# OpenFDA Data Fields for Drugs

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| Limits of openFDA harmonization Not all records have harmonized fields. Because the harmonization process requires an exact match, some drug products cannot be harmonized in this fashion—for instance, if the drug name is misspelled. Some drug products will have **openfda** sections, while others will never, if there was no match during the harmonization process. Conversely, searching in these fields will only return a subset of records from a given endpoint. |

**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.

Values follow this pattern

^[BLA|ANDA|NDA]{3,4}[0-9]{6}$

### brand\_name

array of strings

Brand or trade name of the drug product.

### generic\_name

array of strings

Generic name(s) of the drug product.

### is\_original\_packager

string

Whether or not the drug has been repackaged for distribution.

This is an .exact field. It has been indexed both as its exact string content, and also tokenized.

* search=is\_original\_packager:"FOO+BAR"  
  Searches for records where either FOO or BAR appear anywhere in this field.
* search=is\_original\_packager.exact:"FOO+BAR"  
  Searches for records where exactly and only FOO BAR appears in this field.
* count=is\_original\_packager  
  Counts the tokenized values of this field. Instances of FOO and BAR are counted separately.
* count=is\_original\_packager.exact  
  Counts the exact values of this field. FOO BAR, BAR FOO, FOO, and BAR would all be counted separately, along with other combinations that contain these terms.

### manufacturer\_name

array of strings

Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC.

### nui

array of strings

Unique identifier applied to a drug concept within the National Drug File Reference Terminology (NDF-RT).

Fore more information, see [NDF-RT](https://www.nlm.nih.gov/research/umls/sourcereleasedocs/current/NDFRT/)

Values follow this pattern

^[N][0-9]{10}$

### original\_packager\_product\_ndc

array of strings

This ndc identifies the original packager.

Values follow this pattern

^[0-9]{5,4}-[0-9]{4,3}-[0-9]{1,2}$

### package\_ndc

array of strings

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

^[0-9]{5,4}-[0-9]{4,3}-[0-9]{1,2}$

### 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].

### 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].

### 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].

### 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].

### product\_ndc

array of strings

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

Values follow this pattern

^[0-9]{5,4}-[0-9]{4,3}$

### product\_type

array of strings

Fore more information, see [Type of drug product](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162063.htm)

### route

array of strings

The route of administation of the drug product.

Fore more information, see [Route of administration](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm)

### rxcui

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.

Fore more information, see [RxNorm and RxCUI documentation](https://www.nlm.nih.gov/research/umls/rxnorm/docs/2012/rxnorm_doco_full_2012-3.html" \t "_blank)

Values follow this pattern

^[0-9]{6}$

### 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}$

### 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]{8}-[a-fA-F0-9]{4}-[a-fA-F0-9]{4}-[a-fA-F0-9]{4}-[a-fA-F0-9]{12}$

### substance\_name

array of strings

The list of active ingredients of a drug product.

### 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.

Fore more information, see [Unique Ingredient Identifiers](http://fdasis.nlm.nih.gov/srs/srs.jsp)

Values follow this pattern

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