How FDA Communicates with Stakeholders During the Rulemaking Process

FDA Office of Global Policy and Strategy (OGPS),
Office of Trade and Global Partnerships (OTGP)

November 14, 2023

Good Regulatory Practices (GRPs)

Accessible and consistent communication is an essential part of good regulatory practice.

FDA

Accessible and consistent communication:

- Facilitates public participation
- Promotes accountability and transparency throughout rulemaking
- Provides greater certainty to stakeholders
- Conveys regulatory requirements in a timely manner
- Builds trust

Public Engagement

In 2023, the Office of Information and Regulatory Affairs issued a memorandum providing guidance on how agencies can better engage members of the public when developing a regulation, including members of underserved communities.

One aspect focuses on ensuring that agency policies on communication during the rulemaking process promote **accessible, equitable, and meaningful participation** and engagement, especially **early on in setting regulatory priorities and in the early stages of rule development** before a proposed regulation is issued for comment.

https://www.whitehouse.gov/omb/information-regulatory-affairs/broadening-public-engagement-in-the-federal-regulatory-process/

Barriers that impede greater stakeholder participation in the rulemaking process include lack of awareness or knowledge about:

- The regulatory process and opportunities for input
- Specific regulations or issues that agencies are considering
- Effective ways of participating

Individuals may face **other barriers to participation**, such as:

- Barriers related to the time it takes for participation
- Language and communication access
- Physical access
- Internet access, accessibility, and digital literacy
- Lack of trust in government

https://www.whitehouse.gov/omb/information-regulatory-affairs/broadening-public-engagement-in-the-federal-regulatory-process/

The guidance recommends that agencies:

- Plan and prioritize their participation and engagement activities
- Recognize engagement strategies may be different for each regulation
- Intentionally plan and prioritize regulatory activities to determine where they should direct resources to maximize the quality of participation and engagement, including underserved communities

https://www.whitehouse.gov/omb/information-regulatory-affairs/broadening-public-engagement-in-the-federal-regulatory-process/

Federal Register

Official daily publication for agency rules, proposed rules, notices of Federal agencies and organizations, as well as for Executive Orders and other presidential documents

https://www.federalregister.gov/

Unified Agenda

Provides information about new regulations that the government is considering and existing regulations the government is reviewing

https://www.reginfo.gov/public/do/eAgendaMain

FDA-TRACK

Updated agenda of upcoming rulemakings

FDA-TRACK: Unified Agenda-TRACK

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Regulations specify the details and requirements necessary to implement and to enforce legislation enacted by Congress. Because of their importance, an agency's rulemaking plans are of great interest to a wide range of stakeholders. Therefore, the Federal Government publishes a semi-annual agenda of upcoming regulations in the Federal Register, usually in the Spring and Fall. On this Web page, we will maintain an updated agenda of the agency's upcoming rulemakings.

Formal Title | RIN | Stage | Projected Publication Date

(All) | (All)

