Best Practices for FDA Communication with Interested Parties: Draft Report for Public Comment

I. Executive Summary

The Food and Drug Administration (FDA, the Agency, we) recognizes that clear, concise, and timely communication with medical product sponsors and other industry members, using a variety of communications vehicles and best practices, is essential to our public health mission. FDA communications aim to inform industry and the public about the Agency's regulatory activities; to clarify procedures or other mechanisms for interactions with FDA Centers and program offices regarding product submissions or regulatory questions; to offer insight into the public health priorities and specific activities of FDA leadership; and much more.

To reach our intended audience, FDA uses a wide array of methods that are tailored to the information being conveyed and the audiences to which it will be of interest. These methods are not static; rather, we continuously seek to improve the transparency, clarity, targeting, and reach of our messaging. In particular, the COVID-19 public health emergency (PHE)[1] prompted FDA to consider increased use of innovative communications methods to rapidly communicate information, helping to facilitate industry's pandemic response efforts.

Recognizing the central role that FDA communications to interested or affected parties played in the Agency's COVID-19 response, Congress directed FDA to issue a report on these communications and the Agency's best practices for their development and use. Specifically, section 2505(b) of the Consolidated Appropriations Act of 2023 (Pub. Law 117-328), directs FDA to issue a report on our practices "to broadly communicate with external stakeholders, other than through guidance documents, including: (1) a review of the types and methods of public communication that [FDA] uses to communicate and interact with medical product sponsors and other external stakeholders; (2) the identification of best practices for the efficient development, issuance, and use of such communications; and (3) a plan for implementation of best practices for communication with external stakeholders…." This report must address "(A) advancing the use of innovative forms of communication, including novel document types and formats, to provide increased regulatory clarity to product sponsors and other stakeholders, and advancing

[1] On January 31, 2020, as a result of confirmed cases of COVID-19, and after consultation with public health officials, the Secretary of Health and Human Services (the Secretary), pursuant to section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d), determined that a PHE existed; this declaration was subsequently extended in 90-day increments until the PHE was allowed to expire on May 11, 2023.

methods of communicating and interacting with medical product sponsors and other external stakeholders, including the use of tools such as product submission templates, webinars, and frequently asked questions communications; (B) streamlining processes for regulatory submissions; and (C) implementing innovative communication development processes and transitioning or updating communication practices used during the COVID–19 public health emergency, as appropriate." Further, in developing this report, FDA is directed to consult with interested parties.

To fulfill this mandate, FDA is issuing this draft report and plan, "Best Practices for FDA Communication with Interested Parties," for public review and comment. While this report discusses communications to external stakeholders generally, as required by section 2505(b), we have focused on communications with regulated industry, which is especially attentive to Agency developments. As described in a Federal Register Notice announcing publication of this document, we intend to solicit public comment for a 60-day period, after which we will begin development of a final report to be issued within 180 days after the publication of the draft report and plan, as directed by section 2505(e)(2).

II. Table of Acronyms/Abbreviations

Abbreviation	What it Means
CBER	FDA's Center for Biologics Evaluation and Research
CDER	FDA's Center for Drug Evaluation and Research
CDRH	FDA's Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CFSAN	FDA's Center for Food Safety and Applied Nutrition (As of Oct. 1, 2024, organization name no longer exists (see Human Foods Program)
CTP	FDA's Center for Tobacco Products
CVM	FDA's Center for Veterinary Medicine
FDA	Food and Drug Administration
HFP	FDA's Human Foods Program (formerly FDA's Center for Food Safety and Applied Nutrition)
HHS	Department of Health and Human Services
OCE	FDA's Oncology Center of Excellence
Q&A's	Question and Answers
PHE	Public Health Emergency
RUF	Regan Udall Foundation
SBIA	Small Business and Industry Assistance
U.S.C.	United States Code

On October 1, 2024, FDA began implementing a reorganization impacting many parts of the Agency. Several FDA centers and offices have name changes effective October 1.

III. Methods for FDA Communications

FDA protects public health by regulating human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, electronic radiation emitting products, and tobacco products. Although regulatory documents (such as regulations, guidance documents, procedures, decisional letters) are a primary means of FDA's communication with interested parties, the Agency also uses a wide array of other tools to augment, clarify, or amplify these communications and to otherwise provide information in timely, transparent, and easily accessible ways. In recent years, in response to the challenges posed by the COVID-19 pandemic, the changing digital communication landscape, and evolving public expectations and preferences for how to consume information, FDA has continued to seek new ways both to broaden our reach and refine our targeting for information dissemination.

