Section	Field Name	Туре	Description
	•		Information about the types of abuse that can occur with the drug and adverse reactions pertinent to those types of abuse, primarily
Abuse and overdosage	abuse	string	based on human data. May include descriptions of particularly susceptible patient populations.
Abuse and overdosage	abuse table	string	Information about the types of abuse that can occur with the drug and adverse reactions pertinent to those types of abuse, primarily based on human data. May include descriptions of particularly susceptible patient populations.
Abuse and overdosage	controlled substance	string	Information about the schedule in which the drug is controlled by the Drug Enforcement Administration, if applicable.
· ·	=	· ·	Information about the schedule in which the drug is controlled by the Drug Enforcement Administration, if applicable.
Abuse and overdosage	controlled_substance_table	string	Information about the screening from both psychological and physical dependence that occur with the drug, the
			quantity of drug over a period of time that may lead to tolerance or dependence, details of adverse effects related to chronic abuse
Abuse and overdosage	dependence	string	and the effects of abrupt withdrawl, procedures necessary to diagnose the dependent state, and principles of treating the effects of
			Information about characteristic effects resulting from both psychological and physical dependence that occur with the drug, the
			quantity of drug over a period of time that may lead to tolerance or dependence, details of adverse effects related to chronic abuse
Abuse and overdosage	dependence_table	string	and the effects of abrupt withdrawl, procedures necessary to diagnose the dependent state, and principles of treating the effects of
Abuse and overdosage	drug_abuse_and_dependence	string	Information about whether the drug is a controlled substance, the types of abuse that can occur with the drug, and adverse reactions pertinent to those types of abuse.
		J. J	Information about whether the drug is a controlled substance, the types of abuse that can occur with the drug, and adverse reactions
Abuse and overdosage	drug_abuse_and_dependence_table	string	pertinent to those types of abuse.
Abuse and overdosage	overdosage	string	Information about signs, symptoms, and laboratory findings of acute ovedosage and the general principles of overdose treatment.
Abuse and overdosage	overdosage_table	string	Information about signs, symptoms, and laboratory findings of acute ovedosage and the general principles of overdose treatment.
			Information about undesirable effects, reasonably associated with use of the drug, that may occur as part of the pharmacological action
			of the drug or may be unpredictable in its occurrence. Adverse reactions include those that occur with the drug, and if applicable, with
Adverse effects and interactions	adverse reactions	ctring	drugs in the same pharmacologically active and chemically related class. There is considerable variation in the listing of adverse
Adverse effects and interactions	adverse_reactions	string	reactions. They may be categorized by organ system, by severity of reaction, by frequency, by toxicological mechanism, or by a Information about undesirable effects, reasonably associated with use of the drug, that may occur as part of the pharmacological action
			of the drug or may be unpredictable in its occurrence. Adverse reactions include those that occur with the drug, and if applicable, with
			drugs in the same pharmacologically active and chemically related class. There is considerable variation in the listing of adverse
Adverse effects and interactions	adverse_reactions_table	string	reactions. They may be categorized by organ system, by severity of reaction, by frequency, by toxicological mechanism, or by a
Adverse effects and interactions	$drug_and_or_laboratory_test_interactions$	string	Information about any known interference by the drug with laboratory tests.
Adverse effects and interactions	$drug_and_or_laboratory_test_interactions_tab$	le string	Information about any known interference by the drug with laboratory tests.
Adverse effects and interactions	drug_interactions	string	Information about and practical guidance on preventing clinically significant drug/drug and drug/food interactions that may occur in
Adverse effects and interactions	drug_interactions_table	string	Information about and practical guidance on preventing clinically significant drug/drug and drug/food interactions that may occur in
Clinical pharmacology	clinical_pharmacology	string	Information about the clinical pharmacology and actions of the drug in humans.
Clinical pharmacology	clinical_pharmacology_table	string	Information about the clinical pharmacology and actions of the drug in humans.
			Information about the established mechanism(s) of the drugÕs action in humans at various levels (for example receptor, membrane,
Clinical pharmacology	mechanism_of_action	string	tissue, organ, whole body). If the mechanism of action is not known, this field contains a statement about the lack of information.
