FDA's External Communications

Executive Summary

During the February 2016 Risk Communication Advisory Committee meeting, the Committee recommended that the Food and Drug Administration (FDA) conduct an environmental scan of FDA's risk communications. The purpose of this environmental scan is to collect and describe each communication the FDA uses to inform external stakeholders. The information obtained from this environmental scan can provide external stakeholders with an understanding of the communications the FDA uses to promote better informed decisions about FDA-regulated products.

FDA's environmental scan of external communications is based on information received from the following Centers and Offices:

- Center for Biological Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Center for Tobacco Products (CTP)
- Office of the Commissioner (OC)
    - Office of the Chief Scientist (OCS)
    - Office of External Affairs (OEA)
    - Office of Foods and Veterinary Medicine (OFVM)
    - Office of Global Regulatory Operations and Policy (OGROP)
    - Office of Minority Health (OMH)
    - Office of Women's Health (OWH)
- Office of Regulatory Affairs (ORA)

Each Center and Office develops communications for the products they regulate, suitable for their target audiences. As such, this document contains external communications that are utilized commonly across multiple Centers and Offices. It also contains external communications that are used only by a specific Center or Office.

The collection of external communications from these Centers and Offices resulted in 128 communications. The communications are organized in a table, by the following categories:

- How the agency refers to the communication;
- The intended purpose of the communication;
- The target audience of the communication;
- How the Center or Office ensures comprehension of the communication;
- How the communication is disseminated;
- If the communication is required by regulation;
- If the communication follows a template; and
- If the communication can be modified.

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Center for Biologics and Evaluation Research (CBER) – External Communications							
How the agency refers to the communication	**Describe the intended purpose**	**Target Audience**	**How do you ensure comprehension?**	**How is the communication disseminated?**	**Is it required by regulation?**	**Does it follow a template?**	**Can the communication be modified? If so, do the modifications go through a rulemaking process?**
CBER-Regulated Products: Current Shortages	This page is part of a group of pages on CBER's web site (CBER-Regulated Products: Shortages and Discontinuations) that provide information on availability of licensed biologics regulated by CBER.	Regulated industry, health care professionals, patients, and the general public	Internal review of content	FDA.gov, email listservs, Twitter, targeted outreach to health care providers, patients and professional organizations	No	Yes. Each of the product shortage pages (current shortages, resolved shortages and discontinuations) is in a table format and includes the product name, manufacturer contact, reason for shortage, additional information if available, and date.	Yes, it can be modified. No, it does not have to go through rulemaking.
CBER-Regulated Products: Discontinuations	This page is part of a group of pages on CBER's web site (CBER-Regulated Products: Shortages and Discontinuations) that provide information on availability of licensed biologics regulated by CBER.	Regulated industry, health care professionals, patients, and the general public	Internal review of content	FDA.gov, email listservs, Twitter, targeted outreach to health care providers, patients and professional organizations	Yes. The Food and Drug Safety Innovation Act (FDASIA) requires manufacturers of certain drug products (including biologics) to notify FDA at least six months prior to the date of permanent discontinuance in the manufacture of the drug or an interruption in the manufacturing that is likely to lead to a meaningful disruption in supply. [21 CFR 314.81(b)(3)(iii)]	Yes. Each of the product shortage pages (current shortages, resolved shortages and discontinuations) is in a table format and includes the product name, manufacturer contact, reason for shortage, additional information if available, and date.	Yes, it can be modified. No, it does not have to go through rulemaking.
CBER-Regulated Products: Resolved Shortages	This page is part of a group of pages on CBER's web site (CBER-Regulated Products: Shortages and Discontinuations) that provide information on availability of licensed biologics regulated by CBER.	Regulated industry, health care professionals, patients, and the general public	Internal review of content	FDA.gov, email listservs, twitter, targeted outreach to health care providers, patient and professional organizations	No	Yes. Each of the product shortage pages (current shortages, resolved shortages and discontinuations) is in a table format and includes the product name, manufacturer contact, reason for shortage, additional information if available, and date.	Yes, it can be modified. No, it doesn't have to go through rulemaking.