The COVID-19 PHE touched nearly all industries regulated by FDA, and it necessitated nearly around-the-clock communications as FDA sought to address the breadth of pandemic-related impacts. FDA communications addressed such disparate topics as, for instance, how FDA was working to mitigate supply chain disruptions (such as for personal protective equipment, other medical devices, pharmaceuticals, food and other commodities); information for medical product sponsors seeking to develop and distribute medical countermeasures; procedures for sponsors and others seeking to engage with FDA regulators through entirely remote interactions; and much more. To handle the scope and volume of communications needs, FDA established new tools and increased use of existing methods to reach industry audiences through multiple channels. We deployed new media-focused products such as the "COVID Daily Round-Up"—a summary of FDA's daily response work (e.g., details on new product authorizations, issuance of guidance documents, import activities, etc.). We increased our use of direct communications to broad audiences, such as through virtual town halls, webinars, podcasts, and social media outreach. We established new COVID-19-focused web pages, which we updated routinely (often daily) to keep regulated industry and the public informed of the latest information and developments related to the public health emergency. Website resources included information on emergency use authorizations for medical countermeasures; detailed responses to frequently asked questions; templates for emergency use authorization submissions (which were often part of guidance documents); and a searchable repository for COVID-19 specific guidance documents.[2]

[2] See FY 2021 MCMi Program Update, available at https://www.fda.gov/media/156892/download?attachment.

The COVID-19 PHE challenged FDA to think even more expansively and creatively about how to tailor and target our communications to our intended audience, including the industries we regulate, in a timely fashion. Although the PHE declared under the Public Health Service Act (PHS Act) has ended, FDA continues to explore ways to integrate or refine our communications methods, consistent with the Federal Food, Drug, and Cosmetic Act and FDA's Good Guidance Practices (GGP) regulation.[3] To prepare this report, the Agency reviewed the key ways in which we share relevant information with interested parties—namely:

1. FDA.gov	5. Blogs and Podcasts
2. Town Halls / Webinars	6. Conferences, Workshops, Meetings and Focus Groups
3. Email and Phone Communications	7. Media Affairs
4. Social Media	

Below is a summary of each of these key communications methods.

1. FDA.gov

FDA's website (FDA.gov) contains up-to-date information for the public about all FDA-regulated product areas, including regulatory information, science and research, news and events, educational resources and training opportunities, safety information, and emergency preparedness. The website also serves as a repository for information and resources to assist industry in making regulatory submissions, including technical specification documents, fact sheets, Q&A documents, and more.

FDA.gov is FDA's primary means, and a critical tool, for sharing information and aiding industry engagement with the Agency. FDA.gov has around 15 million visits per month, an average of 500,000 visits daily.

FDA staff carry out the design, content management, usability, and evaluation of the FDA website to continuously measure engagement and improve usability for the public and all stakeholders, including industry. Agency staff develop and interpret the Agency's Web policies. Agency staff also serve as advocates for FDA's Web presence, facilitate the creative use of the Web, and deliver the Agency's messages to the public via FDA.gov and strategic online partnerships in the government, private, and non-profit sectors.

[3] 21 CFR 10.115.

The website contains information that is relevant to all regulated product areas. This includes FDA's Newsroom, information on public meetings, copies of testimony and speeches of FDA officials, and information on product recalls, among other topics. For instance:

- To assist the public in finding an upcoming webinar or meeting of interest, FDA maintains a web page listing upcoming FDA Meetings, Conferences and Workshops. This webpage also enables access to materials on around 400 meetings, webinars, and events that occurred between 2021 and 2023, including meeting materials and transcripts.[4]
- FDA maintains a single web page that provides one-stop access to over 300 forms for submissions across all FDA-regulated product areas, such as marketing applications, veterinary drug adverse event reporting, other reporting, certifications, and inspections.[5]
- FDA maintains a searchable webpage for all official FDA Guidance Documents and other regulatory guidance.[6]

In addition, FDA maintains web pages dedicated to each regulated product area, where interested parties can find valuable information regarding the laws and the regulations specific to that product area, information on how to submit applications to FDA through online portals, and more. These include, for example:

- A centralized webpage of tutorials, a User Manual, Quick Guide, and FAQ to assist with use of FDA's eSubmitter tool, which is a software program that facilitates creation and submission of a variety of regulatory information to FDA within the drug, blood, device, radiological health, tobacco, animal drug and animal food regulated industries;[7]
- CBER's "Vaccine Development – 101" page provides regulatory information about FDA's oversight of the safety, effectiveness and quality of vaccines that are used in the United States;[8]
- CDER's "Electronic Regulatory Submission and Review" page, which provides information about the use of the Electronic Common Technical Document for submissions of New Drug Applications (NDAs), Abbreviated New Drug Application

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[4] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-meetings-conferences-and-workshops-past-events.