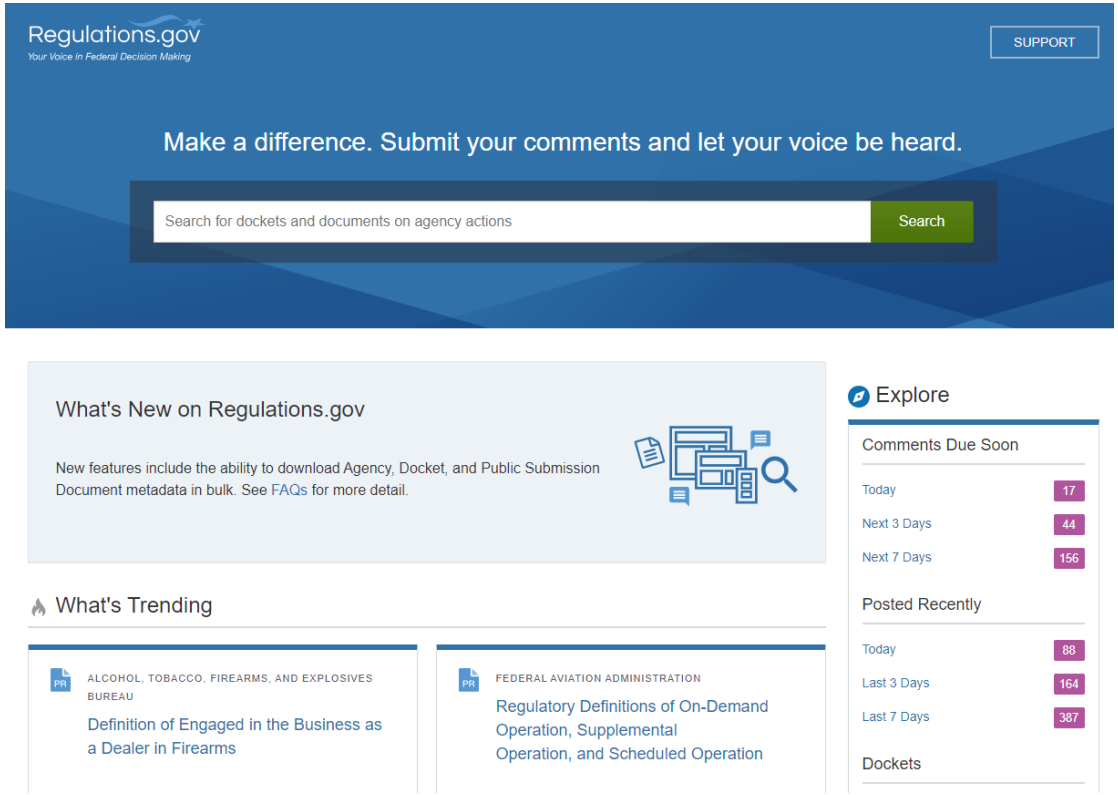
Hover over RIN for additional information

Formal Title	RIN	Projected Publication Date	Stage
Use of Formaldehyde and Formaldehyde-Releasing Chemicals as a..	0910-AI83	April 2024	Proposed Rule Stage
Abbreviated New Animal Drug Applications	0910-AI54	June 2024	Long-Term Actions
Administrative Destruction of Certain Devices Refused Admission ..	0910-AI59	June 2023	Final Rule Stage
Administrative Detention of Tobacco Products	0910-AI05	February 2024	Proposed Rule Stage
Amending Regulations That Require Multiple Copies Submissions	0910-AI50	October 2023	Proposed Rule Stage
Amendment of Procedural Requirements for Color Additive Petitio..	0910-AI53	April 2024	Proposed Rule Stage

https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-unified-agenda-track

Regulations.gov

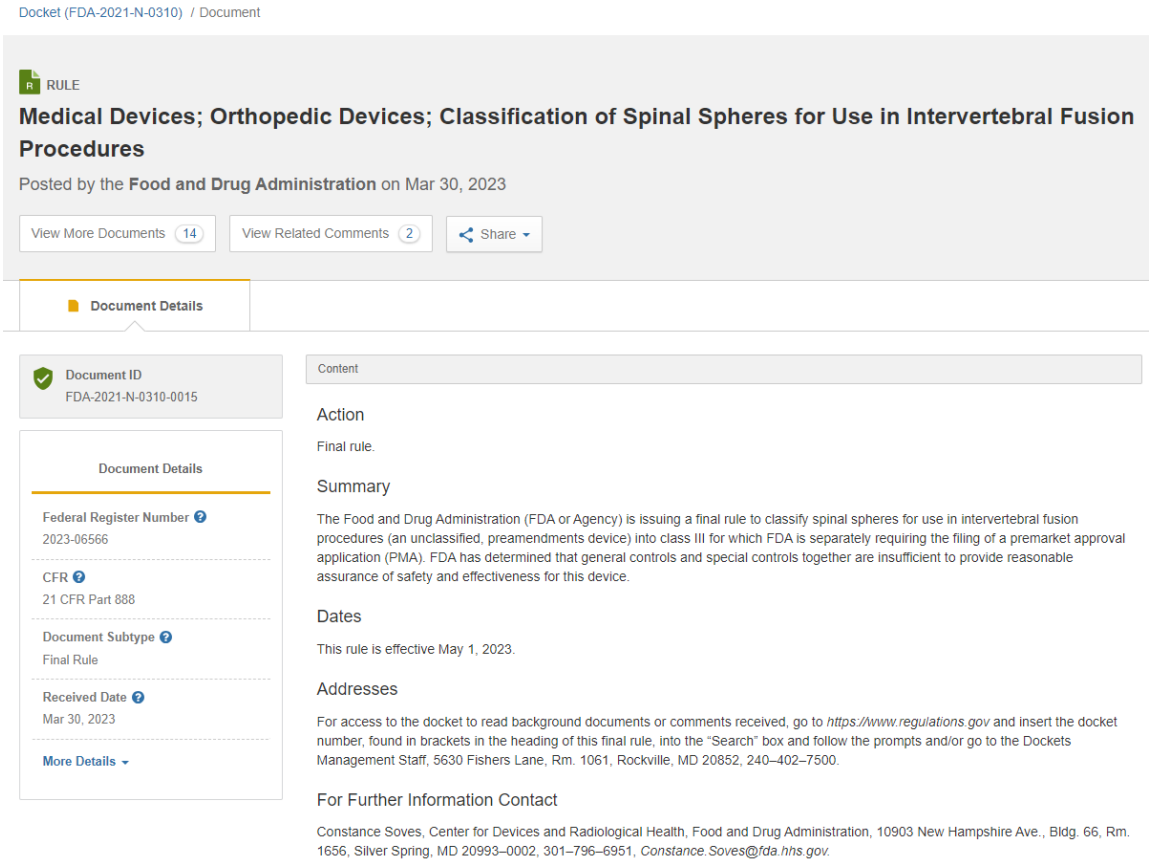
Provides information on the development of Federal Regulations and other related documents issued by the U.S. government