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CBER Safety Communication (examples posted by year on CBER's website)	Share important new and emerging safety information and, where appropriate, recommended actions to take based on the information	Health care professionals, patients, and the general public	Internal review of content	FDA.gov, email listservs, twitter, and targeted outreach to health care professionals, advocacy/patient organizations, professional societies, federal partners	Indirectly. Section 915 of Food and Drug Administraton Amendments Act (FDAAA) requires summaries of safety information be posted on the web	Generally, but depending upon the issue or what is being communicated, there is flexibility (for example, not all headings may apply to each issue)	Yes it can be modified; no it doesn't have to go through rulemaking.
Innovation and Regulatory Science	Provide summaries of research publications by CBER staff for a lay audience. Papers highlighted are on interesting or important work being conducted by CBER's regulatory science program, which supports the Center's mission.	Regulated industry, researchers, health care professionals, and the general public	Internal review of content	FDA.gov, email listservs, Twitter	No	No	Yes, it can be modified; no it doesn't have to go through rulemaking.
Licensed Vaccines for Immunization and Distribution	Make available in one location a list of all vaccines licensed (approved) in the U.S. The page includes links to each individual product – the "product pages" are home to the approval information for each product (approval letter(s), package insert, patient package insert [if available], product reviews in support of approval, and press releases [if issued for the product])	Health care professionals, patients, and the general public	Internal review of content	FDA.gov, email listservs, Twitter	Not this specific page. The product pages contain information that is required to be posted (under FDAAA)	No	Yes, it can be modified. No, it does not have to go through rulemaking.
List of Licensed Products and Establishments	Links to lists of all licensed biological products. Two such lists are included on the page – an alphabetical list of licensed manufacturers including product approval dates and an alphabetical list of licensed products.	Regulated industry, health care professionals, patients, and the general public	Internal review of content	FDA.gov, email listservs, and Twitter. The lists are updated monthly and when updates are posted, they are disseminated.	No	No, this page is not a template, but it is generated from a database. The two documents are generated from a database and posted in PDF format.	Yes, it can be modified, although there isn't much on the page to modify (the lists posted may be more difficult to modify, as they are generated from a database); no it doesn't have to go through rulemaking

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Questions and Answers – consumer content (posted on the Consumers (Biologics) web page)	Provide general information on various products regulated by CBER. Topics range from explaining blood safety and what potential blood donors need to know prior to donation, to information for parents considering banking cord blood, to general information about vaccine safety.	General public (consumers), but information may also be useful to health care professionals	Internal review of content	FDA.gov, email listservs, Twitter	No	No	Yes it can be modified; no it doesn't have to go through rulemaking.
Recalls (Biologics)	Share important information about recalls and market withdrawals of CBER-regulated products, usually prior to inclusion in the agency's Enforcement Report.	Health care professionals, patients, and general public	Internal review of content	FDA.gov, email listservs, Twitter, and targeted outreach to health care professionals, advocacy/patient organizations, professional societies, federal partners.	No. Posting of the information is separate from FDA's recall classification process (21 CFR 7.40)	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Testing for HIV	Provides general information on test options for HIV, including professional use, home collection (send sample to lab) and home use (testing yourself). Links on the page to information about the different types of tests and to information for consumers on HIV/AIDS.	General public (consumers), but information may also be useful to health care professionals	Internal review of content	FDA website, email listservs, and Twitter	No	No	Yes, it can be modified; no it does not have to go through rulemaking.
Vaccines for Children – A Guide for Parents and Caregivers	Intended as a resource guide for parents and caregivers with information on FDA-approved vaccines for children and adolescents. Includes information on benefits and risks, questions and answers, etc. Updated periodically as new vaccines are licensed for pediatric use.	General public (consumers and parents), but information may also be useful to health care professionals	Internal review of content	FDA.gov, email listservs, Twitter, and FDA Consumer Updates	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.

