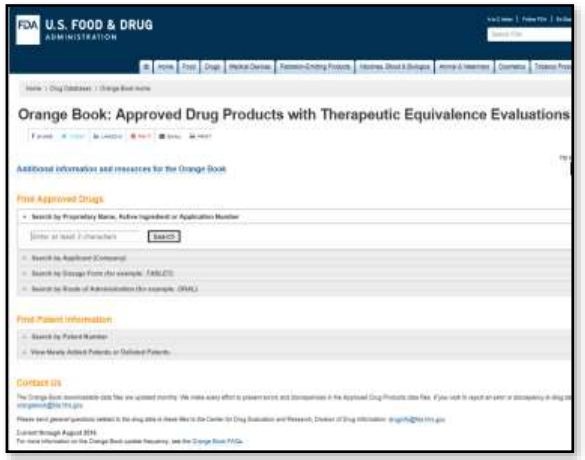
Resources Available on the Orange Book Website



Truong Quach, PharmD
Acting Team Lead, Pharmacist
Division of Orange Book Publication and Regulatory Assessment
Office of Generic Drug Policy
CDER U.S. FDA

SBIA Generic Drug Form, April 12-13, 2023

AGENDA

- Orange Book overview
- How to navigate the Orange Book website
- Orange Book information and resources

Overview of the Orange Book

- List of ***safe*** and ***effective*** Drug products approved under Section 505(c) and 505(j)(7)(A) of the Federal Food Drug and Cosmetic Act (FD&C Act)
- Contains information on which drug products can be substituted for another

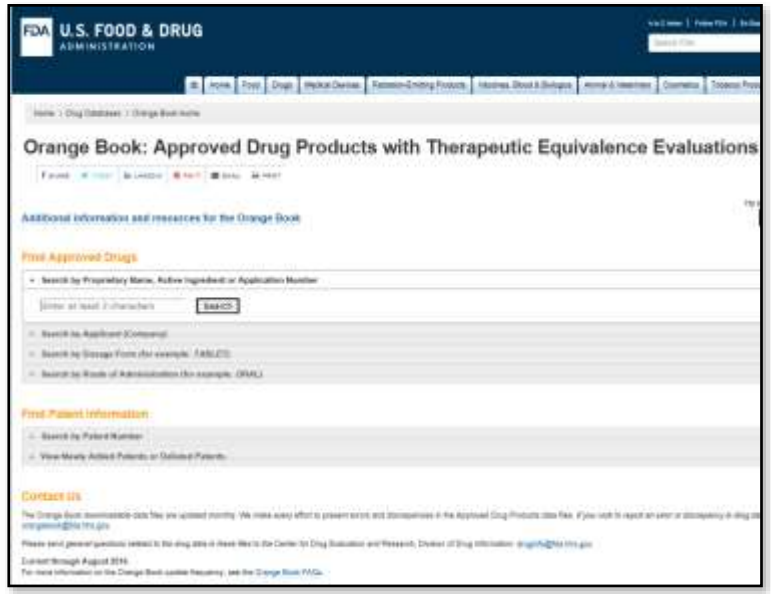
Information Not Included in the Orange Book

- Drugs not approved for both safety and effectiveness
  - Pre-1938 drugs not subject to pre-market clearance procedures
  - Drug products marketed between 1938 and 1962 that have not completed the Drug Efficacy Study Implementation (DESI) process
- Unapproved products e.g., compounded products, OTCs marketed under monograph, and dietary supplements
- Biologics License Applications (BLAs)

