RT).  Chemical structure classification of the drug product's pharmacologic class. Takes the form of
comfda	pharm_class_epc	array of strings	Openical structure classification of the drug product's pharmacologic class. Takes the form of the classification, followed by [Ohemical/Ingredent] (such as 'Thiazides [Ohemical/Ingredent]' or 'Artibodies, Morocclonal [Chemical/Ingredent]. Established observacionistics associated with an accrowed indication of an active moiety
		, w 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 resentingful. Takes the form of the pharmacologic class, followed by [EPC] (such as "Initiatibe Exercic [EPC])
openida	pharm_class_mos	array of strings	or Tumor Necrosis Factor Blocker [EPC]: Mechanism of action of the drug—molecular, subcellular, or cellular functional activity—of the drum's established charmacologic class. Takes the form of the mechanism of action. followed by
			[MoA] (such as 'Calcium Channel Artagonists [MoA]' or 'Tumor Necrosis Factor Receptor Blocking Activity [MoA]'.
openida	pharm_class_pe	array of strings	or Tumor Microscon Facility Blacker [PUR] <sup>2</sup> .  Mechanism of action of the deg—embication, subscribing, or ordinar functional activity—of the day's satisfiabled pharmacologic class. Takes the form of the mechanism of action, followed by [Mosk] (such as Californ Dermark Responsible Mosk) or Tumor Nicroscon Facility Responsible Plancing (Satisfied Annie) [Mosk]. Proposition of the Californ Plancing Californ Californ Plancing Californ Californ Plancing Californ
openida	product_ndc	array of strings	by [PE] (such as increased unures) [PE] or Decreased Uppoint Activity [PE].  The labeler manufacturer code and product code segments of the NDC number, separated by a
openfda	product_type	array of strings	highen.  Type of drug product  The roate of administration of the drug product.  The RoNorm Concept Unique Identifier. RxCUI is a unique number that describes a semantic.
openida openida	route rxcul	array of strings array of strings	The route of administration of the drug product.  The Reform Concept Unique identifier. RoCUI is a unique number that describes a semantic concept about the drug product, including its ingredients, strength, and dose forms.
openida openida openida	natring ratty spl_id	array of strings array of strings array of strings	Unique identifier for a particular version of a Structured Product Label for a product. Also
openida	spl_id spl_set_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.  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.
openida enenida	substance_name	array of strings	The list of active ingredients of a drug product.
opentda opentda		array of strings	Unique legredient Identifier, which is a non-proprietary, free, unique, unambiguous, non- semantic, alphanumenic identifier based on a substance's molecular structure and/or descriptive information.
			Universal Product Code