Clinical pharmacology	mechanism of action table	string	Information about the established mechanism(s) of the drugÖs action in humans at various levels (for example receptor, membrane, tissue, organ, whole body). If the mechanism of action is not known, this field contains a statement about the lack of information.
Cirrical priarriacology	mediamani_or_action_table	Sti ilig	Information about any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drugÕs clinical
Clinical pharmacology	pharmacodynamics	string	effect in preventing, diagnosing, mitigating, curing, or treating disease, or those related to adverse effects or toxicity.
			, , , , , , , , , , , , , , , , , , , ,

			Information about any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drugÕs clinical
Clinical pharmacology	pharmacodynamics_table	string	effect in preventing, diagnosing, mitigating, curing, or treating disease, or those related to adverse effects or toxicity.
			Information about the clinically significant pharmacokinetics of a drug or active metabolites, for instance pertinent absorption,
Clinical pharmacology	pharmacokinetics	string	distribution, metabolism, and excretion parameters.
			Information about the clinically significant pharmacokinetics of a drug or active metabolites, for instance pertinent absorption,
Clinical pharmacology	pharmacokinetics_table	string	distribution, metabolism, and excretion parameters.
ID and version	effective_time	string	Date reference to the particular version of the labeling document.
ID and version	id	string	The document ID, A globally unique identifier (GUID) for the particular revision of a labeling document.
ID and version	set_id	string	The Set ID, A globally unique identifier (GUID) for the labeling, stable across all versions or revisions.
ID and version	version	string	A sequentially increasing number identifying the particular version of a document, starting with 1.
Indications, usage, and dosage	active_ingredient	string	A list of the active, medicinal ingredients in the drug product.
Indications, usage, and dosage	active_ingredient_table	string	A list of the active, medicinal ingredients in the drug product.
			Information about situations in which the drug product is contraindicated or should not be used because the risk of use clearly
Indications, usage, and dosage	contraindications	string	outweighs any possible benefit, including the type and nature of reactions that have been reported.
			Information about situations in which the drug product is contraindicated or should not be used because the risk of use clearly
Indications, usage, and dosage	contraindications_table	string	outweighs any possible benefit, including the type and nature of reactions that have been reported.
			General information about the drug product, including the proprietary and established name of the drug, the type of dosage form and
Indications, usage, and dosage	description	string	route of administration to which the label applies, qualitative and quantitative ingredient information, the pharmacologic or therapeutic class of the drug, and the chemical name and structural formula of the drug.
marcations, asage, and assage	G556. Iption	3c8	General information about the drug product, including the proprietary and established name of the drug, the type of dosage form and
			route of administration to which the label applies, qualitative and quantitative ingredient information, the pharmacologic or
Indications, usage, and dosage	description_table	string	therapeutic class of the drug, and the chemical name and structural formula of the drug.
			Information about the drug product's dosage and administration recommendations, including starting dose, dose range, titration
Indications, usage, and dosage	dosage_and_administration	string	regimens, and any other clinically sigificant information that affects dosing recommendations.
			Information about the drug product's dosage and administration recommendations, including starting dose, dose range, titration
Indications, usage, and dosage	dosage_and_administration_table	string	regimens, and any other clinically sigificant information that affects dosing recommendations.
Indications usage and desage	docago forms and strongths	string	Information about all available dosage forms and strengths for the drug product to which the labeling applies. This field may contain
Indications, usage, and dosage	dosage_forms_and_strengths	string	descriptions of product appearance. Information about all available dosage forms and strengths for the drug product to which the labeling applies. This field may contain
Indications, usage, and dosage	dosage_forms_and_strengths_table	string	descriptions of product appearance.
Indications, usage, and dosage	inactive_ingredient	string	A list of inactive, non-medicinal ingredients in a drug product.
Indications, usage, and dosage	inactive ingredient table	string	A list of inactive, non-medicinal ingredients in a drug product.
		B	A statement of each of the drug productÕs indications for use, such as for the treatment, prevention, mitigation, cure, or diagnosis of a
			disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a
Indications, usage, and dosage	indications_and_usage	string	recognized disease or condition. This field may also describe any relevant limitations of use.
			A statement of each of the drug productÕs indications for use, such as for the treatment, prevention, mitigation, cure, or diagnosis of a
			disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a
Indications, usage, and dosage	indications_and_usage_table	string	recognized disease or condition. This field may also describe any relevant limitations of use.
