Paid Name		
eme, og die let of, of of, o		Description Date reference to the particular version of the labeling document.
wr_pl ground_more document_in former_in f		s REMS append the related document(s) with more detail on how to evaluate and manage ris regarding the product described in the related document(s). The related document(s) SPL document is referred to by its setfd.
Special Control of the Control of th	atring atring	Link to the REMS SPL file. The Set ID, A globally unique identifier (GUID) for the labeling, stable across all versions or
versions ones, verboles opposit opposi	string	revisions. The name of the sponsor for the drug.
versions ones, verboles opposits opposits opposits opposits opposits opposits opposits opposits	string string	Unique identifier for the entire document. Link to the document.
pplication_number pendia ppplication_number	string	There is a title with the 'Risk Evaluation and Mitigation Strategy (REMS)' followed by [Drug/Class Name] REMS Program.
pentis brand name	string	The version of the file. Link to the REMS website.
	array of string	Link to the EDMS website. S This corresponds to the NOA, ANDA, or BLA number reported by the labeller for products with have the corresponding Marketing Category designated. If a the designated Marketing Category Colleges and the product of the special content of COT. Monograph Teal or OTC Monograph Teal or Teal the special Not Final, then the application number will be the citation corresponding to the appropriate Monograph (e.g., "part 341"). For unapproved drugt this field will be set of the special content of the spec
penida manufacturer_name senida tui	array of string array of string array of string	Is Brand or trade name of the drug product.
penida		s Name of manufacturer or company that makes this drug product, corresponding to the label code segment of the NDC. s Unique identifier applied to a drug concept within the National Drug File Reference Termino
	array of string	
penfds pharm_class_cs	array of string	[Main-KE]. So Chemical structure classification of the drug product's pharmacologic class. Takes the form the classification, followed by "(Chemical/Ingredied)" (such as 'Thiazides (Chemical/Ingredied): "(asthus Mannologies (Chemical/Ingred
penfda pharm_class_epc	array of string	the coatsinatator, toolookod by [crientizaryopyroderet] (such as inaziona (crientizaryopyroderet) or Architodies, Monocolonal (Deminisco) from a proposed indication of an adva mointy or Established priemracologic class associated with an approved indication of an adva mointy (peemed deglight but to FLDA had determined to be scientifically valid and olicitally meaningle, Talast the form of the plasmacologic class, followed by [DHC] (such as "Thisolide Sturets (Di or "Tumor Necrosia Facial Studies (Electrica) or "Tumor Necrosia Facial Studies (Electrica)."
		Takes the form of the pharmacologic class, followed by '[EPC]' (such as 'Thiacide Diuretic [El or 'Tumor Necrosis Factor Blocker [EPC]'.
penda pharm_class_rnoa	array of string	g Necessarium or action or the cury —mosecular, subcessuriar, or tessuriar runcional activity—or drug's established pharmacologic class. Takes the form of the mechanism of action, follows: [MoA] (such as 'Calcium Channel Antagonists [MoA] or 'Tumor Necrosis Factor Receptor Obstitute Service (MoA).
pentás plarm_class_pe	array of string	personage review preserve : St Phyliologic effect or pharmacodynamic effect—dissue, organ, or organ system level function schistry—of the drug's established pharmacologic data. Takes the form of the effect, followed by [PE]* (such as 'increased Disresis [PE]* or 'Decreased Cytokine Activity [PE]*).
senfda product_ndc	array of string	The labeler manufacturer code and product code segments of the NCC number, separated by hyphen.
penfda product_type penfda route penfda route	array of string array of string	y Type of lag product gs. The route of administration of the drug product. gs. The Rolform Concept Unique Identifier. ReCUI is a unique number that describes a semantic
sentida encui	array of string	gs The Rollorm Concept Unique Identifier. RxCUI is a unique number that describes a semantic concept about the drug product, including its ingredients, strength, and dose forms.
sentida extring entry	array of string array of string	
penfda spl_id	array of string	Unique identifier for a particular version of a Structured Product Label for a product. Also referred to as the document ID.
penfda spl_set_id	array of string	gs Unique identifier for the Structured Product Label for a product, which is stable across version of the label. Also referred to as the set ID.
penida substance_name unii	array of string array of string	It The list of active ingredients of a drug product. Unique Ingredient identifier, which is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descrip
		semantic, alphanumeric identifier based on a substance's molecular structure and/or descrip information.
penfds upc roducts manufactured_product generic_name	array of string string	s Universal Product Code Generic name(s) of the drug product.
roducts manufactured product brand, name roducts manufactured product package_type	string string	Brand or trade name of the drug product. The package type of the drug.
oducts.marketing_info application_number	string	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products whi
roducts marketing_info approval_holder_org roducts marketing_info marketing_category	string	OTC Monograph Final or OTC Monograph Not Final, then the application The organization that holds the drug approval. Product types are broken down into several potential Marketing Categories, such as
oducts.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.
ms_administrative_information effective_time ms_administrative_information content	string	This is the date the product will no longer be available on the market. Includes all the raw text content for this section.
ms_administrative_information initial_rems_approxal ms_administrative_information most necess revolu-	string e string	Includes an the raw text consert for this section. The initial REMS approval. Date of the most recent REMS update.
ms_administrative_information rooducts rows administrative_information.croducts	string	The risks indicated. The risks indicated.