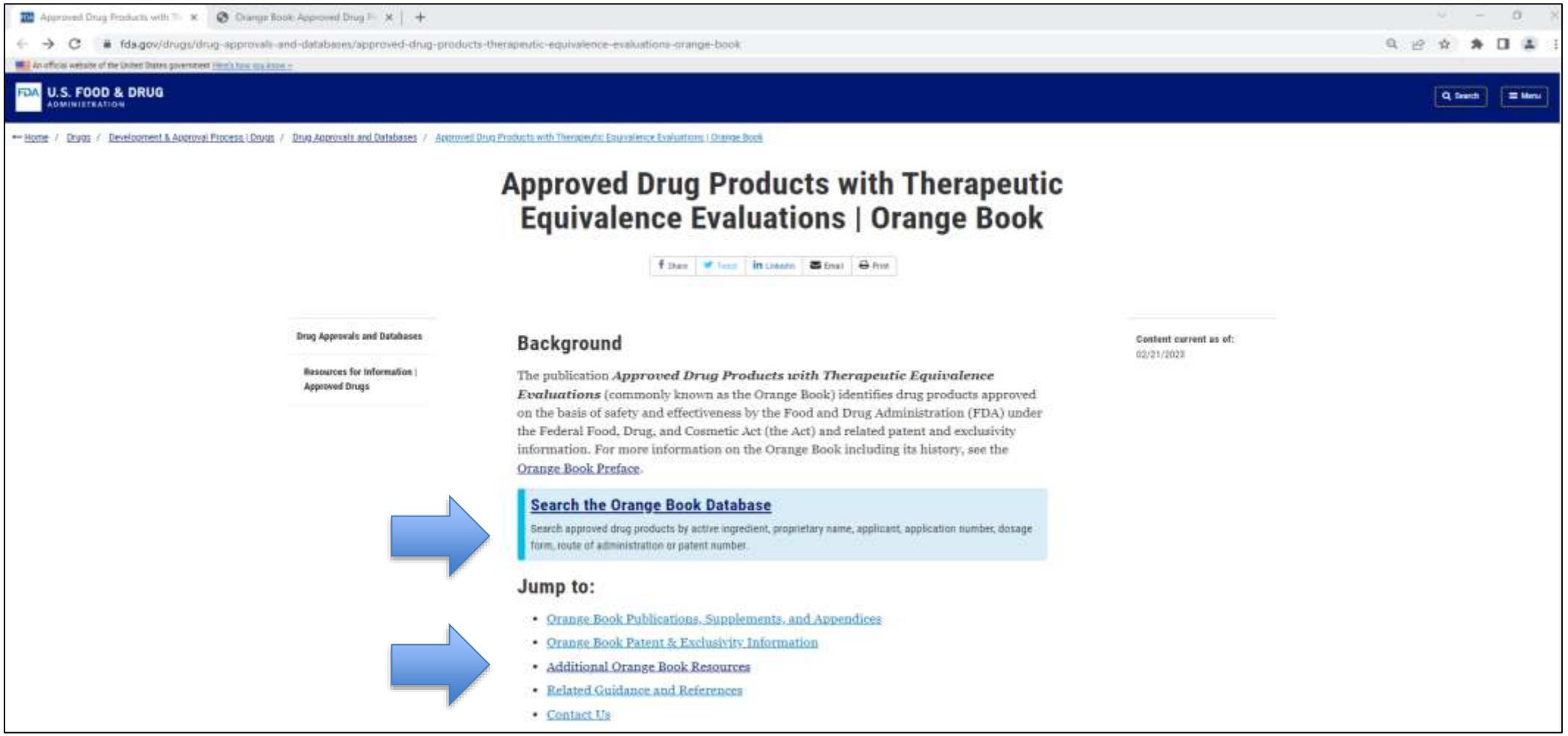
Information Updates to the Orange Book

- Daily (Website and App)
  - Generic drug approvals and patents
- Monthly (Website, App, and Publication)
  - NDA approval, exclusivity, firm name change, active ingredient, discontinuation, strength, dosage form, route, therapeutic equivalence (TE) code, trade name
- Annually (Website, App, and Publication)
  - Annual Orange Book Edition Publication

Available Formats



Orange Book Website



- www.fda.gov/orangebook.

SEARCH THE ORANGE BOOK DATABASE

accessdata.fda.gov/scripts/cder/ob/index.cfm

An official website of the United States government Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Drug Databases / Orange Book Home

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Share Tweet LinkedIn Email Print

Additional information and resources for the Orange Book

We've updated our mobile app!
Download Orange Book Express 2.0
App Store Google play

Find Approved Drugs

- Search by Proprietary Name, Active Ingredient or Application Number

Enter at least 3 characters Search

- Search by Applicant (Company)
- Search by Dosage Form (for example: *TABLET*)
- Search by Route of Administration (for example: *ORAL*)

Find Patent Information

- Search by Patent Number
- View Newly Added Patents or Delisted Patents

Contact Us

The Orange Book downloadable data files are updated monthly. We make every effort to prevent errors and discrepancies in the Approved Drug Products data files. *If you wish to report an error or discrepancy in drug data*, please send a brief description of the problem to: orangebook@fda.hhs.gov.