Indications, usage, and dosage	purpose	string	Information about the drug product's indications for use.

			Information about the drug graduat's indications for use
Indications, usage, and dosage	purpose_table	string	Information about the drug product's indications for use.
Indications, usage, and dosage	spl_product_data_elements	string	Usually a list of ingredients in a drug product.
Indications, usage, and dosage	spl_product_data_elements_table	string	Usually a list of ingredients in a drug product.
Nonclinical toxicology	animal_pharmacology_and_or_toxicology	string	Information from studies of the drug in animals, if the data were not relevant to nor included in other parts of the labeling. Most labels
Nonclinical toxicology	animal_pharmacology_and_or_toxicology_table	e string	Information from studies of the drug in animals, if the data were not relevant to nor included in other parts of the labeling. Most labels
Nonclinical toxicology	carcinogenesis_and_mutagenesis_and_impairm	en string	Information about carcinogenic, mutagenic, or fertility impairment potential revealed by studies in animals. Information from human data about such potential is part of the warnings field. Information about carcinogenic, mutagenic, or fertility impairment potential revealed by studies in animals. Information from human
Nonclinical toxicology	carcinogenesis_and_mutagenesis_and_impairme	en string	data about such potential is part of the warnings field.
Nonclinical toxicology	nonclinical_toxicology	string	Information about toxicology in non-human subjects.
Nonclinical toxicology	nonclinical_toxicology_table	string	Information about toxicology in non-human subjects.
			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 fields	application_number	array of strings	Values follow this pattern:
OpenFDA fields	brand_name	array of strings	Brand or trade name of the drug product.
OpenFDA fields	generic_name	array of strings	Generic name(s) of the drug product.
OpenFDA fields	manufacturer_name	array of strings	Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC.
			Unique identifier applied to a drug concept within the National Drug File Reference Terminology (NDF-RT).
OpenFDA fields	nui	array of strings	Values follow this pattern: ^[N][0-9]{10}\$ This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug.
			Values follow this pattern:
OpenFDA fields	package_ndc	array of strings	^[0-9]{5,4}-[0-9]{4,3}-[0-9]{1,2}\$
OpenFDA fields	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 fields	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 Mechanism of action of the drug—molecular, subcellular, or cellular functional activity—of the drug's established pharmacologic class.
OpenFDA fields	pharm_class_moa	array of strings	Takes the form of the mechanism of action, followed by [MoA] (such as Calcium Channel Antagonists [MoA] or Tumor Necrosis Factor Physiologic effect or pharmacodynamic effect—tissue, organ, or organ system level functional activity—of the drug's established
OpenFDA fields	pharm_class_pe	array of strings	pharmacologic class. Takes the form of the effect, followed by [PE] (such as Increased Diuresis [PE] or Decreased Cytokine Activity [PE].

The labeler manufacturer code and product code segments of the NDC number, separated by a hyphen.

			Values follow this pattern:
OpenFDA fields	product_ndc	array of strings	^[0-9]{5,4}-[0-9]{4,3}\$
OpenFDA fields	product_type	array of strings	
OpenFDA fields	route	array of strings	The route of administation of the drug product.
			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 fields	rxcui	array of strings	Values follow this pattern:
Openi DA neids	TACUI	array of strings	^[0-9]{6}\$ Unique identifier for a particular version of a Structured Product Label for a product. Also referred to as the document ID.
OpenFDA fields	spl_id	array of strings	Values follow this pattern: ^[a-fA-F0-9]{8}-[a-fA-F0-9]{4}-[a-fA-F0-9]{4}-[a-fA-F0-9]{4}-[a-fA-F0-9]{12}\$ 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 fields	spl_set_id	array of strings	Values follow this pattern:
OpenFDA fields	substance_name	array of strings	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 descriptive information.
			Values follow this pattern:
OpenFDA fields	unii	array of strings	^[A-Z0-9]{10}\$
OpenFDA fields	upc	array of strings	Universal Product Code
Other fields	laboratory_tests	string	Information on laboratory tests helpful in following the patient's response to the drug or in identifying possible adverse reactions. If appropriate, information may be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy. Information on laboratory tests helpful in following the patient's response to the drug or in identifying possible adverse reactions. If
Other Calds	laborator toda table		appropriate, information may be provided on such factors as the range of normal and abnormal values expected in the particular
Other fields	laboratory_tests_table	string	situation and the recommended frequency with which tests should be performed before, during, and after therapy. Documentation forthcoming.
