Purple Book Info Sheet

Level 1: Biosimilar Foundational Concepts

Navigating the Purple Book Database of Licensed Biological Products

The Purple Book is an online, searchable database that contains information about FDA-licensed (approved) biological products (biologics). Examples of biologics include therapeutic proteins (e.g., insulins, monoclonal antibodies, growth factors, enzymes), and other types of products such as allergenic products (e.g., allergen extracts, allergen patch tests), cellular and gene therapies, and vaccines. The Purple Book also contains information about whether there are any licensed biosimilar and interchangeable products for a given reference product.

Figure 1: Assessing the FDA's Purple Book

Conducting a Simple Search

Simple Search function is found on the Purple Book homepage. To conduct a search, enter the proprietary (brand) or nonproprietary (proper) name of a biological product into the search bar (**Figure 2**). As the search term is typed, a list of potential results will begin to appear. The list includes each product's brand/proprietary name, proper name, and Biologics License Application (BLA) number. This quick view also includes the license type of each application that indicates which regulatory pathway each product is licensed under, either Section 351(a) (reference products) or 351(k) (biosimilar or interchangeable biosimilar products) of the Public Health Service Act. Click on any product from the auto-populated results to learn more about that selected product.
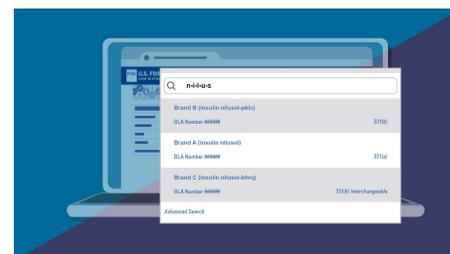

Figure 2: Using the Purple Book Simple Search

The Simple Search Results page for the selected product includes all products that share a core name, including biosimilar and interchangeable biosimilar products, reference products, and related biological products. The core name is the component shared among biological products, as part of the proper names. Two examples of a core name are "filgrastim" and "epoetin alfa." Each product card displays useful information, such as the product's brand/proprietary and proper name as well as an icons indicating the approved product presentations (e.g., autoinjector, multi-dose or single-dose vial, prefilled syringe; **Figure 3**). Hover over this icon to view information about the product's strengths, dosage forms, routes of administration, and product presentation. Click on the product name to view the Product Details page that contains additional information about the original approval date, applicant, and marketing status. To view product labeling, select the "Product Label" link, if available, associated with each product in the database. This link directs users to additional sources a healthcare provider may find useful when prescribing or dispensing a product. For example, links to Drugs@FDA include patient information, labels, approval letters, reviews, and other information on FDA-approved biologics.

STRENGTH
1,000UNITS/10ML (100UNITS/ML)
300UNITS/3ML (100UNITS/ML)

DOSAGE FORM
Injection

ROUTE OF ADMINISTRATION
Subcutaneous

PRODUCT PRESENTATION
Multi-Dose Vial
Autoinjector
Multi-Dose Cartridge

Proprietary Name
Brand B

Proper Name
insulin nilusni-bhrq

PRODUCT LABEL

Figure 3: Example of Simple Search Results
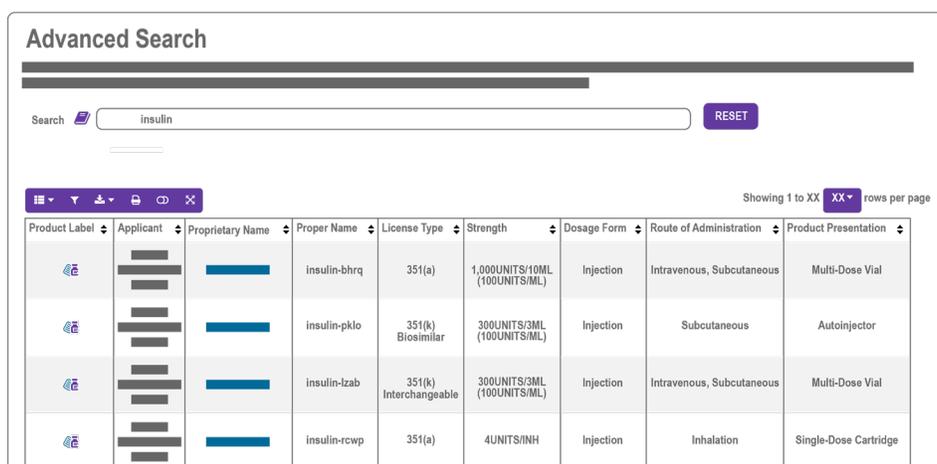
Purple Book Advanced Search

For more specific or flexible search options, the Purple Book also includes an Advanced Search function. Access the Advanced Search using the link found directly under the Simple Search box on the Purple Book homepage. The Advanced Search allows users to include multiple search terms in the search box by using a space between each search term.

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The table below the search box will populate in real time with results based on the search terms entered (**Figure 4**). In the table view, users can apply additional filters ([filter icon]) to include only the most relevant search results based on a wide range of characteristics (e.g., applicant, brand or proper name, license type, and strength). Another feature allows users to show additional columns or hide currently visible columns ([columns icon]) to view only those that are of interest. Users can download the table results, including the applied filters and applicable data, in formats like Excel and PDF ([download icon]).

Advanced Search

Search: insulin   RESET

Showing 1 to XX   XX ▾ rows per page

Product Label	Applicant	Proprietary Name	Proper Name	License Type	Strength	Dosage Form	Route of Administration	Product Presentation
			insulin-bhrq	351(a)	1,000UNITS/10ML (100UNITS/ML)	Injection	Intravenous, Subcutaneous	Multi-Dose Vial
			insulin-pklo	351(k) Biosimilar	300UNITS/3ML (100UNITS/ML)	Injection	Subcutaneous	Autoinjector
			insulin-lzab	351(k) Interchangeable	300UNITS/3ML (100UNITS/ML)	Injection	Intravenous, Subcutaneous	Multi-Dose Vial
			insulin-rcwp	351(a)	4UNITS/INH	Injection	Inhalation	Single-Dose Cartridge

Figure 4: Example Results from an Advanced Search

> FDA maintains up-to-date information in the Purple Book to reflect newly approved biological products and changes to already-approved products. Data in the Purple Book are updated regularly, making it a great resource for timely information about approved biologics, including biosimilar and interchangeable biosimilar products.

Additional Purple Book Features

Purple Book Homepage

About Purple Book

User Guide

FAQs

Patent List

Download Purple Book Data

Figure 5: Purple Book Resources

The **Purple Book Glossary** is accessible from any page on the Purple Book and includes definitions of terms included across the site.

The navigation bar on left side of the screen (**Figure 5**) includes additional links of interest.

User Guide: Instructions on how to use core features of the Purple Book

Frequently Asked Questions: Answers to common questions about the content found in the Purple Book

Patent List: Published patent lists provided by reference product sponsors for certain licensed biological products

Download Purple Book Data: Monthly reports that can be exported in CSV, Excel, and other formats. The monthly reports are divided into two sections: the top section lists the changes that occurred during that month and the bottom section contains all products in the database for that month, including the products listed in the top section that were added or changed.