Please send *general questions related to the drug data in these files* to the Center for Drug Evaluation and Research, Division of Drug Information: druginfo@fda.hhs.gov.

Current through February 2023
For more information on the Orange Book update frequency, see the Orange Book FAQs.

Orange Book Publications, Supplements, and Appendices

- Orange Book Annual Edition (PDF)
- Orange Book Preface (HTML)
- Orange Book Current Cumulative Supplement (PDF)
- Appendix A: Product Name Index (PDF)
- Appendix B: Product Name Sorted by Applicant (PDF)
- Appendix C: Uniform Terms (PDF)

Orange Book Patent & Exclusivity Information

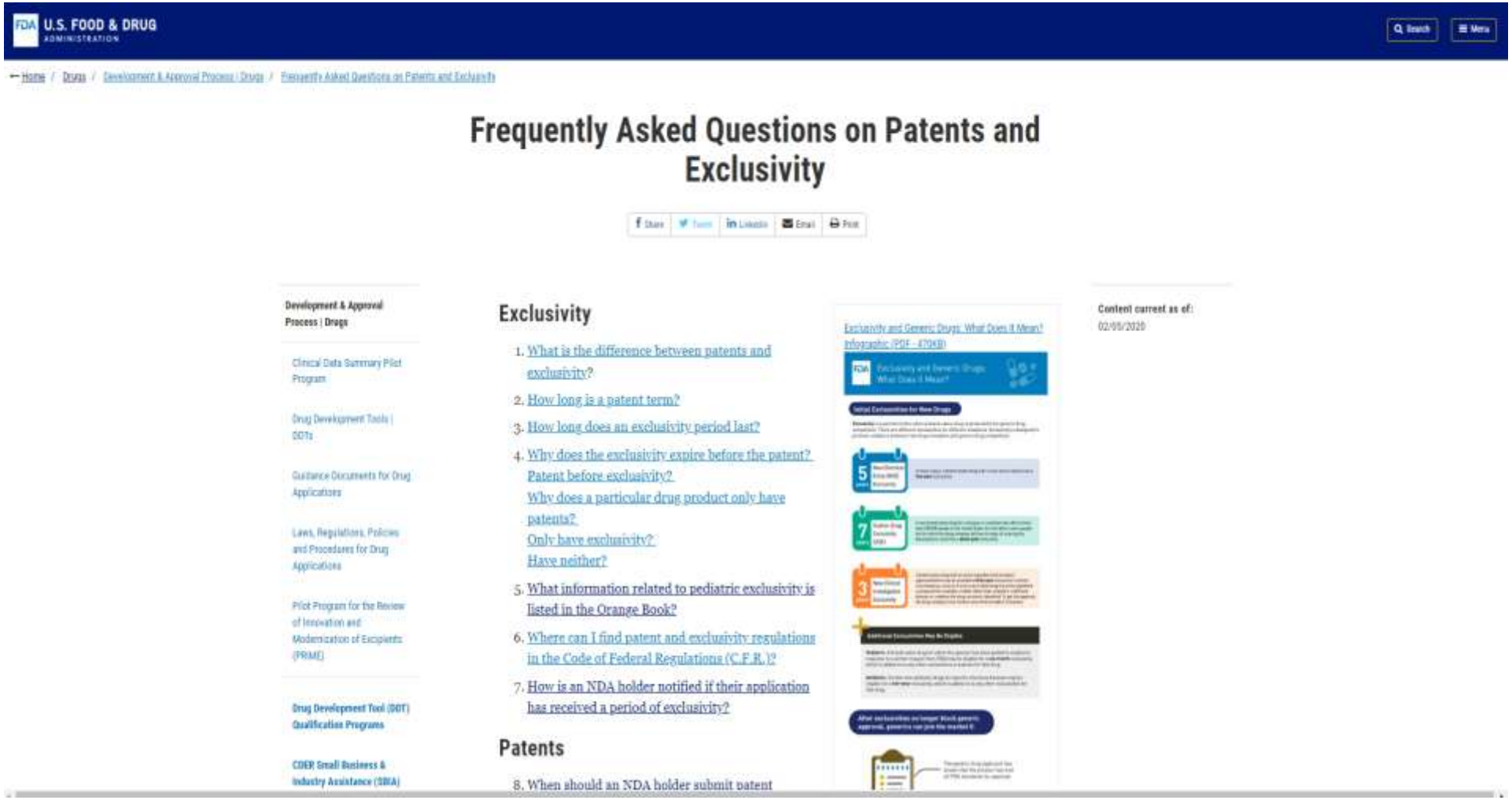
Orange Book Patent Listing Dispute List (PDF)

List of Patent Use Codes and Definitions

List of Exclusivity Codes and Definitions – includes lists of codes with numbers and codes without numbers.