https://www.regulations.gov/

Dockets

Collection of documents related to a rulemaking or other action



https://www.regulations.gov/

Plain Language

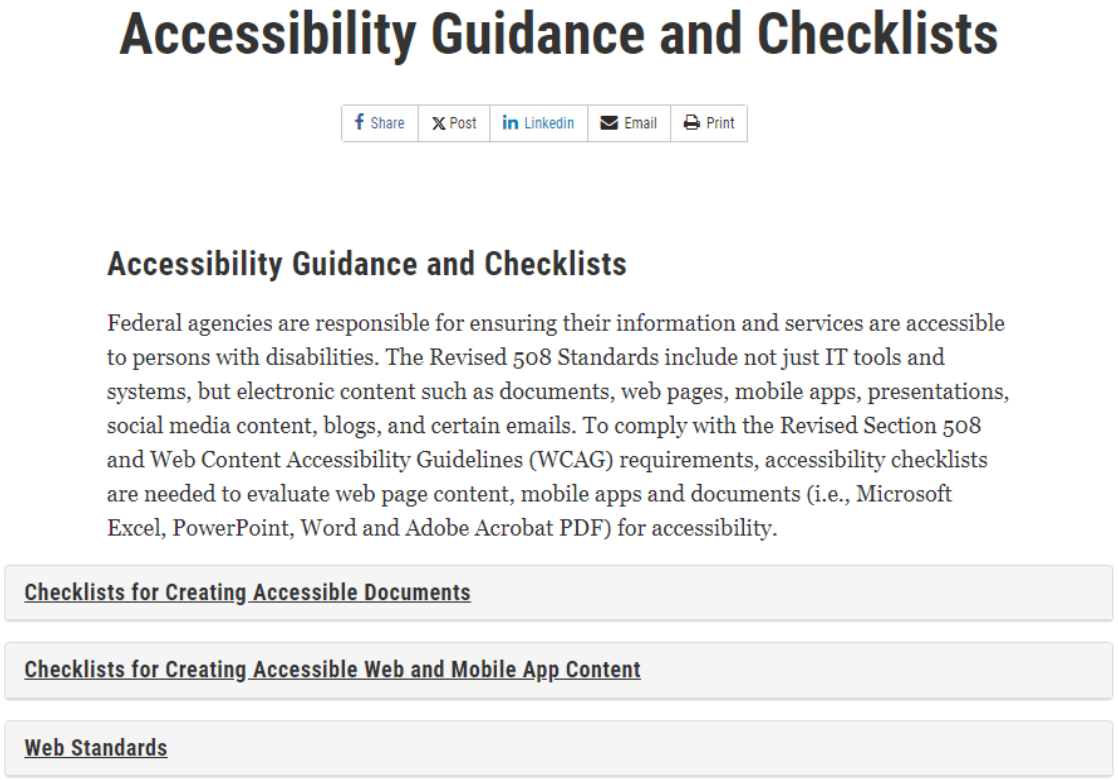
Clear, concise, well-organized communications that the public can understand and use

