How Orange Book Listings Are Added, Updated, and Maintained

A practical look at Orange Book database workflows

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OBJECTIVES

By the end of this session, you should be able to:

- Understand workflows behind Orange Book entries
- Describe common update triggers
- Understand Orange Book publication cadence
- Know where and how to request updates

Background of the Publication

1980 – First edition

1984 – FD&C Act amended to require FDA to publish and regularly update info in Orange Book

1985 – 6th Edition of the Orange Book Annual Publication – discontinued drug products designated by special symbol

1987 – 7th Edition of OB Annual – added the Discontinued section

2026 – 46th Orange Book Edition published in January

Electronic Orange Book Database

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	IBUPROFEN	IBUPROFEN	A074978	SUSPENSION	ORAL	100MG/5ML	AB		RS	ACTAVIS MID ATLANTIC LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC
RX	IBUPROFEN	IBUPROFEN	A209178	SUSPENSION	ORAL	100MG/5ML	AB			AUROBINDO PHARMA LTD
RX	IBUPROFEN	IBUPROFEN	A076925	SUSPENSION	ORAL	100MG/5ML	AB			PADAGIS US LLC
RX	IBUPROFEN	IBUPROFEN	A215311	SUSPENSION	ORAL	100MG/5ML	AB			STRIDES PHARMA GLOBAL PTE LTD
RX	IBUPROFEN	IBUPROFEN	A209204	SUSPENSION	ORAL	100MG/5ML	AB			SUN PHARMA CANADA INC
OTC	IBUPROFEN	CHILDREN'S MOTRIN	N020516	SUSPENSION	ORAL	100MG/5ML		RLD	RS	KENVUE BRANDS LLC
OTC	IBUPROFEN	IBUPROFEN	A210602	SUSPENSION	ORAL	100MG/5ML				ANNORA PHARMA PRIVATE LTD
OTC	IBUPROFEN	IBUPROFEN	A209179	SUSPENSION	ORAL	100MG/5ML				AUROBINDO PHARMA LTD
DISCN	IBUPROFEN	CHILDREN'S ADVIL	N019833	SUSPENSION	ORAL	100MG/5ML				HALEON US HOLDINGS LLC
DISCN	IBUPROFEN	CHILDREN'S ELIXSURE	N021604	SUSPENSION	ORAL	100MG/5ML				MOBERG PHARMA NORTH AMERICA LLC
DISCN	IBUPROFEN	IBU	N019784	SUSPENSION	ORAL	100MG/5ML				ABBOTT LABORATORIES PHARMACEUTICAL PRODUCTS DIV
DISCN	IBUPROFEN	IBUPROFEN	A200457	SUSPENSION	ORAL	100MG/5ML				ARISE PHARMACEUTICALS LLC
DISCN	IBUPROFEN	IBUPROFEN	A205647	SUSPENSION	ORAL	100MG/5ML				PAI HOLDINGS LLC DBA PHARMACEUTICAL ASSOCIATES INC
DISCN	IBUPROFEN	MOTRIN	N019842	SUSPENSION	ORAL	100MG/5ML **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**		RLD		MCNEIL CONSUMER HEALTHCARE DIV MCNEIL PPC INC

Where Orange Book Data Comes From

New drug product line listing

- Original approval, e.g., 505(b) NDA, 505(j) ANDA
- Supplements
- Therapeutic equivalence (TE) evaluations
- Reference listed drug (RLD) and reference standard (RS) designations

Other listed product information

- Patent submissions (Form FDA 3542) and exclusivity listings
- Safety and effectiveness determinations for discontinued drug products

Revisions to listed information

- Marketing status notifications (506I)
- Ownership changes and name changes (refer to 21 CFR 314.72)

Patents & Exclusivity: What Gets Listed (and How)

NDA holder submits patent information

- Submitted to FDA on Form FDA 3542
- DOBPRA reviews for technical completeness (ministerial role)

Orange Book records patent fields

- Patent number, expiry date, Drug Substance (DS), Drug Product (DP), patent use code (for method-of-use (MOU) patents)
- Patent submission date and delist requested flag (where applicable)