[5] https://www.fda.gov/about-fda/reports-manuals-forms/forms. Forms may be sorted alphabetically or by form number, topic area (e.g., cosmetics, foods, human drugs, safety & problem reports, field operations), date, format, or issuing Center.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[7] https://www.fda.gov/industry/fda-esubmitter.

[8] https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101.

(ANDAs), Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), Master files: Drug Master Files (DMFs) and Biologics Master Files (BMFs), and Emergency Use Authorizations (EUAs);[9]

- CDRH's "How to Study and Market Your Device" page, which provides information on premarket requirements generally, as well as resources on electronic submission processes and potentially applicable submission programs like the Breakthrough Devices Program and Total Product Life Cycle Advisory Program;[10] and
- CTP's Electronic Submissions for Tobacco Products page, which centralizes information for manufacturers and other industry to submit regulatory information and correspondence about tobacco products using electronic methods.[11]

In recent years, content on FDA.gov is increasingly presented in a more diverse variety of visual and dynamic formats to help explain regulatory and scientific issues. For example:

- FDA has increased use of short videos—such as those presented in CDER's Small Business and Industry Assistance (SBIA) Learning Library on YouTube,[12] CDRH Learn,[13] and CFSAN's (now part of the HFP's) Education Resource Library[14]—to help educate industry and assist interested parties in navigating FDA policies and procedures;
- We have designed interactive resources—for instance, the Digital Health Policy Navigator,[15] a tool designed to help individuals and companies determine whether a software product may meet the definition of a medical device, based on statute, regulations and guidance;
- We have developed toolkits to aid compliance with regulatory requirements—for instance, CTP's "This is Our Watch" program, which provides posters, stickers, age verification tools, and more—to help retailers better comply with federal tobacco regulations;[16] and,

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[9] https://www.fda.gov/drugs/forms-submission-requirements/electronic-regulatory-submission-and-review.

[10] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device.

[11] https://www.fda.gov/tobacco-products/manufacturing/electronic-submissions-tobacco-products.

[12] https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/cder-sbia-youtube-learning-library.

[13] https://www.fda.gov/training-and-continuing-education/cdrh-learn.

[14] https://www.fda.gov/food/resources-you-food/cfsan-education-resource-library.

[15] https://www.fda.gov/medical-devices/digital-health-center-excellence/step-1-software-function-intended-medical-purpose.

[16] https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch.

- We have continued to use question-and-answer formats to convey complex regulatory and scientific information in a plain language style—for instance, CFSAN's (now a part of the HFP's) Conversations with Experts on Food Topics.[17]

2. Town Halls / Webinars

As part of FDA's COVID-19 response efforts, the Agency expanded its use of product-specific virtual town halls and webinars to provide opportunities for regulated industry and others to hear directly from, and to ask questions to, FDA. Post-PHE, these continue to be important forums for FDA to engage with industry and others about our ongoing regulatory work. In particular, FDA frequently conducts either live or pre-recorded webinars to discuss new or revised guidance documents, as this format allows us to further describe practical application of a guidance, provide additional examples, or otherwise elaborate on guidance contents, consistent with our Good Guidance Practices regulation under 21 CFR 10.115. Webinar recordings and other materials are typically made available in the resources or industry assistance sections of FDA.gov.

For example:

- As part of their SBIA program, CDER held a webinar on December 12-13, 2023, on Navigating Complex Waters: A Deep Dive into FDA Drug Interactions Guidances and Resources.
- On December 5, 2023, CDRH held a webinar for industry and other interested parties to discuss the immediately-in-effect guidance: Antimicrobial Susceptibility Test System Devices - Updating Breakpoints in Device Labeling.
- CBER has held a series of virtual town halls to answer questions related to the development of cell and gene therapy products, including on clinical development of gene therapy products for rare diseases on February 7, 2023, nonclinical assessment of cell and gene therapy products, and chemistry, manufacturing, and controls for gene therapy products.
- In May and June of 2023, CFSAN (now part of the HFP) held webinars to provide stakeholders with information on regulatory requirements and considerations for infant formula ingredients and packaging.