Other fields	microbiology	string	Documentation forthcoming.
Other fields	microbiology_table	string	The content of the principal display panel of the product package, usually including the product's name, dosage forms, and other key
Other fields	package_label_principal_display_panel	string	information about the drug product. The content of the principal display panel of the product package, usually including the product's name, dosage forms, and other key The content of the principal display panel of the product package, usually including the product's name, dosage forms, and other key
Other fields	package_label_principal_display_panel_table	string	information about the drug product.
Other fields	recent_major_changes	string	A list of the section(s) that contain substantive changes that have been approved by FDA in the product labeling. The headings and subheadings, if appropriate, affected by the change are listed together with each section's identifying number and the month and year

			A list of the section(s) that contain substantive changes that have been approved by FDA in the product labeling. The headings and
Other fields	recent_major_changes_table	string	subheadings, if appropriate, affected by the change are listed together with each section's identifying number and the month and year
			Information not classified as belonging to one of the other fields. Approximately 40% of labeling with effective_time between June
Other fields	spl_unclassified_section	string	2009 and August 2014 have information in this field.
Other fields	spl_unclassified_section_table	string	Information not classified as belonging to one of the other fields. Approximately 40% of labeling with effective_time between June 2009 and August 2014 have information in this field.
other helds	spi_undassineu_section_tuble	3611116	Information about when a doctor should be consulted about existing conditions or sumptoms before using the drug product, including all
			warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain
Patient information	ask_doctor	string	symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until
Patient information	ask_doctor_or_pharmacist	string	Information about when a doctor or pharmacist should be consulted about drug/drug or drug/food interactions before using a drug
Patient information	ask_doctor_or_pharmacist_table	string	Information about when a doctor or pharmacist should be consulted about drug/drug or drug/food interactions before using a drug
			Information about when a doctor should be consulted about existing conditions or sumptoms before using the drug product, including all
Dationt information	ante dantan tahun		warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain
Patient information	ask_doctor_table	string	symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until Information about all contraindications for use. These contraindications are absolute and are intended for situations in which consumers
			should not use the product unless a prior diagnosis has been established by a doctor or for situations in which certain consumers should
Patient information	do_not_use	string	not use the product under any circumstances regardless of whether a doctor or health professional is consulted.
			Information about all contraindications for use. These contraindications are absolute and are intended for situations in which consumers
Dating the formation	de cele ce deble		should not use the product unless a prior diagnosis has been established by a doctor or for situations in which certain consumers should
Patient information	do_not_use_table	string	not use the product under any circumstances regardless of whether a doctor or health professional is consulted. Documentation forthcoming.
Patient information	information_for_owners_or_caregivers	string	· · · · · · · · · · · · · · · · · · ·
Patient information	information_for_owners_or_caregivers_table	string	Documentation forthcoming.
Patient information	information for patients	string	Information necessary for patients to use the drug safely and effectively, such as precautions concerning driving or the concomitant use of other substances that may have harmful additive effects.
Tatient miormation	mormation_tor_patients	3611116	Information necessary for patients to use the drug safely and effectively, such as precautions concerning driving or the concomitant use
Patient information	information_for_patients_table	string	of other substances that may have harmful additive effects.
Patient information	instructions_for_use	string	Information about safe handling and use of the drug product.
Patient information	instructions_for_use_table	string	Information about safe handling and use of the drug product.
			Information pertaining to whether the product should be kept out of the reach of children, and instructions about what to do in the
Patient information	keep_out_of_reach_of_children	string	case of accidental contact or ingestion, if appropriate.
Patient information	keep_out_of_reach_of_children_table	string	Information pertaining to whether the product should be kept out of the reach of children, and instructions about what to do in the
		_	case of accidental contact or ingestion, if appropriate. Information about safe use and handling of the product that may not have been specified in another field.
Patient information	other_safety_information	string	Information about safe use and handling of the product that may not have been specified in another field.