Frequently Asked Questions on Patents and Exclusivity

FAQs: Patent and Exclusivity



U.S. FOOD & DRUG ADMINISTRATION

Home / Drugs / Development & Approval Process | Drugs / Frequently Asked Questions on Patents and Exclusivity

Frequently Asked Questions on Patents and Exclusivity

Development & Approval Process | Drugs

- Clinical Data Summary Pilot Program
- Drug Development Tools | DDTs
- Guidance Documents for Drug Applications
- Laws, Regulations, Policies and Procedures for Drug Applications
- Pilot Program for the Review of Innovation and Modernization of Excipients (PRIME)
- Drug Development Tool (DDT) Qualification Programs
- CDER Small Business & Industry Assistance (SBIA)

Exclusivity

1. What is the difference between patents and exclusivity?
2. How long is a patent term?
3. How long does an exclusivity period last?
4. Why does the exclusivity expire before the patent?
   Patent before exclusivity?
   Why does a particular drug product only have patents?
   Only have exclusivity?
   Have neither?
5. What information related to pediatric exclusivity is listed in the Orange Book?
6. Where can I find patent and exclusivity regulations in the Code of Federal Regulations (C.F.R.)?
7. How is an NDA holder notified if their application has received a period of exclusivity?

Patents

8. When should an NDA holder submit patent

Exclusivity and Generic Drugs: What Does It Mean? Infographic (PDF - 470KB)

Content current as of: 02/05/2020

Frequently Asked Questions on Patents and Exclusivity

Additional Orange Book Resources

- Frequently Asked Questions on The Orange Book
- Orange Book Data Files (compressed .zip file) — includes additional information, such as descriptions of data fields in the Orange Book Search
- Additions/Deletions for Prescription and OTC Drug Product Lists
- Reference Listed Drugs by ANDA Reference Standard List (PDF)
- Pre-Hatch-Waxman Abbreviated New Drug Applications (PANDA) in the Orange Book (PDF)

Orange Book FAQs

U.S. FOOD & DRUG ADMINISTRATION

Search | Menu

Home / Drugs / Development & Approval Process | Drugs / Drug Approvals and Databases / Frequently Asked Questions on The Orange Book

Frequently Asked Questions on The Orange Book

Share | Tweet | Linkedin | Email | Print

Drug Approvals and Databases

Resources for Information | Approved Drugs

Content current as of:
02/05/2020

1. How often is the Orange Book updated?
2. How do I obtain the Orange Book?
3. How do I use the Electronic Orange Book to find approved generic drugs?
4. I want drug information not found in the Orange Book. How do I go about getting it?