[17] https://www.fda.gov/food/resources-you-food/conversations-experts-food-topics.

3. Email and Phone Communications

FDA offers an email alert service, which allows interested parties to receive FDA updates on selected topics as new information on those topics becomes available.[18] Currently, FDA has over 185 content topics available, and over 1 million individuals have opted-in to receive emails on one or more topics. In FDA's experience, recipients of these emails often further share this information within their networks, thereby expanding the reach of information shared via FDA distribution lists. Agency emails include distribution of press releases and blogs; announcements of program-specific updates, which may take the form of newsletters, fact sheets, Q&As, or links to source documents, such as new guidance documents; distribution of webinar materials; and more.

In addition to using email to share information externally, all Centers and many other FDA Offices have dedicated email in-boxes to receive inquiries from regulated industry and others on important and timely subjects. Further, most FDA Centers and Offices provide toll-free numbers for external inquiries, including dedicated numbers for small businesses and other external parties.

4. Social Media

FDA uses multiple social media platforms (e.g., LinkedIn, X, Facebook, Instagram, Threads), as well as blogs and podcasts, to engage with intended audiences and to increase collaboration and information exchange in support of FDA's mission to protect and promote public health. FDA has a total of 2.6 million followers on the main Agency social media accounts. FDA has 4 million followers across all 40 Agency-affiliated social media accounts, including those of FDA Centers and Offices. FDA's YouTube channel offers approximately 2,921 videos and has over 165,400 subscribers.

FDA utilizes different technologies depending upon the audience for a particular communication. For example:

- FDA uses LinkedIn to communicate important announcements to its professional audience, including members of regulated industry. FDA uses LinkedIn to publicize guidance documents, annual reports, pilots, Center and Office initiatives, and important public meetings or events.
- FDA's YouTube channel offers content for all audiences, including regulated industry, as well as professional, patient, and consumer audiences. FDA's YouTube channel includes recordings of webinars, video podcasts, advisory committee meetings, stakeholder calls, scientific and research conversations, and small business

[18] https://www.fda.gov/about-fda/contact-fda/get-email-updates.

and industry assistance videos. FDA's YouTube page also makes available educational videos, including "Just A Minute" videos to provide helpful information related to the COVID-19 vaccines approved or authorized for use in the United States, as well as numerous Spanish-language videos.

- FDA uses X (formerly known as Twitter) and other social media platforms (Facebook, Instagram, Threads) to communicate across audiences on a variety of issues—for instance, to highlight issuance of regulatory documents, provide high-level explanations of Agency initiatives, alert the public to new recalls or import alerts, publicize other important safety information, or to promote forthcoming webinars or other events. FDA maintains social media accounts in both English and Spanish.[19] The Agency also maintains social media toolkits, often available in multiple languages, with social media messages, graphics, videos, and downloadable fact sheets.
- Finally, FDA uses Flickr[20] to share photos of agency leadership, events, and various activities, including photos to explain regulatory actions (e.g., pictures of fraudulent products).

5. Blogs and Podcasts

FDA provides insights from Agency leadership, or regulators within the Centers and Offices, through the format of blogs and podcasts, which provide a less formal mechanism for sharing leadership perspectives or diving deeper on specific regulatory topics.

FDA's marquee blog series, "FDA Voices,"[21] addresses topics across FDA's regulated product areas. It features posts such as a Commissioner series called "Catching Up with Califf," as well as issue-specific thought pieces that shed light on the Agency's thinking about timely regulatory and public health issues, such as overdose prevention, postmarket surveillance, food safety and more. To aid readers that want to find discussion of a specific issue(s), the FDA Voices website provides a structured search function that facilitates searching by key word, type of regulated product, health topic, and date. In addition to "FDA Voices," some individual FDA Offices also maintain blogs, such as a video blog "On the Road with Jim Jones,"[22] which captures insights from FDA's first Deputy Commissioner for Human Foods.

In recent years, FDA has also made increasing use of podcasts as another mechanism to highlight FDA activities, including deeper dives into specific regulatory topics. For instance,

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[19] https://www.fda.gov/news-events/interactive-and-social-media#espanol.

[20] https://www.flickr.com/photos/fdaphotos/.