Patient information	other_safety_information_table	string	Information or instructions to patients about safe use of the drug product, sometimes including a reference to a patient medication
Patient information	patient_medication_information	string	
Patient information	patient_medication_information_table	string	Information or instructions to patients about safe use of the drug product, sometimes including a reference to a patient medication
Patient information	questions	string	A telephone number of a source to answer questions about a drug product. Sometimes available days and times are also noted.
Patient information	questions_table	string	A telephone number of a source to answer questions about a drug product. Sometimes available days and times are also noted.

Daticat information	onl modernido	atrina	Information about the patient medication guide that accompanies the drug product. Certain drugs must be dispensed with an
Patient information	spl_medguide	string	accompanying medication guide. This field may contain information about when to consult the medication guide and the contents of the
Patient information	spl_medguide_table	string	Information about the patient medication guide that accompanies the drug product. Certain drugs must be dispensed with an accompanying medication guide. This field may contain information about when to consult the medication guide and the contents of the
Patient information	spl patient package insert	string	Information necessary for patients to use the drug safely and effectively.
Patient information	spl patient package insert table	string	Information necessary for patients to use the drug safely and effectively.
	-b	g	Information about when use of the drug product should be discontinued immediately and a doctor consulted. Includes information about
Patient information	stop_use	string	any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product.
			Information about when use of the drug product should be discontinued immediately and a doctor consulted. Includes information about
Patient information	stop_use_table	string	any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product.
Patient information	when_using	string	Information about side effects that people may experience, and the substances (e.g. alcohol) or activities (e.g. operating machinery,
ratient information	when_using	String	driving a car) to avoid while using the drug product. Information about side effects that people may experience, and the substances (e.g. alcohol) or activities (e.g. operating machinery,
Patient information	when_using_table	string	driving a car) to avoid while using the drug product.
References	clinical studies	string	This field may contain references to clinical studies in place of detailed discussion in other sections of the labeling.
References	clinical studies table	string	This field may contain references to clinical studies in place of detailed discussion in other sections of the labeling.
		J	This field may contain references when prescription drug labeling must summarize or otherwise relay on a recommendation by an
References	references	string	authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to
			This field may contain references when prescription drug labeling must summarize or otherwise relay on a recommendation by an
References	references_table	string	authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to
Special populations	geriatric_use	string	Information about any limitations on any geriatric indications, needs for specific monitoring, hazards associated with use of the drug in
Special populations	geriatric_use_table	string	Information about any limitations on any geriatric indications, needs for specific monitoring, hazards associated with use of the drug in
			Information about the drug's use during labor or delivery, whether or not the use is stated in the indications section of the labeling,
			including the effect of the drug on the mother and fetus, on the duration of labor or delivery, on the possibility of delivery-related
Special populations	labor_and_delivery	string	interventions, and the effect of the drug on the later growth, development, and functional maturation of the child.
			Information about the drug's use during labor or delivery, whether or not the use is stated in the indications section of the labeling, including the effect of the drug on the mother and fetus, on the duration of labor or delivery, on the possibility of delivery-related
Special populations	labor_and_delivery_table	string	interventions, and the effect of the drug on the later growth, development, and functional maturation of the child.
Special populations	nursing mothers	string	Information about excretion of the drug in human milk and effects on the nursing infant, including pertinent adverse effects observed in
Special populations	nursing mothers table	string	Information about excretion of the drug in human milk and effects on the nursing infant, including pertinent adverse effects observed in
Special populations	nuising_mothers_tuble	String	Information about any limitations on any pediatric indications, needs for specific monitoring, hazards associated with use of the drug in
			any subsets of the pediatric population (such as neonates, infants, children, or adolescents), differences between pediatric and adult
Special populations	pediatric_use	string	responses to the drug, and other information related to the safe and effective pediatric use of the drug.
			Information about any limitations on any pediatric indications, needs for specific monitoring, hazards associated with use of the drug in
			any subsets of the pediatric population (such as neonates, infants, children, or adolescents), differences between pediatric and adult
Special populations	pediatric_use_table	string	responses to the drug, and other information related to the safe and effective pediatric use of the drug.
			Information about effects the drug may have on pregnant women or on a fetus. This field may be ommitted if the drug is not absorbed
Special populations	pregnancy	string	systemically and the drug is not known to have a potential for indirect harm to the fetus. It may contain information about the established pregnancy category classification for the drug. (That information is nominally listed in the teratogenic_effects field, but may
Special populations		string	Documentation forthcoming.