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Center for Devices for Radiological Health (CDRH) – External Communications							
CDRH Initiatives Websites	CDRH Initiatives include Digital Health, Postmarket Surveillance, Medical Device Innovation, Patient Preferences, International Programs, Unique Device Identifiers (UDI), Initiative to Reduce Unnecessary Radiation Exposure from Medical Devices, and other topics. They explain the goals and objectives of each initiative, and may indicate how stakeholders may participate in or provide feedback to CDRH on the initiative goals and outcomes.	All CDRH Stakeholders	Not aware of testing that has been conducted for these pages.	Web pages and updates are posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists	No	Yes, websites follow a standard format.	Yes, it can be modified. No, it does not have to go through rulemaking.
CDRH Learn	This multimedia industry education tool consists of learning modules describing many aspects of medical device and radiation emitting product regulations, covering both premarket and postmarket topics. This tool is intended to provide industry with information that is comprehensive, interactive, and easily accessible.	Industry (medical devices and radiation-emitting electronic products regulated by CDRH)	Feedback from industry is regularly incorporated into CDRH Learn modules.	Modules are provided in various formats, including videos, audio recordings, and slide presentations. All are available on FDA.gov, and new modules are announced via GovDelivery to registered firms and other appropriate industry lists.	No	Yes, the various tools follow a standard format.	Yes, it can be modified. No, it does not have to go through rulemaking.
CDRHNew	CDRH New is a daily subscription email that includes links to all items posted to CDRH's FDA.gov pages from the previous business day.	All CDRH stakeholder audiences who want notification of new CDRH-related items posted to FDA.gov	Not necessary – emails contain links to newly-posted website items.	Emails are distributed via GovDelivery subscriber lists; daily new item lists with corresponding links are also posted to FDA.gov.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
CDRH Organizational Websites	Site provides organizational information including CDRH mission and vision, organizational structure, strategic priorities, contact information and key policies and/or initiatives.	All CDRH Stakeholders	Not aware of testing that has been conducted for these pages.	Web pages and updates are posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists	No	Yes, websites follow a standard format.	Yes, it can be modified. No, it does not have to go through rulemaking.

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CDRH Outreach Emails	CDRH Outreach emails send timely information to external stakeholders on a variety of hot topics, such as newly published guidance documents, proposed and final rules and regulations, policy updates and other regulatory matters.	Primarily industry, but may include other stakeholders, such as health care providers, patients and home caregivers.	Not typically pretested	Emails are distributed via GovDelivery subscriber lists; text is also posted to FDA.gov.	No	Generally follow a standard format	Yes, it can be modified. No, it does not have to go through rulemaking.
Device Advice: Comprehensive Regulatory Assistance Website	Device Advice is CDRH's web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies, covering both premarket and postmarket topics. Device Advice is intended to provide industry with information that is accurate, timely, comprehensive, and useful. For multi-media industry education, please also see CDRH Learn.	Patients, caregivers, health care professionals	Safety Communications may be pretested with internal FDA testing cadre, and/or with representatives of partnering stakeholder organizations with whom CDRH has entered a Confidential Disclosure Agreement (CDA) for pre-release review.	Notices are posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Mammography Quality Standards Act Program	This website informs mammography facility personnel, inspectors, and other interested individuals about the implementation of the Mammography Quality Standards Act of 1992 (MQSA). Notices about facility adverse events, such as MQSA certification revocation, are also posted to this website, as are "MQSA Insights Articles" that provide tips and recommendations for facility staff, inspectors, certifiers and others responsible for performing mammograms or implementing MQSA.	Mammography facility personnel, inspectors, patients, health professionals	Unaware of any testing that has been conducted for these pages.	Updates posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists.	No	Yes (Mammography Facility Adverse Event and Action Reports)	Yes, it can be modified. No, it does not have to go through rulemaking.

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Notifications	The FDA posts Mammography Safety Notifications in cases where a mammography facility cannot or will not demonstrate to FDA's satisfaction that all affected patients were successfully notified.	Patients who have undergone mammography at the facility, caregivers and health care providers.	Mammography Safety Notifications are drafted jointly by Mammography Quality Standards Act (MQSA) staff and CDRH risk communication experts using best practices in Plain Language Writing and risk communication. Comprehension testing is not typically conducted.	Mammography Safety Notifications are posted to FDA.gov, tweeted, and redistributed through relevant CDRH GovDelivery subscriber lists.	No. Under the Mammography Quality Standards Act (MQSA) of 1992, the FDA requires that all mammography facilities meet certain high quality standards. When a facility fails to meet the standards, the FDA requires it to notify affected patients and their referring health care providers that their recent mammograms could have unreliable results. In the cases where a facility cannot or will not demonstrate to FDA's satisfaction that all affected patients were successfully notified, the FDA posts Mammography Safety Notifications to this website.	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Medical Device Products and Medical Device Procedures Websites	CDRH websites provide balanced benefit-risk information about CDRH regulated products and procedures that use these products. They are intended to provide patients, caregivers and health care providers with balanced benefit-risk information to assist them in making informed decisions about the use of these products and procedures in an individual's health care.	Patients, caregivers, health professionals	Some website messages may be pretested with the FDA's internal testing cadre, coordinated by the OPL/Risk Communication Staff. Some have also been reviewed as assignments to FDA risk communication SGEs.	New and updated websites posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists.	No	Yes, Medical Device Products and Procedures websites generally follow a standard format and navigation	Yes, it can be modified. No, it does not have to go through rulemaking.
Medical Device Recalls	FDA posts consumer-friendly information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death.	Patients, caregivers, health care professionals	Template and contents pretested with FDA's internal message testing cadre, organized by OPL/Risk Communication staff	Notices are posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