- The Plain Writing Act of 2010 requires that all federal agencies use **“clear government communication that the public can understand and use.”**
- FDA proactively expands awareness about the Plain Writing Act to FDA employees:
  - Provides training to educate staff
  - Uses plain language awards to recognize excellence in communication
- Plain language also facilitates public comment on proposed regulations.

https://www.fda.gov/about-fda/plain-writing-its-law

Accessibility

Accessibility can be measured by how successfully a person with a disability can locate, get to, and understand the wanted or needed information.



Accessibility Guidance and Checklists

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Accessibility Guidance and Checklists

Federal agencies are responsible for ensuring their information and services are accessible to persons with disabilities. The Revised 508 Standards include not just IT tools and systems, but electronic content such as documents, web pages, mobile apps, presentations, social media content, blogs, and certain emails. To comply with the Revised Section 508 and Web Content Accessibility Guidelines (WCAG) requirements, accessibility checklists are needed to evaluate web page content, mobile apps and documents (i.e., Microsoft Excel, PowerPoint, Word and Adobe Acrobat PDF) for accessibility.

Checklists for Creating Accessible Documents

Checklists for Creating Accessible Web and Mobile App Content

Web Standards

https://www.fda.gov/about-fda/accessibility-fda/accessibility-guidance-and-checklists

FDA Website

Includes information related to proposed and final regulations, including:

- Links to the Federal Register Notice and docket
- Ability to register for automatic email updates, as well as
- Other information that can support understanding of proposed and final regulations

OTC Hearing Aids: What You Should Know

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Close to 30 million adults living in the U.S. have some degree of hearing loss. Despite the high number of people affected by hearing loss, only about one-fifth of those who could benefit from a hearing aid seek intervention. Using hearing aids may reduce the frequency or severity of cognitive decline, depression, and other health problems in adults. Added benefits can include improved social participation and a better quality of life. To increase the public's access to hearing aids and improve hearing, the FDA established a new category of over-the-counter (OTC) hearing aids for adults 18 years of age and older with perceived mild to moderate hearing loss that went into effect on October 17, 2022.

On this page:

- Over-the-Counter (OTC) Hearing Aids
- Before You Buy an OTC Hearing Aid: What You Should Know
- After You Buy an OTC Hearing Aid: What You Should Know
- OTC Hearing Aid Resources

FDA Website

Includes preliminary and final regulatory impact analyses in a searchable format

Regulatory Impact Analyses (RIAs)

Rule Type

Topic

Clear Filters

Search:

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Show 10 entries

Publication Date	Rule	Rule Type	Docket	Topic
9/29/2023	Laboratory Developed Tests Regulatory Impact Analysis (Proposed Rule)	Proposed	FDA-2023-N-2177	device;laboratory;testing
8/25/2023	Fish and Shellfish; Canned Tuna Standard of Identity and Standard of Fill of Container RIA	Proposed	FDA-2016-P-0147	food; standards
8/8/2023	Direct Final Rule for Revocation of Uses of Partially Hydrogenated Oils in Foods	Direct Final Rule	FDA-2019-N-4750	food; nutrition
8/8/2023	Proposed Rule for Revocation of Uses of Partially Hydrogenated Oils in Foods	Proposed	FDA-2019-N-4750	food; nutrition
5/31/2023	Medication Guides: Patient Medication Information (Proposed Rule) Preliminary Regulatory Impact Analysis	Proposed	FDA-2019-N-5959	human drug; labeling
3/30/2023	Medical Devices; Orthopedic Devices; Classification of Spinal Spheres for Use in Intervertebral Fusion Procedures (Final Rule) Final Regulatory Impact Analysis	Final	FDA-2021-N-0310	device; classification

https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria

Meetings, Conferences, and Workshops

Virtual or in-person events can facilitate and support public participation on proposed regulations as well as communicate about final regulations.

Following meetings, FDA makes recordings and transcripts available on our website.