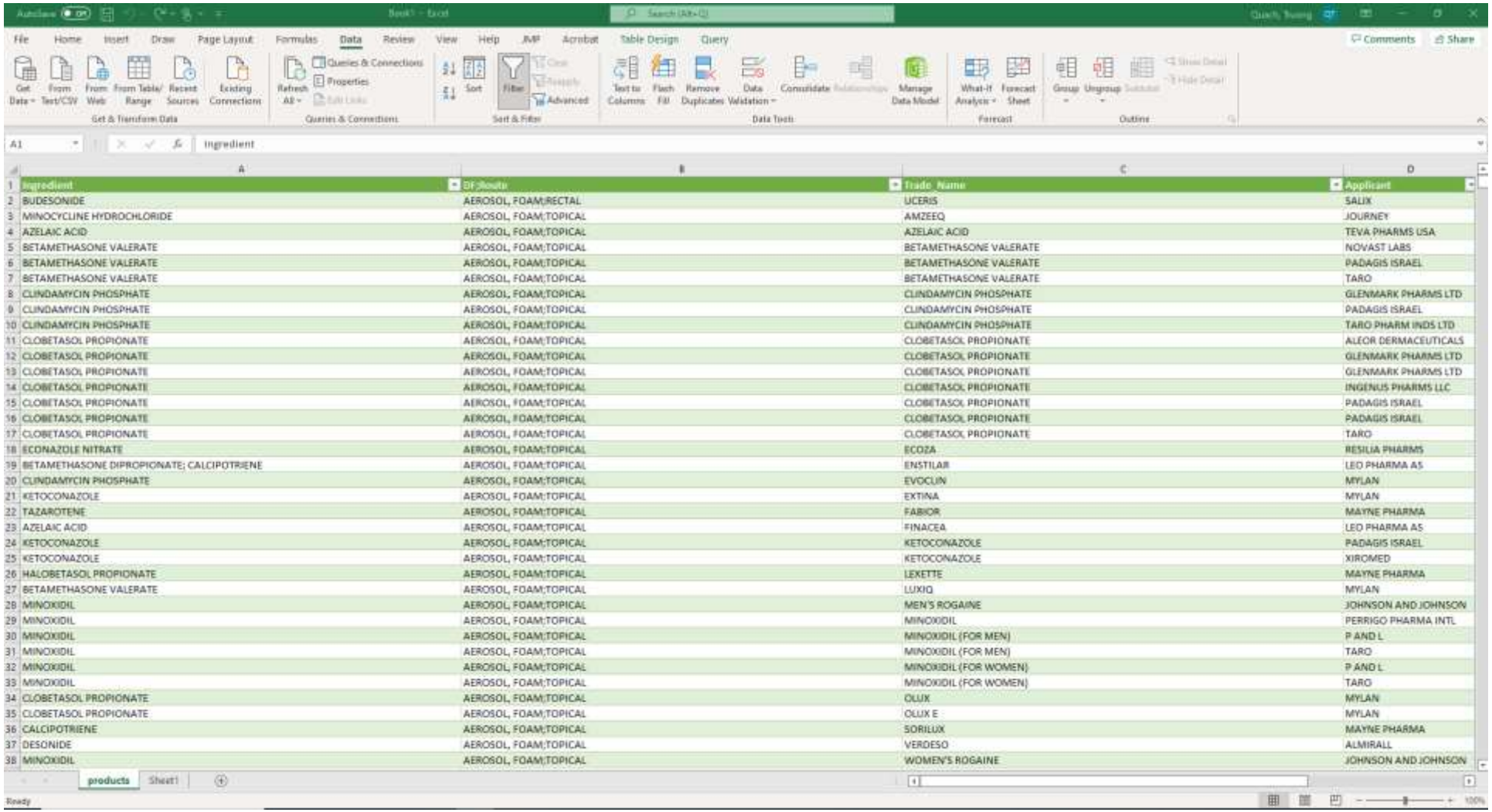
1. **How often is the Orange Book updated?**

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the EOB for several weeks.

The monthly EOB update goal is by the end of the following month's second work week (e.g., November's EOB will be updated by the end of the second full work week in December).

