



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0437]

Purple Book Enhancement; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announced the completion of the first phase of the enhanced Purple Book on February 24, 2020. FDA is transitioning the current table format “Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations” to a searchable, public-facing online database entitled “Purple Book: Database of FDA-Licensed Biological Products.” FDA is establishing a docket for public comment to gather stakeholder feedback on the new database to inform the next phase of development.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. FDA is establishing a docket for public comment. The docket number is FDA-2020-N-0437. The docket will close on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2020-N-0437 for “Purple Book Enhancement; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leila Hann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1141, Silver Spring, MD 20993, 301-796-3367, leila.hann@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, stephen.ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the completion of the first phase of the enhancement of the “Purple Book: Database of FDA-Licensed Biological Products” (Purple Book) on February 24, 2020, transitioning the current table format “Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations” to a searchable, public-facing online database (available on the FDA website at <https://purplebooksearch.fda.gov/>).

As part of FDA’s commitment to encouraging innovation and competition among biological products and the development of biosimilars, and to fulfill goals described in the letter entitled “Biosimilar Biological Product Reauthorization Performance Goals and Procedures

Fiscal Years 2018 Through 2022,” (available on the FDA website at <https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf>) and commitments described in the Biosimilar Action Plan (available on the FDA website at <https://www.fda.gov/media/114574/download>), FDA has created the Purple Book database. The new database provides the public with timely information about FDA-licensed biological products, including biosimilar and interchangeable products, through a dynamic, accessible, easy-to-use online search engine. This expanded Purple Book will offer more information about approved biological products, including information about whether a biological product is a reference product for a licensed biosimilar or interchangeable product, in a user-friendly format to help users quickly identify FDA-approved biosimilar and interchangeable products.

The initial Purple Book Version 1.0 announced on February 24, 2020 contains a limited data set that includes all approved biosimilars products and their related reference products, with simple search and advanced search functionality. The goal of the initial release is to gather stakeholder feedback and conduct user testing on the new database to inform the next phases of development. FDA intends to release additional phased enhancements to the database. Taking user testing and stakeholder input into consideration, the enhanced Purple Book is expected ultimately to include all Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) regulated biological products, including transition products, in addition to enhanced functionality. A later release of the enhanced Purple Book will include determinations that have been made pertaining to exclusivity.

The new Purple Book database is intended to improve transparency and functionality for stakeholders by providing a complete view of biological product options, including biosimilar

and interchangeable products, and to advance public awareness about licensed biological products.

FDA is committed to making the Purple Book database interactive, user-friendly, and functional for multiple stakeholders with varying information needs. FDA is publishing this *Federal Register* notice and opening a docket to gather public comment on this version of the database. At the close of the comment period, the Agency will collect this feedback for consideration as additional functionality and improvements are developed and implemented.

FDA welcomes any relevant information that stakeholders and other members of the public wish to share. FDA is particularly interested in input on how the Agency can improve the Purple Book database in future releases, including on the questions set forth below.

1. How user-friendly is the information in the new Purple Book database?
 - a. Are navigation resources and instructions user-friendly?
 - b. Do the definitions and hover overs (information available when a person positions a computer cursor over an image or icon without selecting it) assist in your understanding?
2. Does the new Purple Book database help improve understanding of available biological product options among patients, payors, clinicians, and other parties?
 - a. What additional information or modifications could improve understanding about available biological product options?
3. Which functionalities of the new database are most useful to patients, payors, clinicians, and other parties (e.g., simple search results, advanced search results, hover over definitions, monthly historical data change reports, data download capabilities)?

- a. Which aspects of the simple search functionality are most useful for navigating the database and which need improvement?
 - b. Which aspects of the advanced search functionality are most useful for navigating the database and which need improvement?
 - c. What other modifications or enhancements could improve the new database's functionality or usability?
4. Are there other types of information or functionalities that would be useful to include in the Purple Book database?

II. Electronic Access

Persons with access to the internet may access the Purple Book at

<https://purplebooksearch.fda.gov/>.

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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