

| 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_link | string | Link to the 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 | nu | 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 administration of the drug product. |
| openfda | rcui | 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 | rxstring | array of strings | |
| openfda | rxty | array of strings | |
| 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. |
| 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 | content | string | Includes all the raw text content for this section. |
| 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 | content | string | Includes all the raw text content for this section. |
| rems_elements.rems_implementation_system | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_elements.rems_implementation_system | content | string | Includes all the raw text content for this section. |
| 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 | content | string | Includes all the raw text content for this section. |
| rems_elements.rems_summary | text | string | Includes all the raw text content for this section. |
| rems_elements.rems_summary | title | string | The title of this section. |
| rems_elements.rems_summary | effective_time | string | Date reference to the particular version of the labeling document. |
| 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_elements.rems_material | name | string | The name of the REMS material document that are part of the program. |
| rems_elements.rems_material | reference | string | The location of the appended REMS material that are part of the program. |
| rems_elements.rems_material | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_elements.rems_material | content | string | Includes all the raw text content for this section. |
| rems_elements.rems_material | content | string | Includes all the raw text content for this section. |
| rems_elements.rems_material | title | string | The title of this section. |
| rems_elements.rems_material | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_elements.rems_material | name | string | The name of this document. |
| rems_elements.rems_material | reference | string | The reference to this document. |
| rems_requirements | text | string | Includes all the raw text content for this section. |
| rems_requirements | title | string | The title of this section. |
| rems_requirements | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_requirements.rems_participant_requirements | content | string | Includes all the raw text content for this section. |
| rems_requirements.rems_participant_requirements | title | string | The title of this section. |
| rems_requirements.rems_participant_requirements | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_participant_requirements.substance_administration.protocol | code | string | The code for this protocol in substance administration. |
| rems_participant_requirements.substance_administration.protocol | code_system | string | The code system used for this protocol in substance administration. |
| rems_participant_requirements.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_participant_requirements.substance_administration.approval | code | string | The code for this protocol in substance administration. |
| rems_participant_requirements.substance_administration.approval | code_system | string | The code system used for this protocol in substance administration. |
| rems_participant_requirements.substance_administration.approval | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_participant_requirements.substance_administration.approval | name | string | The name of this protocol in substance administration. |
| rems_requirements.rems_application_requirements | content | string | Includes all the raw text content for this section. |
| rems_requirements.rems_application_requirements | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_application_requirements.substance_administration.protocol | code | string | The code for this protocol in substance administration. |
| rems_application_requirements.substance_administration.protocol | code_system | string | The code system used for this protocol in substance administration. |
| rems_application_requirements.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_application_requirements.substance_administration.approval | code | string | The code for this protocol in substance administration. |
| rems_application_requirements.substance_administration.approval | code_system | string | The code system used for this protocol in substance administration. |
| rems_application_requirements.substance_administration.approval | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_application_requirements.substance_administration.approval | name | string | The name of this protocol in substance administration. |
| rems_requirements.rems_communication | content | string | Includes all the raw text content for this section. |
| rems_requirements.rems_communication | effective_time | string | Date reference to the particular version of the labeling document. |
| rems_submission_assessments_timetable | content | string | Includes all the raw text content for this section. |
| rems_submission_assessments_timetable | effective_time | string | Date reference to the particular version of the labeling document. |
| spl_unclassified_section | record_details | array of strings | Key points of what's covered in the REMS SPL record |
| spl_unclassified_section | effective_time | string | Date reference to the particular version of the labeling document. |
| spl_unclassified_section | title | string | The title of this section. |