Frequently Asked Questions on The Orange Book

How to Convert Text Format to Excel



Ingredient	DF;Route	Trade_Name	Applicant
BUDESONIDE	AEROSOL, FOAM;RECTAL	UCERIS	SALIX
MINOCYCLINE HYDROCHLORIDE	AEROSOL, FOAM;TOPICAL	AMZEEQ	JOURNEY
AZELAIC ACID	AEROSOL, FOAM;TOPICAL	AZELAIC ACID	TEVA PHARMS USA
BETAMETHASONE VALERATE	AEROSOL, FOAM;TOPICAL	BETAMETHASONE VALERATE	NOVAST LABS
BETAMETHASONE VALERATE	AEROSOL, FOAM;TOPICAL	BETAMETHASONE VALERATE	PADAGIS ISRAEL
BETAMETHASONE VALERATE	AEROSOL, FOAM;TOPICAL	BETAMETHASONE VALERATE	TARO
CLINDAMYCIN PHOSPHATE	AEROSOL, FOAM;TOPICAL	CLINDAMYCIN PHOSPHATE	GLENMARK PHARMS LTD
CLINDAMYCIN PHOSPHATE	AEROSOL, FOAM;TOPICAL	CLINDAMYCIN PHOSPHATE	PADAGIS ISRAEL
CLINDAMYCIN PHOSPHATE	AEROSOL, FOAM;TOPICAL	CLINDAMYCIN PHOSPHATE	TARO PHARM INDS LTD
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	CLOBETASOL PROPIONATE	ALECR DERMACEUTICALS
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	CLOBETASOL PROPIONATE	GLENMARK PHARMS LTD
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	CLOBETASOL PROPIONATE	GLENMARK PHARMS LTD
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	CLOBETASOL PROPIONATE	INGENUS PHARMS LLC
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	CLOBETASOL PROPIONATE	PADAGIS ISRAEL
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	CLOBETASOL PROPIONATE	PADAGIS ISRAEL
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	CLOBETASOL PROPIONATE	TARO
ECONAZOLE NITRATE	AEROSOL, FOAM;TOPICAL	ECOZA	RESILIA PHARMS
BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE	AEROSOL, FOAM;TOPICAL	ENSTILAR	LEO PHARMA AS
CLINDAMYCIN PHOSPHATE	AEROSOL, FOAM;TOPICAL	EVOCLIN	MYLAN
KETOCONAZOLE	AEROSOL, FOAM;TOPICAL	EXTINA	MYLAN
TAZAROTENE	AEROSOL, FOAM;TOPICAL	FABIOR	MAYNE PHARMA
AZELAIC ACID	AEROSOL, FOAM;TOPICAL	FINACEA	LEO PHARMA AS
KETOCONAZOLE	AEROSOL, FOAM;TOPICAL	KETOCONAZOLE	PADAGIS ISRAEL
KETOCONAZOLE	AEROSOL, FOAM;TOPICAL	KETOCONAZOLE	XIROMED
HALOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	LEXETTE	MAYNE PHARMA
BETAMETHASONE VALERATE	AEROSOL, FOAM;TOPICAL	LUXIQ	MYLAN
MINOXIDIL	AEROSOL, FOAM;TOPICAL	MEN'S ROGAINE	JOHNSON AND JOHNSON
MINOXIDIL	AEROSOL, FOAM;TOPICAL	MINOXIDIL	PERRIGO PHARMA INTL
MINOXIDIL	AEROSOL, FOAM;TOPICAL	MINOXIDIL (FOR MEN)	P AND L
MINOXIDIL	AEROSOL, FOAM;TOPICAL	MINOXIDIL (FOR MEN)	TARO
MINOXIDIL	AEROSOL, FOAM;TOPICAL	MINOXIDIL (FOR WOMEN)	P AND L
MINOXIDIL	AEROSOL, FOAM;TOPICAL	MINOXIDIL (FOR WOMEN)	TARO
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	OLUX	MYLAN
CLOBETASOL PROPIONATE	AEROSOL, FOAM;TOPICAL	OLUX E	MYLAN
CALCIPOTRIENE	AEROSOL, FOAM;TOPICAL	SORILUX	MAYNE PHARMA
DESONIDE	AEROSOL, FOAM;TOPICAL	VERDESO	ALMIRALL
MINOXIDIL	AEROSOL, FOAM;TOPICAL	WOMEN'S ROGAINE	JOHNSON AND JOHNSON

Related Guidance and References

•Guidance for Industry:

- Orange Book Questions and Answers (July 2022)
- Evaluation of Therapeutic Equivalence (July 2022)
- Referencing Approved Drug Products in ANDA Submissions (October 2020)
- Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act (August 2020)

•Reference standard data updates to the Orange Book (January 2017)

•Biologics Price Competition and Innovation Act (BPCIA) of 2009:

- BPCIA Orange Book Transition Edition (PDF)
- "Deemed to be a License" Provision of the BPCI Act (April 2020)

Challenge Question 1

- **The Orange Book data files include approved drug products, exclusivity, and unexpired patents in text and pdf files?**

A.TRUE

B.FALSE

Challenge Question 2

What should I do if my drug product is not listed in the Orange Book?

A. Search the Orange Book database
B. Send E-mail to OrangeBook@fda.hhs.gov
C. Search the Orange Book Preface
D. B and C
E. All the above

- The Orange Book identifies drug products approved on the basis of safe and effectiveness by the FDA
- The website is accessible at www.fda.gov/orangebook
- The Orange Book Website is not just a database, but it holds ample information and resources relating to the Orange Book
- Users can access the Orange Book downloadable data files, which is updated monthly and can be converted by Excel

Questions? Contact us

OrangeBook@fda.hhs.gov.