ms_administrative_information_products code_system	string	The risk indicated. This is the date the conduct will no longer by
ms, administrative information products name	string	The name of this protocol in substance administration.
ms_elements.medication_guide effective_time ms_elements.medication_guide content	string string	ans is one date the product will no longer be available on the market. Includes all the raw text content for this section.
ms_erements_elements_to_assure_safe_use effective_time ons_elements_elements_to_assure_safe_use content	string string	use reserved to the particular version of the labeling document. Includes all the raw text content for this section.
ms_elements.rems_implementation_system effective_time ims_elements.rems_implementation_system content	string	Date reference to the particular version of the labeling document. Includes all the raw text content for this section.
ms_elements.rems_submission_assessments_timetable effective_time ims_elements.rems_submission_assessments_timetable content	string	Date reference to the particular version of the labeling document. Includes all the raw text content for this section.
ims_elements.rems_summary test ims_elements.rems_summary title	string string	Includes all the raw text content for this section. The title of this section.
ons elements rems summary effective time ems summary substance administration protocol timing code	string string	Date reference to the particular version of the labeling document. The text for the timing in substance administration.
ens summary substance administration protocol timing text ens summary substance administration protocol text	string	The code for the timing in substance administration. Includes all the raw text content for this section.
ems_summary.substance_administration.protocol protocol_code	string	The code for this protocol in substance administration. The code vertex used for this protocol in substance administration.
ens_summay_substance_administration_protocol name ens_summay_substance_administration_protocol requirement	string string	The name of this protocol in substance administration. The requirement of the drug being a component of a REMS protocol described in the REMS.
rotocol requirement activity text	string	Summary.
rotocol requirement schitty_name rotocol requirement schitty_name	string	The rame of the activity that just of the program. The code for this activity in substance administration. The code for the timing in substance administration.
rotocal requirement timing text	string	The code for the timing in substance administration. The text for the timing in substance administration.
rotocol requirement requirement test	string	Includes all the requirement test content for this section. The code for this requirement in substance administration.
rotocol requirement rame	string	The name of the appended REMS material that are part of the program.
rotocol requirement stakeholder_code	string	The code of the stakeholder for the requirement in substance administration.
rotocol requirement statement statement document_reference_root	string	The name of the stateholder for the requirement in substance administration. Reference id for the document root.
ens_summary.substance_administration.approval code_system	string	The code system used for this protocol in substance administration.
ens_turmary.tubitance_administration.approval reflective_time ens_turmary.substance_administration.approval range ens_ens_ens_ens_ens_ens_ens_ens_ens_ens_	string	Uses reference to the particular version of the useing occurrent. The name of this protocol in substance administration. Date reference to the particular version of the labeling document. The name of the REMS material document that are part of the program.
ens_material.document rame	string	The name of the REMS material document that are part of the program.
ms, goals effective, time	string	Date reference to the particular version of the labeling document.
rms_goals content rms_material content	string	Includes all the raw text content for this section. The little of little and little raw text content for this section.
ms_material effective_time	string	Date reference to the particular version of the labeling document.
ins_material document tens_electronic_resource_ ins_material document feedore.cd_the_standan ins_material document version_standant	d string string	The name of the REMS electronic resource The developer of the standard. The version of the standard.
ims, material document transaction ims, material document destination, address ims, material document destination, address	string string	Information about the transaction.
ens_material_document id_nems_material_docume	ent string	The destination address. The ld of the RIMS Material document.
ms_material_document reference	string	The reference to this document.
ms_requirements title	string	Includes an the raw text content for this section. The title of this section.
ms_requirements effective_time ms_requirements.rems_participant_requirements content	string	Date reference to the particular version of the labeling document. Includes all the raw text content for this section.
ims_requirements.rems_participant_requirements title ims_requirements.rems_participant_requirements effective_time	string	The title of this section. Date reference to the particular version of the labeling document.
ims_summary.substance_administration.protocol timing_code ems_summary.substance_administration.protocol timing_text	string	The text for the timing in substance administration. The code for the timing in substance administration. Includes all the cave text content for this section.
ens_summary.substance_administration.protocol test ens_summary.substance_administration.protocol protocol_code	string	The code for this protocol in substance administration.
ems_summary.substance_administration.protocol code_system ems_summary.substance_administration.protocol name ems_summary.substance_administration.protocol name ems_summary.substance_administration.protocol semi-	string	The code system used for this protocol in substance administration. The name of this protocol in substance administration. The requirement of the day being a component of a REMS protocol described in the REMS.
res_summary.substance_administration.protocol requirement	string	The requirement of the drug being a component of a REMS protocol described in the REMS Summary.
	string	The test included with the activity. The name of the activity that is part of the program.
roscos requirement activity text rotocol requirement activity name	string	The code for this activity in substance administration. The code for the timing in substance administration.
recoost.regulement activity_text retocost.regulement activity_name retocost.regulement activity_name retocost.regulement activity_code trotocost.regulement timing_text	string	The text for the timing in substance administration. Includes all the requirement text content for this section.
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2000.00 applications	string string string string 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 id for the document root.
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which department with the property of the prop	string	The code of the stateholder for the registered is substantially and administration. The code of the stateholder for the registered in substance administration. Methods so the behavior and the substance administration. Methods so the behavior made. Methods so the behavior made of the protect in substance administration. The code region and for this protect in substance administration. Other affection is the particular version of the labeling document. The same of they appear to which the protection is substance administration.
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