

Cómo se Comunica la FDA con las Partes Interesadas Durante el Proceso de Desarrollo Regulatorio

FDA, Oficina de Estrategia y Política Global (OGPS),
Oficina de Comercio y Alianzas Globales (OTGP)

14 de noviembre de 2023

Buenas Prácticas Regulatorias (BPRs)

La comunicación accesible y constante es una parte esencial de las buenas prácticas regulatorias.

Comunicación accesible y constante :

- Facilita la participación pública
- Promueve la responsabilidad y transparencia a lo largo del proceso de desarrollo regulatorio
- Provee mayor certeza a las partes interesadas
- Comunica los requisitos regulatorios de manera oportuna
- Construye confianza

Participación Pública

En 2023, la Oficina de Información y Asuntos Regulatorios emitió un memorándum con guía sobre cómo las agencias pueden promover la participación del público en el desarrollo regulatorio, incluyendo miembros de comunidades desatendidas.

Un aspecto se enfoca en asegurar que las políticas de la agencia sobre comunicación durante el proceso de desarrollo regulatorio promuevan **participación accesible, equitativa y significativa,** especialmente **en la etapa temprana en la que se establecen las prioridades regulatorias** antes de que se publique la regulación para consulta pública.

Las barreras que impiden una mayor participación de las partes interesadas en el proceso de desarrollo regulatorio incluye la falta de conocimiento sobre:

- El proceso regulatorio y las oportunidades de aporte
- Las regulaciones o temas específicos que las agencias están considerando
- Formas efectivas de participar

Los individuos pueden enfrentar otras barreras para la participación, como:

- Barreras relacionadas con el tiempo que toma participar
- Idioma y acceso a la comunicación
- Acceso físico
- Acceso a internet, accesibilidad y conocimiento digital
- Falta de confianza en el gobierno

La guía recomienda que las agencias:

- Planifiquen y prioricen su participación y actividades para la misma
- Reconozcan que las estrategias de participación pueden ser diferentes para cada regulación
- Planifiquen y prioricen intencionalmente las actividades regulatorias para determinar hacia dónde se deben dirigir los recursos a fin de maximizar la calidad de la participación y el compromiso, incluyendo las comunidades desatendidas



Federal Register

Publicación diaria oficial para los reglamentos, reglamentos propuestos, notificaciones de las agencias y organizaciones Federales, así como las Órdenes Ejecutivas y otros documentos presidenciales

The screenshot shows the top navigation bar with links for Home, Sections, Browse, Search, Reader Aids, and My FR. A search bar is located on the right. Below the navigation is the National Archives logo and the text "FEDERAL REGISTER The Daily Journal of the United States Government". To the right is the seal of the National Archives and Records Administration. A blue bar indicates the date "Tuesday, October 17th".

The main content area features a "Current Issue" section with a green header, reporting "104 documents from 47 agencies (266 Pages)" and "83 Notices 6 Proposed Rules 15 Rules 3 Significant Documents". Below this is a "Public Inspection" section with a dark red header, divided into "Special Filing" and "Regular Filing".

Special Filing	Regular Filing
updated on 11:15 AM on Tuesday, October 17, 2023	updated on 8:45 AM on Tuesday, October 17, 2023
9 documents from 6 agencies	97 documents from 44 agencies
4 Notices 5 Rules	75 Notices 3 Presidential Documents 9 Proposed Rules 10 Rules

Below the public inspection section is a search bar titled "Search Federal Register Documents" with a search input field containing the text "Enter a search term or citation" and a search button. To the right of the search bar, it displays "929,838 documents". Below the search bar are four filter buttons labeled R, PR, N, and PD. A note at the bottom states: "Note: Documents older than 1994 are not searchable but can be found by FR citation."

Agenda Unificada

Provee información sobre nueva regulación que el gobierno esta considerando y Regulaciones existentes que el gobierno está revisando



The screenshot shows the Reginfo.gov website header with the following elements:

- Logo of the Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President.
- Text: "OFFICE of INFORMATION and REGULATORY AFFAIRS", "OFFICE of MANAGEMENT and BUDGET", "EXECUTIVE OFFICE of the PRESIDENT".
- Logo of the U.S. General Services Administration (GSA).
- Text: "U.S. General Services Administration".
- Search bar with radio buttons for "Agenda", "Reg Review", and "ICR".
- Navigation menu: Home | Unified Agenda | Regulatory Review | Information Collection Review | FAQs / Resources | Contact Us.

The main content area features the following text:

Spring 2023 Unified Agenda of Regulatory and Deregulatory Actions

The Biden Administration's Unified Agenda of Regulatory and Deregulatory Actions (Agenda) reports on the actions administrative agencies plan to issue in the near and long term. Released by the Office of Information and Regulatory Affairs, the Agenda provides important public notice and transparency about proposed regulatory and deregulatory actions within the Executive Branch.

The Regulatory Information Service Center (RISC) was created in June 1981. The Center undertakes projects that will facilitate development of and access to information about Federal regulatory and deregulatory activities. The Center's principal publication is the Unified Agenda in coordination with the Office of Information and Regulatory Affairs. Since 1978, Federal agencies have been required by Executive orders to publish agendas of regulatory and deregulatory activities. Reginfo.gov displays editions of the Unified Agenda of Federal Regulatory and Deregulatory Actions beginning with fall 1995.

Spring 2023 Unified Agenda of Regulatory and Deregulatory Actions
Active Regulatory Actions Listed by Agency

Select Agency

(Only agencies with information relevant to this report appear in the list.)