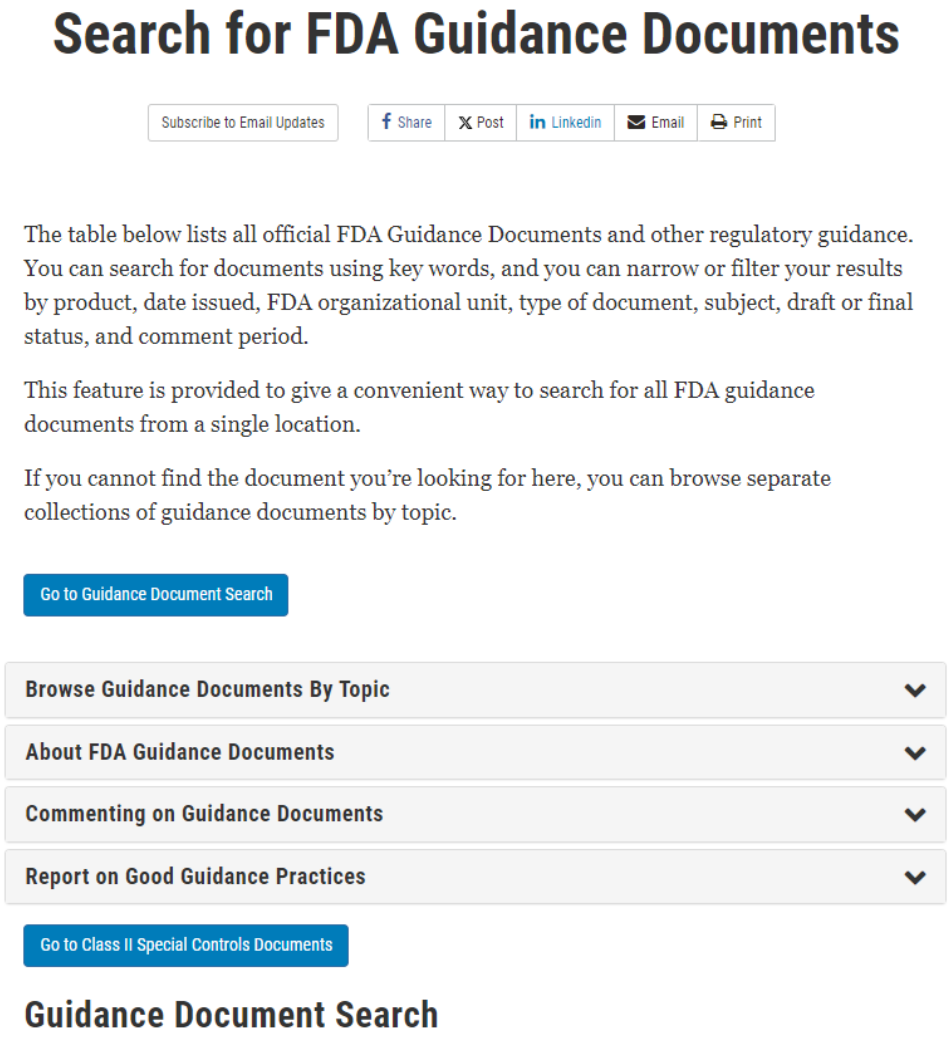
Examples of past events include:

- Webinar to provide information on the proposed rule regarding Laboratory Developed Tests
- Public workshop to obtain public input on the appropriate use of voluntary consensus standards in premarket submissions for medical devices
- Public workshop to communicate how to use and reference standards in device submissions

https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops

Guidance Documents

Documents prepared for FDA staff, applicants/sponsors, and the public that describe the Agency's interpretation of or policy on a regulatory issue.



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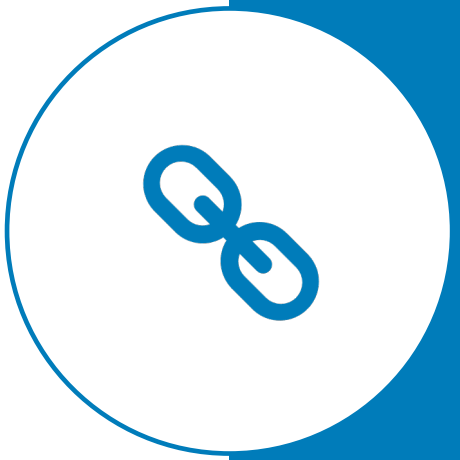


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