Marketing exclusivity

- The Orange Book is the official reference for information about marketing exclusivity periods associated with listed drugs

Public dissemination

- Patent listings are published in the electronic Orange Book daily
- Available changes are also in the monthly CS pdf files and Annual edition (as of December 31) via Patent.txt and Exclusivity.txt downloads

Marketing Status Changes

How products get moved to the "Discontinued" section

- Applicant 506I notification to Agency
- Agency Withdrawal Acknowledgement letter
- Correspondences, e.g., controlled correspondence

Section 506I reminders

Application holders must notify DOBPRA about withdrawing from sale (generally 180 days prior, or by withdrawal date if not practicable) and about products not available within 180 days of approval

How Often Does DOBPRA Update the Orange Book

What's in each cadence

- Daily website updates
- Semi-monthly website updates
- Monthly website
- Annual edition

Approved Drug Products with Therapeutic Equivalence Evaluation | Orange Book

Additional Orange Book Resources

- Frequently Asked Questions on The Orange Book
- Orange Book Data Files (compressed .zip file)

  For additional information, such as descriptions of data fields in the Orange Book Search, please see Orange Book Data Files.
- Additions/Deletions for Prescription and OTC Drug Product Lists
- Reference Listed Drugs by ANDA Reference Standard List (PDF - 115 KB)
- Pre-Hatch-Waxman Abbreviated New Drug Applications (PANDA) in the Orange Book (PDF - 1.76MB)

Current through March 2026.
For more information on the Orange Book update frequency, see the Orange Book FAQs.

Orange Book Data Files

Products.txt

- Ingredients, dosage form/route, strength
- Trade name, applicant, NDA/ANDA, product no.
- TE code, approval date, RLD/RS (in downloads/search output)

Patent.txt

- Patent number
- Expiry date
- DS/DP flags
- Use code
- Submission date, delist-request flag

Exclusivity.txt

- Exclusivity code
- Exclusivity expiration date
- Links to NDA/ANDA + product number

Questions on Orange Book Entries

A simple triage flow

1) Is it a timing issue?

Check daily postings vs. monthly CS/data files (and the CS month label).

2) Is it a field that requires an application action prior to being updated?

Example: proprietary name changes generally require an approved supplement.

3) Is it a marketing status change?

Confirm 506I notification has been provided.

4) Is it a potential discrepancy?

- Examples: different proprietary name or applicant holder name not updated.
- Report to orangebook@fda.hhs.gov with specifics (application no., product no., expected vs. observed values).

Challenge Question #1

Which scenario most directly results in a product being moved to the Discontinued Drug Product List?

A. FDA approves a labeling supplement for the product.

B. The applicant notifies DOBPRA that the product is not marketed.

C. A new patent is submitted on Form FDA 3542.

D. The product receives a TE code.

Challenge Question #2

Which information has been provided as "daily" Electronic Orange Book updates since February 2005?

A. Annual Edition appendices (A/B/C).

B. New generic drug approvals.

C. All line listing changes (including ownership and TE codes).

D. Monthly Cumulative Supplements.

Challenge Question #3

DOBPRA generally will act on a request to change a proprietary (brand) name in the Orange Book only after:

A. A citizen petition is submitted.

B. The applicant updates its website and labeling.

C. The Agency approves a supplement for the proprietary name change.

D. The next Annual Edition is published.

Conclusion

Key takeaways

- DOBPRA relies on different sources to update the information provided in the Orange Book (e.g., Agency approval actions or applicant notifications)
- Depending on the type of data, our publication is updated daily, bi-monthly, monthly, or annually
- Be proactive by keeping DOBPRA informed of marketing status and ownership changes

Recommended Resources

- FDA Orange Book homepage
  - Search the Orange Book Database
  - Preface
  - Guidance for Industry FAQs
  - Instruction on how to download data files
  - Downloadable data files (Products / Patent / Exclusivity)
- FDLI: "Freshly Squeezed: Orange Book History and Key Updates at 45" (context for updates over time)
- New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers (March 2026)


Questions?
Contact us
OrangeBook@fda.hhs.gov