| Section | Field Name | Type | Description |
|---|---|---|---|
| Active Ingredients | name | string | The names of the active, medicinal ingredients in the drug product. |
| Active Ingredients | strength | string | The strength of the active, medicinal ingredients in the drug product. |
| | dosage_form | string | The drug's dosage form. There is no standard, but values may include terms like `tablet` or `solution for injection`. |
| | route | string | The route of administation of the drug product. |
| | brand_name | string | Brand or trade name of the drug product. |
| | applicant_number | string | Name of the Applicant for the drug product. |
| | applicant_full_name | string | The full name of the firm holding legal responsibility for the new drug application. |
| | application_type | string | The type of new drug application approval. |
| | application_number | string | The FDA assigned number to the application. |
| | product_number | string | The FDA assigned number to identify the application products. Each strength is a separate |
| | therapeutic_equivalence_codes | string | The TE Code indicates the therapeutic equivalence rating of generic to innovator Rx |
| | approval_date | string | The date the product was approved as stated in the FDA approval letter to the applicant. |
| | approved_prior_to_1982 | string | Products approved prior to the January 1, 1982 contain the phrase: "Approved prior to Jan 1, |
| | reference_listed_drug | string | he RLD is a drug product approved under section 505(c) of the FD&C Act for which FDA has made a finding of safety and effectiveness. In the electronic Orange Book, an RLD is identified by "RLD" in the RLD column. |
| | product_type | string | The group or category of approved drugs. |
| patents | patent_number | string | Patent numbers as submitted by the applicant holder for patents covered by the statutory |
| patents | expire_date | string | The date the patent expires as submitted by the applicant holder including applicable |
| patents | drug_substance_flag | string | Patents submitted on FDA Form 3542 and listed after August 18, 2003 may have a drug |
| patents | drug_product_flag | string | Patents submitted on FDA Form 3542 and listed after August 18, 2003 may have a drug |
| patents | patent_use_code | string | Code to designate a use patent that covers the approved indication or use of a drug product. |
| patents | patent_delist_flag | string | Sponsor has requested patent be delisted. This patent has remained listed because, under |
| patents | patent_submission_date | string | The date on which the FDA receives patent information from the new drug application |
| exclusivity | exclusivity_code | string | Code to designate exclusivity granted by the FDA to a drug product. |
| exclusivity | exclusivity_expire_date | string | The date the exclusivity expires. |