

<https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files>

Data Descriptions

1. Products.txt

- **Ingredient**

The active ingredient(s) for the product. Multiple ingredients are in alphabetical order, separated by a semicolon.

- **Dosage form; Route of Administration**

The product dosage form and route separated by a semi-colon. The format is not all uppercase.

- **Trade Name**

The trade name of the product as shown on the labeling.

- **Applicant**

The firm name holding legal responsibility for the new drug application. The firm name is condensed to a maximum twenty character unique string.

- **Strength**

The potency of the active ingredient. May repeat for multiple part products.

- **New Drug Application Type**

The type of new drug application approval. New Drug Applications (NDA or innovator) are "N". Abbreviated New Drug Applications (ANDA or generic) are "A".

- **New Drug Application (NDA) Number**

The FDA assigned number to the application. Format is nnnnnn.

- **Product Number**

The FDA assigned number to identify the application products. Each strength is a separate product. May repeat for multiple part products. Format is nnn.

- **Therapeutic Equivalence (TE) Code**

The TE Code indicates the therapeutic equivalence rating of generic to innovator Rx products.

- **Approval Date**

- The date the product was approved as stated in the FDA approval letter to the applicant. The format is Mmm dd, yyyy. Products approved prior to the January 1, 1982 contain the phrase: "Approved prior to Jan 1, 1982".
- **Reference Listed Drug (RLD)**
The 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.
- **Reference Standard (RS)**
A "reference standard" is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval of an ANDA. In the electronic Orange Book, a reference standard is identified by "RS" in the RS column.
- **Type**
The group or category of approved drugs. Format is RX, OTC, DISCN.
- **Applicant Full Name**
The full name of the firm holding legal responsibility for the new drug application.

2. Patent.txt

- **New Drug Application Type**
The type of new drug application approval. New Drug Applications (NDA or innovator) are "N". Abbreviated New Drug Applications (ANDA or generic) are "A".
- **New Drug Application (NDA) Number**
The FDA assigned number to the application. Format is nnnnnn.
- **Product Number**
The FDA assigned number to identify the application products. Each strength is a separate product. May repeat for multiple part products. Format is nnn.
- **Patent Number**
Patent numbers as submitted by the applicant holder for patents covered by the statutory provisions. May repeat for multiple applications and multiple products. Includes pediatric exclusivity granted by the agency. Format is nnnnnnnnnnn.

- **Patent Expire Date**

The date the patent expires as submitted by the applicant holder including applicable extensions. The format is MMM DD, YYYY.

- **Drug Substance Flag**

Patents submitted on FDA Form 3542 and listed after August 18, 2003 may have a drug substance flag indicating the sponsor submitted the patent as claiming the drug substance. Format is Y or null.

- **Drug Product Flag**

Patents submitted on FDA Form 3542 and listed after August 18, 2003 may have a drug product flag indicating the sponsor submitted the patent as claiming the drug product. Format is Y or null.

- **Patent Use Code**

Code to designate a use patent that covers the approved indication or use of a drug product. May repeat for multiple applications, multiple products and multiple patents. Format is nnnnnnnnnn.

- **Patent Delist Request Flag**

Sponsor has requested patent be delisted. This patent has remained listed because, under Section 505(j)(5)(D)(i) of the Act, a first applicant may retain eligibility for 180-day exclusivity based on a paragraph IV certification to this patent for a certain period. Applicants under Section 505(b)(2) are not required to certify to patents where this flag is set to Y. Format is Y or null.

- **Patent Submission Date**

The date on which the FDA receives patent information from the new drug application (NDA) holder. Format is Mmm d, yyyy

3. Exclusivity.txt

- **New Drug Application Type**

The type of new drug application approval. New Drug Applications (NDA or innovator) are "N". Abbreviated New Drug Applications (ANDA or generic) are "A".

- **New Drug Application (NDA) Number**

The FDA assigned number to the application. Format is nnnnnn.

- **Product Number**

The FDA assigned number to identify the application products. Each strength is a separate product. May repeat for multiple part products. Format is nnn.

- **Exclusivity Code**

Code to designate exclusivity granted by the FDA to a drug product. Format is nnnnnnnnnn.

- **Exclusivity Date**

The date the exclusivity expires. Format is MMM DD, YYYY.