<table>
<thead>
<tr>
<th>Section</th>
<th>Field Name</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse effects and interactions</td>
<td>adverse_reactions</td>
<td>string</td>
<td>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 reactions. They may be categorized by organ system, by severity of reaction, by frequency, by toxicological mechanism, or by a combination of these criteria. May include descriptions of particularly susceptible patient populations.</td>
</tr>
<tr>
<td>Adverse effects and interactions</td>
<td>adverse_reactions_table</td>
<td>string</td>
<td>Information about any known interference by the drug with laboratory tests.</td>
</tr>
<tr>
<td>Adverse effects and interactions</td>
<td>drug_and_or_laboratory_test_interactions</td>
<td>string</td>
<td>Information about and practical guidance on preventing clinically significant drug/drug and drug/food interactions that may occur in the presence of concomitant use of other drugs, and information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Adverse effects and interactions</td>
<td>drug_interactions</td>
<td>string</td>
<td>Information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Adverse effects and interactions</td>
<td>drug_interactions_table</td>
<td>string</td>
<td>Information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Clinical pharmacology</td>
<td>clinical_pharmacology</td>
<td>string</td>
<td>Information about the schedule in which the drug is controlled by the Drug Enforcement Administration, if applicable.</td>
</tr>
<tr>
<td>Clinical pharmacology</td>
<td>clinical_pharmacology_table</td>
<td>string</td>
<td>Information about the schedule in which the drug is controlled by the Drug Enforcement Administration, if applicable.</td>
</tr>
<tr>
<td>Clinical pharmacology</td>
<td>mechanism_of_action</td>
<td>string</td>
<td>Information about the established mechanism(s) of the drug's 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. Information about the clinical pharmacology and actions of the drug in humans.</td>
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<tr>
<td>Clinical pharmacology</td>
<td>mechanism_of_action_table</td>
<td>string</td>
<td>Information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Clinical pharmacology</td>
<td>pharmacodynamics</td>
<td>string</td>
<td>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 and the effects of abrupt withdrawal, and the general principles of overdose treatment.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>abuse</td>
<td>string</td>
<td>Information about the types of abuse that can occur with the drug and the adverse reactions pertinent to those types of abuse. 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.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>abuse_table</td>
<td>string</td>
<td>Information about the established mechanism(s) of the drug's 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. Information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>controlled_substance</td>
<td>string</td>
<td>Information about adverse effects and interactions that may occur in the presence of concomitant use of other drugs, and information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>controlled_substance_table</td>
<td>string</td>
<td>Information about the schedule in which the drug is controlled by the Drug Enforcement Administration, if applicable.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>dependence</td>
<td>string</td>
<td>Information about the types of abuse that can occur with the drug and adverse reactions pertinent to those types of abuse. 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.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>dependence_table</td>
<td>string</td>
<td>Information about adverse effects and interactions that may occur in the presence of concomitant use of other drugs, and information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>drug_abuse_and_dependence</td>
<td>string</td>
<td>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. Information about the types of abuse that can occur with the drug and adverse reactions pertinent to those types of abuse. Information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>drug_abuse_and_dependence_table</td>
<td>string</td>
<td>Information about adverse effects and interactions that may occur in the presence of concomitant use of other drugs, and information about the clinical pharmacology and actions of the drug in humans.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>overdosage</td>
<td>string</td>
<td>Information about signs, symptoms, and laboratory findings of acute overdose and the general principles of overdose treatment.</td>
</tr>
<tr>
<td>Abuse and overdosage</td>
<td>overdosage_table</td>
<td>string</td>
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</tr>
<tr>
<td>Abuse and overdosage</td>
<td>mechanism_of_action</td>
<td>string</td>
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</tr>
</tbody>
</table>
Indications, usage, and dosage

- **Clinical pharmacology**
  - pharmacodynamics_table
  - pharmacokinetics
  - pharmacokinetics_table

- **ID and version**
  - effective_time
  - id
  - set_id
  - version

- **Indications, usage, and dosage**
  - active_ingredient
  - active_ingredient_table
  - contraindications
  - contraindications_table
  - description
  - description_table
  - dosage_and_administration
  - dosage_and_administration_table
  - dosage_forms_and_strengths
  - dosage_forms_and_strengths_table
  - inactive_ingredient
  - inactive_ingredient_table
  - indications_and_usage
  - indications_and_usage_table
  - purpose

Information about the drug product’s indications for use, such as for the treatment, prevention, mitigation, cure, or diagnosis of a disease or condition, or for the relief of symptoms associated with a recognized disease or condition. This field may also describe any relevant limitations of use.

- Information about the clinically significant pharmacokinetics of a drug or active metabolites, for instance pertinent absorption, distribution, metabolism, and excretion parameters.