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MedSun Educational Webinars	Adverse event reporting program that works collaboratively with approximately 250 hospitals, nursing homes and home health facilities around the United States. The MedSun Educational Webinars provide facilities with medical device safety information of interest to health care providers, patients and caregivers, on specific topics and interest/specialty areas.	Health care providers and facilities, including MedSun participating facilities	Feedback from MedSun sites and webinar participants.	MedSun Educational Webinar transcripts, audio recordings, and slide presentations are posted to FDA.gov.	No	Webinars follow a standard format	Yes, it can be modified. No, it does not have to go through rulemaking.
MedSun Newsletter	Adverse event reporting program that works collaboratively with approximately 250 hospitals, nursing homes and home health facilities around the United States. The newsletter provides facilities with information on current medical device recalls, new product approvals, facility surveys and other information to assist MedSun sites in detecting, understanding, and sharing information concerning the safety of medical products.	Health care providers and facilities, including MedSun participating facilities	Feedback from MedSun sites.	MedSun Newsletters are posted to FDA.gov and redistributed through GovDelivery	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Radiation-Emitting Products and Medical Procedures Websites	CDRH websites provide balanced benefit-risk information about CDRH-regulated radiation-emitting devices and electronic products, and the medical procedures that use these products. They are intended to provide patients, caregivers and health care providers with balanced benefit-risk information to assist them in making informed decisions about the use of these products and procedures in an individual's health care. Radiation safety information includes recommendations for how people can reduce their risk of harmful or unnecessary radiation exposure.	Patients, caregivers, health professionals	Some website messages may be pretested with the FDA's internal testing cadre, coordinated by the OPL/Risk Communication Staff. Some have also been reviewed as assignments to FDA risk communication SGEs.	New and updated websites posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

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Recently Approved Devices (one-pagers)	Recently Approved Devices "One-Pagers" provide information about newly approved or cleared PMA, 510(k), HDE and De novo products. Information includes what the device is, how it works, when it can be used and when it should not be used, in a plain-language and consumer-friendly format. They include links to the device's Summary of Safety and Effectiveness and the product labeling, when available.	Patients, caregivers, health professionals	Not aware of testing that has been conducted for these pages.	Posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Science and Research Websites (Medical Devices)	CDRH Science and Research websites describe the Center's initiatives to advance regulatory science, including laboratory and field research to develop new tools, standards and approaches to assessing the safety, efficacy, quality and performance of medical devices and radiation-emitting products.	Internal and external stakeholders interested in CDRH regulatory science initiatives	Comprehension testing has not been conducted for these websites.	New and updated websites posted to FDA.gov are tweeted, and distributed through appropriate GovDelivery subscriber lists	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.
Center for Drug Evaluation and Research (CDER) – External Communications							
CDER Alert	Compliance and safety information that is not appropriate for a drug safety communication.	Industry, General Public, HCPs, Media, Advocacy information	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web & email listserv, Twitter and Facebook (if requested)	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
CDER Conversation	To bring awareness to center actions on issues of importance to CDER's stakeholders, topics the center needs to get ahead of, or where additional context is needed.	Policy makers, Advocacy Groups, and Consumers	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, Listservs, trade press, Facebook and Twitter	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
CDER Exhibit Program	Educational materials on the latest regulatory and clinical information presented at conferences.	Industry, HCPs, professional associations and societies	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Conference exhibits	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.