эремат роритаціона	pregnancy_or_breast_feeding	ou mg	······································

Special populations	pregnancy_or_breast_feeding_table	string	Documentation forthcoming.
			Information about effects the drug may have on pregnant women or on a fetus. This field may be ommitted if the drug is not absorbed
Special populations	pregnancy_table	string	systemically and the drug is not known to have a potential for indirect harm to the fetus. It may contain information about the established pregnancy category classification for the drug. (That information is nominally listed in the teratogenic_effects field, but may Pregnancy category A: Adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the
Special populations	teratogenic effects	string	first trimester of pregnancy, and there is no evidence of a risk in later trimesters. Pregnancy category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women. Pregnancy category C: Animal reproduction studies have shown an adverse effect on the fetus, there are no adequate and well-controlled studies in humans, and the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. Pregnancy category D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective). Pregnancy category X: Studies in animals or humans have demonstrated fetal abnormalities or there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug
	о <u>-</u>	J	Pregnancy category A: Adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy, and there is no evidence of a risk in later trimesters. Pregnancy category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women. Pregnancy category C: Animal reproduction studies have shown an adverse effect on the fetus, there are no adequate and well-controlled studies in humans, and the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. Pregnancy category D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective). Pregnancy category X: Studies in animals or humans have demonstrated fetal abnormalities or there is positive evidence of
Special populations	teratogenic_effects_table	string	fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug
Special populations	use_in_specific_populations	string	Information about use of the drug by patients in specific populations, including pregnant women and nursing mothers, pediatric
Special populations	use_in_specific_populations_table	string	Information about use of the drug by patients in specific populations, including pregnant women and nursing mothers, pediatric
Supply, storage, and handling	how_supplied	string	Information about the available dosage forms to which the labeling applies, and for which the manufacturer or distributor is responsible. This field ordinarily includes the strength of the dosage form (in metric units), the units in which the dosage form is available for prescribing, appropriate information to facilitate identification of the dosage forms (such as shape, color, coating, scoring, Information about the available dosage forms to which the labeling applies, and for which the manufacturer or distributor is responsible. This field ordinarily includes the strength of the dosage form (in metric units), the units in which the dosage form is
Supply, storage, and handling	how_supplied_table	string	available for prescribing, appropriate information to facilitate identification of the dosage forms (such as shape, color, coating, scoring,
Supply, storage, and handling	safe_handling_warning	string	Documentation forthcoming.
Supply, storage, and handling	safe_handling_warning_table	string	Documentation forthcoming.
Supply, storage, and handling	storage_and_handling	string	Information about safe storage and handling of the drug product.
Supply, storage, and handling	storage_and_handling_table	string	Information about safe storage and handling of the drug product.
Warnings and precautions	boxed_warning	string	Information about contraindications or serious warnings, particularly those that may lead to death or serious injury.
Warnings and precautions	boxed_warning_table	string	Information about contraindications or serious warnings, particularly those that may lead to death or serious injury.
Warnings and precautions	general_precautions	string	Information about any special care to be exercised for safe and effective use of the drug.

Warnings and precautions	general_precautions_table	string	Information about any special care to be exercised for safe and effective use of the drug.
Warnings and precautions	precautions	string	Information about any special care to be exercised for safe and effective use of the drug.
Warnings and precautions	precautions_table	string	Information about any special care to be exercised for safe and effective use of the drug.
Warnings and precautions	user_safety_warnings	string	When a drug can pose a hazard to human health by contact, inhalation, ingestion, injection, or by any exposure, this field contains information which can prevent or decrease the possibility of harm.
Warnings and precautions	user_safety_warnings_table	string	When a drug can pose a hazard to human health by contact, inhalation, ingestion, injection, or by any exposure, this field contains information which can prevent or decrease the possibility of harm.
Warnings and precautions	warnings	string	Information about serious adverse reactions and potential safety hazards, including limitations in use imposed by those hazards and steps that should be taken if they occur.
Warnings and precautions	warnings_table	string	Information about serious adverse reactions and potential safety hazards, including limitations in use imposed by those hazards and steps that should be taken if they occur.