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- Date reference to the particular version of the labeling document.
  - The document ID, A globally unique identifier (GUID) for the particular revision of a labeling document.
  - The Set ID, A globally unique identifier (GUID) for the labeling, stable across all versions or revisions.
  - A sequentially increasing number identifying the particular version of a document, starting with 1.

- Information about situations in which the drug product is contraindicated or should not be used because the risk of use clearly outweighs any possible benefit, including the type and nature of reactions that have been reported.

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- 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 therapeutic class of the drug, and the chemical name and structural formula of the drug.

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- Information about the drug product’s dosage and administration recommendations, including starting dose, dose range, titration regimens, and any other clinically significant information that affects dosing recommendations.

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- Information about all available dosage forms and strengths for the drug product to which the labeling applies. This field may contain descriptions of product appearance.

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- A list of inactive, non-medicinal ingredients in a drug product.

- A list of the active, medicinal ingredients in the drug product.

- A list of the active, medicinal ingredients in the drug product.
The labeler manufacturer code and product code segments of the NDC number, separated by a hyphen.

OpenFDA fields
- product_ndc: array of strings
  Values follow this pattern: ^[0-9]{5,4}-[0-9]{4,3}$

OpenFDA fields
- product_type: array of strings
  The route of administration 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: ^[0-9]{6}$

OpenFDA fields
- 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.
  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}$

OpenFDA fields
- 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.
  Values follow this pattern: *[a-fA-F0-9]{10}$

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: ^[A-Z0-9]{10}$

OpenFDA fields
- unii: array of strings
  Universal Product Code
  Values follow this pattern: *[a-zA-9-0]{10}$

OpenFDA fields
- upc: array of strings

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.

Other fields
- laboratory_tests_table: string
  Documentation forthcoming.

Other fields
- microbiology: string
  The content of the principal display panel of the product package, usually including the product’s name, dosage forms, and other key information about the drug product.

Other fields
- microbiology_table: string
  Documentation forthcoming.

Other fields
- package_label_principal_display_panel: string
  The content of the principal display panel of the product package, usually including the product’s name, dosage forms, and other key information about the drug product.

Other fields
- package_label_principal_display_panel_table: 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.

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 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.

Information about when a doctor should be consulted about existing conditions or symptoms before using the drug product, including all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until information about when a doctor or pharmacist should be consulted about drug/drug or drug/food interactions before using a drug product.

Information about when a doctor or pharmacist should be consulted about drug/drug or drug/food interactions before using a drug product.

Information about when a doctor should be consulted about existing conditions or symptoms before using the drug product, including all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain 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 not use the product under any circumstances regardless of whether a doctor or health professional is consulted.

Information about when a doctor should be consulted about existing conditions or symptoms before using the drug product, including all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain 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 not use the product under any circumstances regardless of whether a doctor or health professional is consulted.

Documentation forthcoming.

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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.

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Information about safe handling and use of the drug product.

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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.

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A telephone number of a source to answer questions about a drug product. Sometimes available days and times are also noted.

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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 information necessary for patients to use the drug safely and effectively.

Information about when use of the drug product should be discontinued immediately and a doctor consulted. Includes information about 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 any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product.

Information about any limitations on any pediatric indications, needs for specific monitoring, hazards associated with use of the drug in the geriatric population.

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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 interventions, and the effect of the drug on the later growth, development, and functional maturation of the child.

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Information about side effects that people may experience, and the substances (e.g. alcohol) or activities (e.g. operating machinery, driving a car) to avoid while using the drug product.

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<table>
<thead>
<tr>
<th>Special populations</th>
<th>pregnancy_or_breast_feeding_table</th>
<th>string</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special populations</td>
<td>pregnancy_table</td>
<td>string</td>
</tr>
<tr>
<td>Special populations</td>
<td>teratogenic_effects</td>
<td>string</td>
</tr>
</tbody>
</table>

Documentation forthcoming.

Information about effects the drug may have on pregnant women or on a fetus. This field may be omitted if the drug is not absorbed 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 be omitted.)

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 fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

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 fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

Information about use of the drug by patients in specific populations, including pregnant women and nursing mothers, pediatric patients, and geriatric patients.

Information about how the drug is supplied, including 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, 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 be omitted.)

Information about effects the drug may have on pregnant women or on a fetus. This field may be omitted if the drug is not absorbed 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 be omitted.)

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 fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

Information about use of the drug by patients in specific populations, including pregnant women and nursing mothers, pediatric patients, and geriatric patients.

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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, 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 be omitted.)

Information about effects the drug may have on pregnant women or on a fetus. This field may be omitted if the drug is not absorbed 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 be omitted.)

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 fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

Information about use of the drug by patients in specific populations, including pregnant women and nursing mothers, pediatric patients, and geriatric patients.

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Information about any special care to be exercised for safe and effective use of the drug.

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.

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.