



# Orange Book: Looking Towards the Future

**CAPT Kendra Stewart, R.Ph., Pharm.D.**  
**Office of Generic Drug Policy**  
**Supervisor, Orange Book Staff**

A thick, horizontal blue brushstroke with a textured, painterly appearance, spanning the width of the slide. The stroke has irregular edges and some darker blue areas, giving it a hand-painted look.

# Looking towards the future....

***A vision of Orange Book's future  
would not be possible without  
understanding Orange Book of the past***

# Orange Book: Looking towards the future...



- The provision of timely and accurate information about approved drugs supports the FDA's priority of facilitating the efficient development and approval of generic drug products and fostering competition in the marketplace
- As we celebrate the 40<sup>th</sup> anniversary of the first official publication of the Orange Book, a highly utilized resource, we want to ensure that it provides as much value as possible to those that rely on it, including patients, health care professionals, students, and the regulated industry

# 2020 and beyond: Orange Book Modernization



- Publication of the Draft Guidance “Orange Book Questions and Answers”
- Final guidance: Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format, published August 11, 2020
- Publication of two public Orange Book-focused dockets – Request for Comments
  - [Approved Drug Products With Therapeutic Equivalence Evaluations \(the “Orange Book”\); Establishment of a Public Docket; Request for Comments](#)
  - [Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments](#)

# Common reasons people use the Orange Book



- Substitution-related decisions
- Search for specific drug products – including for marketing status information, therapeutic equivalence (i.e., substitutability of approved drug products), patent information, and exclusivity information
- In consideration of purchasing and inventory needs for pharmacies
- Educational needs

**DISCLAIMER:**

***DISCUSSION OF DOCKET COMMENTS IN THIS PRESENTATION DOES NOT INDICATE FDA AGREEMENT WITH THOSE COMMENTS NOR INTENTION BY THE FDA TO ADOPT THE PROVIDED SUGGESTIONS.***

# Orange Book: Establishment of a Public Docket



## Sample Comments (see [FDA-2020-N-1069](#)):

- Therapeutic Equivalence (TE) Codes – do not find the second letter of the code valuable
- Enhance TE code evaluations for 505(b)(2)s
- Add TE codes to OTC products
- Include manufacturing quality as a part of the evaluation of TE code recommendations
- Include all medications approved since the establishment-of the Federal Food, Drug and Cosmetic (FD&C) Act and not just the medications marketed since the initial publication of the Orange Book



# Orange Book: Establishment of a Public Docket



## **Sample Comments – *Cont'd* (see [FDA-2020-N-1069](#)):**

- The paper and PDF publications of the Orange Book should reflect the same information
- Products approved under a suitability petition should be clearly identified in the Orange Book
- Identify distinct products in the Orange Book (including parenteral products)
- Differentiate between discontinued and withdrawn applications
- Create a separate section for drug product approvals that include digital applications



# Listing of Patent Information in the Orange Book Docket



## **Sample Comments (see [Docket FDA-2020-N-1127](#)):**

- Limit the time in which late listed patents could be included in the Orange Book
- FDA should continue to play a ministerial role with respect to patent listing
- Convene public meetings or workshops to discuss patent listings with stakeholders

# Listing of Patent Information in the Orange Book Docket



## **Sample Comments -*Cont'd* (see [Docket FDA-2020-N-1127](#)):**

- Make clearer the rules for listing patents claiming drug-device combinations
- Limit scenarios in which patents for digital applications could be included in the Orange Book
- FDA should/should not accept REMS-related patents for listing in the Orange Book

# Other Proposed Orange Book Enhancements



- **Website**

- Addition of more detailed Method of Use Information
- Enhanced search capabilities and filters
- Addition of reference listed drug information to ANDA listings

- **Orange Book Publication**

- Overhaul of the Orange Book Preface
- Modernize the format of the Orange Book Publication


- **Transparency**

- Additional Orange Book related MAPPs and/or guidance's to ensure clear communication to industry

# Summary



- Stakeholders refer to the Orange Book for a wide range of information
- The FDA is interested in information or features that could be incorporated in the Orange Book to increase its usefulness
- The feedback we receive from our public dockets will be utilized as we consider how to further enhance the Orange Book publication



***The future of the Orange Book  
is very bright...***