[21] https://www.fda.gov/news-events/fda-newsroom/fda-voices.

[22] https://www.fda.gov/food/news-events-cfsan/road-jim.

"Guidance Snapshots" aid with dissemination and explanation of some FDA guidance documents.[23] The "Health Equity Forum" is produced by FDA's Office of Minority Health and Health Equity as a forum to convene experts for conversations around health topics impacting the lives and well-being of diverse communities.[24] The "New Era of Smarter Food Safety TechTalk" is a four-episode series that focused on the development and use of new technologies to prevent outbreaks, speed outbreak response, and more swiftly adapt to crises that could affect the human and animal food supply.[25] FDA encourages the public to subscribe to FDA podcasts.[26] In addition to FDA-produced podcasts, FDA leadership also participate in podcasts produced by other organizations.

6. Conferences, Workshops, Meetings and Focus Groups

FDA frequently leads and participates in conferences, workshops, meetings, and focus groups on scientific and regulatory topics. In 2022, FDA led over 140 meetings with interested parties, not including Advisory Committee meetings. FDA also partners with outside institutions, such as the Reagan Udall Foundation (RUF)[27] or the Duke-Margolis Center for Health Policy, to facilitate engagement with a range of interested or affected outside parties, including industry, patients, consumers, academic institutions, policymakers, and others. And FDA frequently partners with other government regulators at the local, state, national, and international levels, to host public meetings, to share information, and otherwise collaborate. Recent meetings with interested parties and upcoming events, meeting materials, recordings, and transcripts are available on FDA's Meetings, Conferences and Workshops web page.[28]

FDA senior leadership, including the Commissioner, those in the Office of the Commissioner, and FDA Centers and Offices, frequently give speeches at conferences, such as the Food and Drug Law Institute Conference, the International Bar Association World Life Sciences Conference, and the Food Is Medicine National Summit.[29] In addition, FDA

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[23] https://www.fda.gov/drugs/guidances-drugs/guidance-snapshot-pilot.

[24] https://www.fda.gov/consumers/minority-health-and-health-equity/health-equity-forum-podcast.

[25] https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-techtalk-podcast#:~:text=The%20podcast%20will%20be%20hosted,facilitate%20and%20enhance%20food%20safety.

[26] https://www.fda.gov/about-fda/contact-fda/subscribe-podcasts-and-news-feeds.

[27] RUF is an independent 501(c)(3) organization created by Congress to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. See 21 U.S.C. § 379dd.

[28] See https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops. This web page allows users to sort meetings by parameters such as start and end date, event title, event type (e.g., webcast, workshop, meeting), and lead Center.

[29] https://www.fda.gov/news-events/speeches-fda-officials.

employees often make presentations and participate on panels or in roundtable discussions at conferences.

7. Media Affairs

FDA routinely uses media channels and engagement to publicize, contextualize, and otherwise disseminate information about our regulatory activities that would be relevant to interested parties. Depending on factors such as the public health impact, high profile nature, or anticipated stakeholder interest in a topic, FDA may proactively share information with media outlets, such as published proposed or final rules, published draft or final guidances, or information about other Agency actions through press releases and statements that are posted on FDA.gov and distributed via various email lists and promoted on social media. FDA uses a variety of tools—such as publicly livestreamed teleconferences with members of large mass news media and press outlets geared toward FDA-regulated industry; media interviews of FDA leadership; and written responses to media inquiries—to provide further comment or context on agency activities, including those relevant to regulated industry. Additionally, FDA issues a twice-weekly "FDA Roundup" communication that highlights a variety of the critical public health activities, such as guidances, industry-focused webinars, and regulatory resources, from across the Agency.

IV. Communications Best Practices

FDA has developed numerous processes to promote quality, consistency, and clarity of the Agency's communications to interested parties. Below is a summary of key best practices:

1. Organizational Structure

Within FDA, the Office of External Affairs oversees Agency-wide communications activities regarding FDA's public health mission. Beyond the Office of External Affairs, across the Agency, multiple Centers and Offices—who are the experts in their subject areas—carry out communication with industry directly. The Centers and Offices have dedicated staff to develop and carry out extensive engagement and communications with regulated industry, according to product area.

2. Content and Format of Communications

FDA utilizes best practices and procedures for timely, transparent, and effective communications between industry and the Agency throughout the development of the specific FDA-regulated product. Depending on the commodity, the practices and procedures may vary.

