**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.

**My notes:** For example, one product can have multiple strengths (Amoxicillin 100 mg or Amoxicillin 50 mg for the kids version). Different strengths have different product numbers, however, they constitute one single NDA or ANDA. One product may be constituted by different parts, for example, an inhaler (device + canister). Both parts share product number, they are considered just one product.

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

**My Notes:** Each type of exclusivity has its own code (See Patents-and-Exclusivity-May-19--2015-Issue.pdf).

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

**FDA Post-Approval Exclusivity Codes**

| **Exclusivity Code** | **Type** | **Duration** | **Description** |
| --- | --- | --- | --- |
| **NCE** | New Chemical Entity Exclusivity | **5 years** | Granted for a **new active moiety** (never before approved by FDA). Blocks the **filing** of ANDA or 505(b)(2) for 5 years (or 4 years if a Paragraph IV certification is filed). |
| **PED** | Pediatric Exclusivity | **6 months** | Adds **6 months** to any existing exclusivity or patent protection if the company conducts **pediatric studies** requested by the FDA. |
| **ODE** | Orphan Drug Exclusivity | **7 years** | Granted for drugs treating **rare diseases** (affecting <200,000 people in the U.S.). Blocks **approval** of similar drugs for the same indication. |
| **NDF** | New Dosage Form Exclusivity | **3 years** | Granted for a **new dosage form** of a previously approved active ingredient (e.g., changing from tablet to liquid). Requires **new clinical trials**. |
| **NCB** | New Combination Exclusivity | **3 years** | Granted for a **new combination** of previously approved active ingredients when clinical trials are required. |
| **I** | New Indication Exclusivity | **3 years** | Granted for a **new therapeutic use** of a previously approved drug when supported by new clinical trials. |
| **D** | New Delivery System Exclusivity | **3 years** | Granted for a **new route of administration** or **delivery system** (e.g., switching from oral to transdermal patch). |
| **RTO** | New Route of Administration | **3 years** | Granted when a drug is approved for **a different administration route** (e.g., IV to oral) and requires new clinical trials. |
| **O** | Other Exclusivity | **3 years** | Covers any **other significant change** that required new clinical trials (e.g., new dosing regimen, reformulation). |
| **DES** | Designated Drug Exclusivity | **7 years** | Similar to **ODE**, but typically used for **drugs receiving special status under health programs**. |
| **FDAAA** | FDA Amendments Act Exclusivity | **3 years** | Exclusivity under **special FDA programs**, often linked to safety studies. |

**Key Notes:**

* **5-Year NCE exclusivity** is the strongest—it **prevents generic applications from even being filed** for 5 years.
* **3-Year exclusivities (NDF, NCB, I, D, RTO, O)** apply when the drug requires **new clinical trials** but does **not** contain a new active moiety.
* **Pediatric Exclusivity (PED)** extends **any** exclusivity or patent protection by 6 months.
* **Orphan Drug Exclusivity (ODE)** grants **7 years** of market protection for rare disease treatments.

When **exclusivity is granted** while the **patent is still active**, the NDA applicant benefits in several ways, as the exclusivity and patent provide **complementary protections**. Here's how:

**1️⃣ Blocking Generic Competition More Effectively**

* **Exclusivity (FDA-based protection):**
  + Prevents the FDA from **approving or even reviewing** generic (ANDA) or 505(b)(2) applications for a set period.
  + Works **independently** of patents.
* **Patent (Legal protection):**
  + Prevents generics from **launching** the drug unless they successfully **challenge the patent** in court.
  + Allows the NDA holder to **sue** generic manufacturers for patent infringement.

✅ **Benefit:** If an NDA applicant holds both exclusivity and an active patent, **generics are blocked from both filing applications and launching the product, maximizing market control**.

**2️⃣ Delaying Generic Entry Even After Exclusivity Ends**

Even if **exclusivity expires**, a strong **patent portfolio** can still prevent generic entry.

🔹 **Example Scenario:**

* **Drug approval:** Jan 1, 2025
* **NCE Exclusivity (5 years) expires:** Jan 1, 2030
* **Patent expires:** Jan 1, 2040

**What happens?**

* Until **Jan 1, 2030** → **FDA cannot accept generic applications** due to **NCE exclusivity**.
* After **Jan 1, 2030** → Generics **can file** ANDAs, but if patents are still valid until **2040**, they must either:
  + Wait until **2040** to launch, OR
  + **Challenge the patents in court (Paragraph IV certification)**—which can take years.

✅ **Benefit:** Even after exclusivity ends, **patents extend market exclusivity for years, keeping generics out**.

**3️⃣ Extending Revenue Maximization**

* During the **exclusivity period**, the NDA holder enjoys **premium pricing** without generic competition.
* Even after exclusivity ends, **patents prevent generics from launching**, allowing continued revenue from **branded sales**.
* This is **especially useful if multiple exclusivities apply** (e.g., **NCE + Pediatric Exclusivity** adds 6 more months).

✅ **Benefit:** **More time to recoup R&D costs and maximize profits** before generic erosion starts.

**4️⃣ Patent Linkage in the Orange Book**

* NDA holders **list patents in the FDA's Orange Book**.
* If a generic company **files a Paragraph IV certification** challenging a listed patent, the NDA holder gets an **automatic 30-month stay** of FDA approval while the patent lawsuit is resolved.

✅ **Benefit:** **Further delays generic competition** even after exclusivity ends.

**🔹 Conclusion:**

When **both exclusivity and patents overlap**, the NDA holder benefits from **multiple layers of protection**, keeping generics out for as long as possible and **maximizing market exclusivity & profits**. 🚀