[Current Agenda Agency Preambles](#)
[Current Long Term Actions](#)
[About the Unified Agenda](#)
[How To Use the Unified Agenda](#)
[Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions](#)
[Abbreviations](#)
[Obtaining Printed Copies](#)



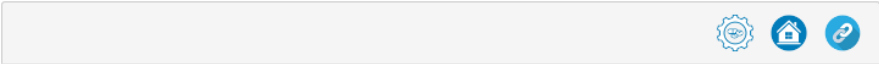
FDA-TRACK

Agenda actualizada de los procesos de desarrollo regulatorio próximos

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

Hover over RIN for additional information

Formal Title	RIN	Projected Publication Date	Stage
Use of Formaldehyde and Formaldehyde-Releasing Chemicals as a...	0910-A183	April 2024	Proposed Rule Stage
Abbreviated New Animal Drug Applications	0910-A154	June 2024	Long-Term Actions
Administrative Destruction of Certain Devices Refused Admission ..	0910-A159	June 2023	Final Rule Stage
Administrative Detention of Tobacco Products	0910-A105	February 2024	Proposed Rule Stage
Amending Regulations That Require Multiple Copies Submissions	0910-A150	October 2023	Proposed Rule Stage
Amendment of Procedural Requirements for Color Additive Petitio..	0910-A153	April 2024	Proposed Rule Stage

Regulations.gov

Provee información sobre el desarrollo de Regulación Federal u otros documentos relacionados publicados por el gobierno de los Estados Unidos

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What's New on Regulations.gov

New features include the ability to download Agency, Docket, and Public Submission Document metadata in bulk. See FAQs for more detail.



What's Trending

ALCOHOL, TOBACCO, FIREARMS, AND EXPLOSIVES BUREAU
Definition of Engaged in the Business as a Dealer in Firearms

FEDERAL AVIATION ADMINISTRATION
Regulatory Definitions of On-Demand Operation, Supplemental Operation, and Scheduled Operation

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Comments Due Soon

Today	17
Next 3 Days	44
Next 7 Days	156

Posted Recently

Today	88
Last 3 Days	164
Last 7 Days	387

Dockets

Expedientes

Colección de documentos relacionados con el proceso de desarrollo regulatorio u otras acciones

Docket (FDA-2021-N-0310) / Document



Medical Devices; Orthopedic Devices; Classification of Spinal Spheres for Use in Intervertebral Fusion Procedures


Posted by the Food and Drug Administration on Mar 30, 2023

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Document Details

 Document ID
FDA-2021-N-0310-0015

Document Details

Federal Register Number 
2023-06566

CFR 
21 CFR Part 888

Document Subtype 
Final Rule

Received Date 
Mar 30, 2023

[More Details](#)

Content

Action

Final rule.

Summary

The Food and Drug Administration (FDA or Agency) is issuing a final rule to classify spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately requiring the filing of a premarket approval application (PMA). FDA has determined that general controls and special controls together are insufficient to provide reasonable assurance of safety and effectiveness for this device.

Dates

This rule is effective May 1, 2023.

Addresses

For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this final rule, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

For Further Information Contact

Constance Soves, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1656, Silver Spring, MD 20993-0002, 301-796-6951, Constance.Soves@fda.hhs.gov.

Lenguaje sencillo

Comunicaciones claras, concisas, bien organizadas que el público puede entender y utilizar

- La Ley de Escritura Sencilla del 2010 requiere que todas las agencias federales usen “**comunicación del gobierno clara que el público pueda entender y utilizar.**”
- La FDA amplía proactivamente el conocimiento sobre la Ley de Escritura Sencilla a los empleados de la FDA:
 - Provee capacitación para educar al personal
 - Usa premios al lenguaje sencillo para reconocer la excelencia en comunicación
- El lenguaje sencillo también facilita los comentarios públicos a la regulación propuesta.

Accesibilidad

La accesibilidad puede medirse por el éxito con el que una persona con capacidades diferentes puede localizar, obtener y entender la información que quiere o necesita.

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](#)

Sitio de internet de la FDA

Incluye información relacionada con la regulación propuesta y final, incluyendo:

- Enlaces a la notificación en el Federal Register y el expediente
- Capacidad de registro para recibir automáticamente correos electrónicos con actualizaciones, así como
- Otra información que puede apoyar el entendimiento de la regulación propuesta y final.

OTC Hearing Aids: What You Should Know



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](#)

Sitio de internet de la FDA

Incluye análisis de impacto regulatorio preliminares y finales en un formato de búsqueda

Regulatory Impact Analyses (RIAs)

Rule Type

Topic

Clear Filters

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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

Reuniones, Conferencias y Talleres

Los eventos virtuales o presenciales pueden facilitar y apoyar la participación pública en el desarrollo regulatorio así como comunicar la regulación final.

Luego de las reuniones la FDA pone a disponibilidad las grabaciones y transcripciones de las mismas en su sitio de internet.

Ejemplos de eventos anteriores incluyen:

- Seminario virtual para dar información sobre el reglamento propuesto en materia de Pruebas Desarrollados en Laboratorio
- Taller público para obtener aportes sobre el uso apropiado de normas consensuadas voluntarias en las solicitudes de autorización de comercialización para dispositivos médicos
- Taller público para comunicar cómo utilizar y referenciar normas en las solicitudes de dispositivos

Documentos Guía

Documentos preparados para el personal de la FDA, solicitantes/patrocinadores, y el público que describen la interpretación o la política de la Agencia sobre un tema regulatorio.

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

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