Search for FDA Guidance Documents

The table below lists all official FDA Guidance Documents and other regulatory guidance. You can search for documents using key words, and you can narrow or filter your results by product, date issued, FDA organizational unit, type of document, subject, draft or final status, and comment period.

This feature is provided to give a convenient way to search for all FDA guidance documents from a single location.

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- General and Cross-Cutting Topics (/regulatory-information/search-fda-guidance-documents/fda-guidance-documents-general-and-cross-cutting-topics)
- Advisory Committees (/regulatory-information/search-fda-guidance-documents/advisory-committee-guidance-documents)
- Animal and Veterinary (/guidance-industry)
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    - Product-Specific Guidances for Generic Drug Development (Bioequivalence Recommendations) (/drugs/guidances-drugs/product-specific-guidances-generic-drug-development)
- Food (/guidance-documents-regulatory-information-topic)
- Import and Export (/regulatory-information/search-fda-guidance-documents/import-and-export-guidance-documents)
- International Council for Harmonisation (ICH) - select "ICH" in the Topic filter of the Guidance Document Search
- Medical Devices (/guidance-documents-medical-devices-and-radiation-emitting-products)
- Pediatric Product Development – select "Pediatric Product Development" in the Topic filter of the Guidance Document Search
- Radiation-Emitting Products (/industry-guidance-radiation-emitting-products)
- Tobacco Products (/tobacco-products/rules-regulations-guidance/guidance)
- Veterinary International Conference on Harmonization (VICH) (/animal-veterinary/guidance-industry/veterinary-international-conference-harmonization-vich-guidance-documents)

About FDA Guidance Documents

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If you believe an FDA employee is not following FDA's Good Guidance Practice regulations (http://www.ecfr.gov/cgi-bin/text-idx?SID=7c0a5352a78ff3516507e550a9d5487d&mc=true&node=se21.1.10_1115&rgn=div8) (21 CFR 10.115), you should contact the employee's supervisor in the issuing office or Center. If the issue is not resolved, contact the next highest supervisor or the Center's Ombudsman. If the issue is still not resolved, contact the FDA's Office of the Ombudsman at:

FDA Office of the Ombudsman
10903 New Hampshire Avenue
WO Bldg. 1, room 4208

Silver Spring, MD 20993
Phone : 301-796-8530
Email: Ombuds@oc.fda.gov (mailto:Ombuds@oc.fda.gov)

Some Web links (URLs) embedded within guidance documents may have changed since the document was published. If you find a link that does not work, please try searching for the document using the document title. For more assistance, go to Contact FDA (/contact-fda-1).

Commenting on Guidance Documents

Some FDA guidance documents on this list are indicated as open for comment. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5) (http://www.ecfr.gov/cgi-bin/text-idx?SID=7c0a5352a78ff3516507e550a9d5487d&mc=true&node=se21.1.10_1115&rgn=div8)), to ensure that the Agency considers your comment on a draft guidance that is open for comments before it begins work on the final version of the guidance, submit either electronic or written comments by the closing date. Comments are submitted electronically through regulations.gov. For more information, see:

- How to Use Regulations.gov (/regulatory-information/federal-register-fr-notices/how-use-regulationsgov)
- Find and Comment on FDA Dockets (/find-and-comment-fda-dockets)

Report on Good Guidance Practices

As part of the FDA's Transparency Initiative, Dr. Margaret A. Hamburg, the Commissioner of Food and Drugs, called for a cross-Agency working group to prepare a report identifying FDA's "best practices" for making the agency's guidance development processes more transparent and efficient.

The working group prepared a report, entitled "Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency."