The use of best practices ensures quality and consistency of messages and appropriate levels of outreach to intended and targeted audiences. These best practices include leveraging a

variety of communications, such as press releases and FDA statements; broadcast emails to subscribers (also called "burst" announcements) for medical product approvals; content on FDA.gov; questions and answers to media inquiries; media interviews with the general media, trade press, or professional society and patient advocacy groups and publications; participation by FDA employees in externally hosted podcasts; communication plans; social media content; graphics and videos; and any communication related to an agency announcement. More specifically, FDA uses communications such as podcasts, webinars, templates for Emergency Use Authorization (EUA) or other product submissions (which are part of guidance documents), Questions and Answers (Q&As), and other tools to provide increased regulatory clarity to product sponsors and industry and to streamline the process for regulatory submissions.

Here are more examples of how FDA implements it best practices for communication:

- CDRH hosts webinars and calls to educate industry and stakeholders on guidances, to answer technical questions on the development and validation of certain tests, and to discuss other topics related to the regulation of medical devices and radiation-emitting products. For example, on September 14, 2023, CDRH held a webinar for industry and other interested stakeholders to discuss the draft guidance: Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder.
- CFSAN (now part of the HFP) issues Constituent Updates, to communicate with industry, including information regarding guidance documents.[30] For example, on September 28, 2023, through a CFSAN (now part of the HFP) Constituent Update, FDA released two guidance documents that outline recommendations for how sprout operations may comply with the Produce Safety Rule.
- CDER conducts meetings, conferences, and workshops to communicate information with industry and stakeholders. For example, FDA hosted a workshop on October 30, 2023, on Defining "Candy-like" Nonprescription Drug Products.[31] And the FDA Guidance for Industry titled "Best Practices for Communication Between IND Sponsors and FDA During Drug Development"[32] includes an overview of CDER and CBER's best practices between IND Sponsors and FDA during drug development.
- CBER sponsors or co-sponsors public meetings, conferences, workshops and webinars to help enhance communication efforts, provide educational outreach and seek the opinion of interested parties in support of U.S. and global public health related to the Center's oversight of biological products. For example, CBER hosted a virtual town hall on June

[30] https://www.fda.gov/food/news-events-cfsan/cfsan-constituent-updates.

[31] https://www.fda.gov/drugs/news-events-human-drugs/defining-candy-nonprescription-drug-products-10302023.

[32] https://www.fda.gov/media/94850/download.

8, 2023, focused on cell therapy chemistry, manufacturing, and controls (CMC), including tissue-engineered medical products regulated by FDA.[33]

- CVM offers several webinars annually, often in the field of animal biotechnology, where the issues are complex and the audiences may reflect various levels of experience working with a regulatory agency. For example, the CVM Bioinformatics staff prepared webinars during CVM's transition to e-submission to assist regulated industry in making regulatory submissions to the agency.
- CTP issues periodic newsletters to industry and stakeholders to communicate information, for example, on modified risk tobacco product application updates, how to submit a tobacco product application, and scientific issues related to tobacco regulation.
- OCE issues a report annually ("OCE Annual Report")[34] which summarizes the oncology programs' and projects' progress and achievements. In addition, OCE issues a monthly newsletter to inform industry about OCE webinars, recent cancer drug approvals and guidances, and journal publications. OCE also issues a quarterly newsletter for patients with cancer, advocates, and healthcare providers on upcoming events to the advocacy and survivorship community.

FDA also uses best practices to communicate and promote openness in scientific decision-making and to strengthen the quality, integrity, and credibility of scientific activities at the Agency. FDA encourages staff to share scientific or technical information that may benefit public health by giving speeches and publishing articles in professional journals or other publications, consistent with applicable laws and agency policies.

Additionally, FDA has worked to increase public access to peer-reviewed articles and data generated from FDA-funded research, whether conducted by FDA staff or outside organizations with funding from FDA. The broad availability of scientific information and underlying data allow for the critical review, replication, and verification of findings that are central to the scientific method. Making research findings and the data supporting those findings accessible and analyzable promotes robust and open communication between FDA and the scientific community, thereby bolstering the credibility of scientific findings and the regulatory decision-making based upon those findings.

FDA also seeks expert and public input on a broad scope of complex issues related to the products it regulates, consistent with the Federal Advisory Committee Act (FACA) and the

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[33] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/otp-town-hall-cell-therapy-chemistry-manufacturing-and-controls-june-2023-06082023.