- Fact Sheet: FDA Good Guidance Practices (/about-fda/transparency-initiative/fact-sheet-fda-good-guidance-practices)
- Report on Good Guidance Practices: Improving Efficiency and Transparency (/about-fda/transparency-initiative/background-report-good-guidance-practices)
- Federal Register Notice of Availability (https://federalregister.gov/a/2011-33573)

Go to Class II Special Controls Documents (https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents)

Guidance Document Search

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Document Type

Comment Closing Date on Draft*

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Summary	Document	Issue Date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft
+ Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies (/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-considerations-human-radiolabeled-mass-balance-studies)	PDF (271.51 KB) (/media/158178/download)	07/18/2024	Center for Drug Evaluation and Research	Clinical - Pharmacology	Final	No	08/04/2022
+ Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment (/regulatory-information/search-fda-guidance-documents/pediatric-inflammatory-bowel-disease-developing-drugs-treatment)	PDF (388.92 KB) (/media/180126/download)	07/18/2024	Center for Drug Evaluation and Research	Clinical - Medical	Draft	Yes	09/16/2024
+ Blood Pressure and Pulse Donor Eligibility Requirements – Compliance Policy: Guidance for Industry (/regulatory-information/search-fda-guidance-documents/blood-pressure-and-pulse-donor-eligibility-requirements-compliance-policy)	PDF (218.93 KB) (/media/158609/download)	07/17/2024	Center for Biologics Evaluation and Research	Blood, Blood Products	Final	No	
+ Application User Fees for Combination Products: Guidance for Industry and FDA Staff (/regulatory-information/search-fda-guidance-documents/application-user-fees-combination-products)	PDF (314.74 KB) (/media/76413/download)	07/16/2024	Office of the Commissioner,Office of Clinical Policy and Programs,Office of Combination Products	User Fees, Combination Products, Pediatric Product Development	Final	No	
+ Drugs for the Treatment of Partial Onset Seizures: Extrapolation of Efficacy from Adults to Pediatric Patients 1 Month of Age and Older (/regulatory-information/search-fda-guidance-documents/drugs-treatment-partial-onset-seizures-extrapolation-efficacy-adults-pediatric-patients-1-month-age)	PDF (200.85 KB) (/media/130449/download)	07/15/2024	Center for Drug Evaluation and Research	Clinical - Pharmacology, Pediatric Product Development	Final	No	

Summary	Document	Issue Date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft
+ Dental Composite Resin Devices - Premarket Notification (510(k)) Submissions: Draft Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/dental-composite-resin-devices-premarket-notification-510k-submissions)	PDF (532.96 KB) (/media/179983/download)	07/12/2024	Center for Devices and Radiological Health	Premarket, 510(k), Dental	Draft	Yes	09/10/2024
+ Dental Curing Lights - Premarket Notification (510(k)) Submissions: Draft Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/dental-curing-lights-premarket-notification-510k-submissions)	PDF (511.87 KB) (/media/179991/download)	07/12/2024	Center for Devices and Radiological Health	Premarket, 510(k), Dental	Draft	Yes	09/10/2024
+ Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder: Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/clinical-considerations-studies-devices-intended-treat-opioid-use-disorder)	PDF (538.76 KB) (/media/170561/download)	07/11/2024	Center for Devices and Radiological Health		Final	No	
+ Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers (/regulatory-information/search-fda-guidance-documents/addressing-misinformation-about-medical-devices-and-prescription-drugs-questions-and-answers)	PDF (374.75 KB) (/media/179827/download)	07/08/2024	Center for Veterinary Medicine Center for Biologics Evaluation and Research Center for Devices and Radiological Health Center for Drug Evaluation and Research	Advertising	Draft	No	
+ Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products (/regulatory-information/search-fda-guidance-documents/purpose-and-content-use-related-risk-analyses-drugs-biological-products-and-combination-products)	PDF (324.44 KB) (/media/179858/download)	07/08/2024	Center for Biologics Evaluation and Research Center for Devices and Radiological Health Center for Drug Evaluation and Research Office of the Commissioner,Office of Clinical Policy and Programs,Office of Combination Products		Draft	Yes	09/09/2024

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