[34] https://www.fda.gov/about-fda/oncology-center-excellence/oce-annual-reports.

Agency's implementing regulations.[35] FDA has many advisory committees, some with multiple panels. The committees are established in the interest of obtaining advice or recommendations for the Agency on a range of complex scientific, technical and policy issues. As the Agency makes its final decisions, it considers the advice provided by advisory committees. Advisory committee meetings can generally occur during any stage of a review process or after a product has been approved or marketed. For example, an advisory committee meeting is often held to assist the review division with questions or difficulties related to the interpretation of medical product trial data. During the COVID-19 public health emergency, all FDA advisory committee meetings were held virtually, with public access, to ensure transparent discussions. FDA continues to use an online video teleconferencing platform for its advisory committee meetings.

3. Application of Social and Behavioral Science Research to Communications

FDA uses social and behavioral science research to guide the development of our messaging and communication. This research includes, for instance:

- Patient and consumer interviews and surveys to determine how messaging, labeling statements, and claims related to a product's attributes, consumption and usage affect patients' and consumers' understanding and decision-making;
- Data from social media posts and FDA archival data (e.g., FDA's Advisory Committee transcripts) to better understand stakeholder perspectives; and
- Focus groups and usability and comprehension studies to test accessibility and comprehension of FDA's messaging with industry, as appropriate.

4. Accessibility of Communications

All FDA communications, including communications with regulated industry, are developed with accessibility considerations being a priority. FDA's website follows Web Content Accessibility Guidelines (WCAG) international standards and U.S. Web Design System standards (USWDS). FDA is committed to making Information and Communication Technology (ICT) accessible to individuals with disabilities, including members of the public and federal employees. Such ICT includes third-party content published on our intranet and internet websites

[35] 5 U.S.C. App. II; see also 21 CFR part 14.

and contained within our software and web applications. FDA is subject to the requirements of Section 508 of the Rehabilitation Act of 1973, as amended.[36]

FDA also strives to make its website as comprehensible as possible, for example by using plain language where appropriate, headers and captions, strategic use of type/font sizes, layout, contrast, graphic design, and spacing; FDA communicators often use the CDC's Clear Communication Index to assess the incorporation of these best practices. FDA also uses voting buttons, infographics, animated images (e.g., GIFs), and other visuals to grab attention and optimize engagement.

As part of FDA's Language Access program,[37] FDA also translates certain materials into Spanish and other languages, depending on the content of the communication and intended audience as resources permit, so that we can reach the diverse communities we serve, including people with limited English proficiency. FDA.gov offers translated health education resources in 15 languages.

5. News Media Policy

FDA is committed to a culture of openness in its interaction with the news media and the public. The Agency seeks to respond quickly, thoroughly and openly with news organizations and with the public about its activities, scientific research and analysis, programs and recommendations. As FDA is an operating division of the HHS, FDA follows HHS's news media policy, Guidelines on the Provision of Information to the News Media.[38]

6. Use of Data Analytics to Measure Public Engagement

FDA regularly employs data analytics to measure the public's engagement with FDA communications. For instance, during the COVID-19 PHE, FDA used data analytics information to inform our iterative updates and improvements to FDA's landing page for COVID-19. FDA Centers and Offices routinely measure open and click rates for their emails. The data are analyzed and used to inform best practices, to improve communications tools and tactics, and to increase intended audience participation.

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[36] 29 U.S.C. § 794d. Section 508 requires agencies, during the procurement, development, maintenance, or use of ICT, to make sure that individuals with disabilities have access to and use of ICT comparable to the access and use afforded to individuals without disabilities ("ICT accessibility"), unless an undue burden would be imposed on the agency. The Section 508 standards are the technical requirements and criteria that are used to measure conformance with the law and incorporates the W3C Web Content Accessibility Guidelines (WCAG) 2.0. More information on Section 508 and the technical standards can be found on Section508.gov and HHS.gov.

[37] https://www.fda.gov/consumers/minority-health-and-health-equity/language-access.

[38] https://www.hhs.gov/sites/default/files/media_policy.pdf.

7. Coordinating Communications with other Agencies/State and Tribal Governments/International Counterparts

FDA regularly collaborates with other federal Agencies and public health counterparts, state and tribal governments, and international regulatory counterparts on messaging and communications.

For example, since 1971, FDA and the Drug Enforcement Administration (DEA) have regulated the manufacture, importation, possession, use, and distribution of particular substances under the Controlled Substances Act. The Agencies work in concert, as appropriate, on protocols, recommendations, and information-sharing relating to schedule I through V substances.

FDA has dedicated staff who work with State and Tribal governments and coordinate across FDA Offices, Centers and/or Directorates to respond to inquiries from States and to engage in proactive outreach to States on important FDA policy issues. The Agency develops and maintains relationships with policymaking State and Tribal partners, including State officials such as Governors, Attorneys General, and State legislators, national associations representing those State officials, and Tribal governments and Tribal organizations.

FDA also fosters international partnerships with counterpart foreign government agencies and international organizations. The tools that FDA uses to set up and memorialize these partnerships include two categories of International Arrangements: Cooperative Arrangements (which include Memoranda of Understanding and similar documents) and Confidentiality Commitments.

V. Plan for Implementation of Best Practices for Communications with Interested Parties

FDA intends to continue ongoing efforts to optimize communications with interested parties through a variety of communications vehicles that are clear, concise, timely, and geared toward this audience.

We welcome stakeholder feedback on additional ways to communicate with interested parties. Below are some, but not all, of FDA's current plans to implement best practices going forward:

1. Incorporating Communications Strategies from the Reagan-Udall Foundation Report

The Reagan-Udall Foundation's (RUF) October 2023 report on Strategies for Improving Public Understanding of FDA Regulated Products reaffirms the importance of many of the

communications strategies the Agency is increasingly using to deliver accurate, understandable and timely health information to the public. The Agency is reviewing and considering for incorporation many of the helpful suggestions in the RUF report to enhance communications with regulated industry.[39]

2. Exploring Website Enhancements to Further Assist with Regulatory Submissions

FDA's website currently provides information and resources to assist industry in submitting regulatory information, and going forward the Agency plans to explore enhancements that would further aid processes for regulatory submissions to the Agency. For instance, FDA is considering ways to improve the utility of information related to guidance documents, technical specification documents, fact sheets, Q&A documents, and webinars. FDA also plans to explore mechanisms to increase accessibility and diversity in its communications to facilitate broader engagement by interested or affected parties, including regulated industry.

3.Webinars and Learning Modules to Help Explain Important Rules and Guidance Documents

The Agency plans to continue to explore and implement many of the innovative communications processes and practices, such as those used during the COVID-19 PHE as appropriate. FDA is also planning future webinars for important rules and guidance documents, as well as other significant Agency initiatives. The Agency currently partners with the SBIA and external stakeholders, as appropriate, and is exploring new partnerships to disseminate webinars to reach a wider audience, including industry. These modules provide industry with information that is comprehensive, interactive, and easily accessible. Modules are provided in various formats, including videos, audio recordings, and slide presentations.

4. FDA Information Technology Strategy

As outlined in FDA's Information Technology Strategy for FY 2024 – FY 2027 ("IT Strategy"),[40] FDA has established an enterprise-wide plan to guide the Agency's information technology direction and investments for the next four years.[41] As a key pillar of this plan, FDA

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[39] https://www.fda.gov/news-events/speeches-fda-officials/remarks-commissioner-califf-reagan-udall-foundations-public-meeting-strategies-improving-public.

[40] https://www.fda.gov/about-fda/office-digital-transformation/fda-information-technology-strategy-fy-2024-fy-2027.

[41] 88 Fed. Reg. 64435 (Sept. 19, 2023).

is in the process of creating a "Shared OneFDA Ecosystem" which will shift FDA's culture to make sharing across Centers and Offices and with external stakeholders (where appropriate) the norm. Our objectives include enhancing communication and collaboration by (1) fostering information and resource sharing with internal and external parties to achieve both Agency and stakeholder outcomes, and (2) enabling collaboration and the development of strong partnerships across FDA Centers and Offices through integrated technology platforms. A unified information technology approach, as outlined in the IT Strategy, will enable FDA to innovate and enhance public health outcomes.

5. FDA's Multilingual Communications Services

The Agency is growing its multilingual communications services. FDA's language access work (see section IV) provides meaningful access to members of the public who do not speak English as their primary language, including those in industry and small business. FDA's multilingual communications services help the Agency better serve diverse communities within the United States, including people with limited English proficiency; connect with entities outside of the United States; and meet language access requirements, such as requirements under Executive Order 13166: Improving Access to Services for Persons with Limited English Proficiency.[42]

[42] https://www.justice.gov/sites/default/files/crt/legacy/2010/12/14/eolep.pdf.