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CDER From Our Perspective	Further explain CDER's current thinking on issues of importance to our industry, health care provider and academic audiences. Provide an in-depth look at the science and/or rationale behind an issue and also describe examples of the center's ongoing work to tackle its current and anticipated future challenges.	Industry, HCPs-Clinical Trialists, and Academia	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, listservs, trade press, and Facebook	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
CDERLearn	Webpage platform for educational training courses.	Consumers, Health care providers. industry	For continuing education (CE) courses, we receive evaluations from users. We have never received questions from users that indicate the materials were not comprehensible.	FDA.gov, FDA Listservs, Division of Drug Info's social media outreach	No	No	No, it cannot be modified.
CDER Statement	Provides information that is not appropriate for a Drug Safety Communication.	Industry, General Public, HCPs, Media, Advocacy information	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, email listserv, Twitter and Facebook (if requested)	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Director's Corner Podcast	Provides information on Dr. Janet Woodcock, Director of the Center for Drug Evaulation and Research's high-priority areas.	Varied- Topic dependent (Industry, Advocacy groups, HCPs, Policy Makers, etc.)	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, Listservs, trade press, Facebook and Twitter	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Division of Drug Information Webinars	Webinars with continuing education for physicians, pharmacists, nurse practitioners, pharmacy technicians for HCPs	Health Care Providers	Attendee feedback and course evaluations, and comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, targeted listservs	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.

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Drop-in Articles	Articles about CDER topics of interest	Health Care Professional, Targeted Consumers, Industry	Informally through comments from publication editors	Targeted submissions to various topic/field-appropriate publications	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Drug prescribing information (PI)	The PI contains a summary of the essential scientific information needed for the safe and effective use of the human prescription drug or biological product.	Healthcare providers (e.g., doctors, nurses, physician assistants, nurse practitioners, pharmacists)	Unfortunately, comprehension of the PI in healthcare providers has not been adequately studied.	The PI is included within or on the container for the product. The PI is also included on multiple external FDA websites (e.g., drugs@fda, labels.FDA.gov, FDALabel search tool, New Drugs at FDA), non-FDA governmental websites (e.g., NIH's DailyMed), and pharmaceutical company websites. Additionally, the drug information in the PI is acquired, edited and disseminated by healthcare and drug-information organizations (e.g., pharmacy benefit managers, insurance companies, hospital systems, health information technology suppliers). Organizations use PI in executing such functions as clinical decision-making, safety assurance, and pharmacy benefits management.	Yes, the PI is required by regulation. PI in Physician Labeling Rule (PLR) format must follow 21 CFR 201.56(a) and (d) and 21 CFR 201.57. PI in non-PLR "old" format must follow 21 CFR 201.56(a) and (e) and 21 CFR 201.80.	Yes, the PI follow a very specific template (see the above regulations). Also the content, organization, and format of the PI is guided by FDA guidances. See the PLR Requirements for Prescribing Information website for the key labeling guidances.	Yes, the PI is updated continuously. In fact, the PI "must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading." (see 21 CFR 201.56(a)(2)). Changes to the PI do not need to go through rulemaking.
Drugs@FDA	To provide approval information including patient information, labels, approval letters, and reviews, and other information about FDA-approved brand name and generic prescription and over-the-counter human drugs and biological therapeutic products.	Industry, healthcare providers, consumers, FDA and other federal agencies	Comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Searchable database with daily updates. New information is disseminated by distribution emails to subscribers.	Yes, Title IX, Subtitle B: Sec. 916. Action package for approval.	No	Yes, it can be modified. No, it does not go through the rulemaking process.

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Drug Safety Communication	New and emerging Safety information for health care professionals and patient/caregivers and the public, including in Spanish.	Health care professionals, Patients	Formative and evaluative risk communication research; Informally through comments to Division of Drug Info (855)-543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	FDA website: email listservs including those received by media: podcast; Twitter, Facebook and LinkedIn: targeted outreach to HCPs, advocacy organizations, professional societies; federal agencies; Japanese and European drug regulatory agencies. Additionally, the DSCs are is acquired, synthesized and disseminated by numerous third-party healthcare and drug-information organizations (e.g., pharmacy benefit managers, insurance companies, clinical newsletters, drug information vendors, large hospital systems, health information technology suppliers).	Yes, they are required generally under section 915 of FDAAA (FDA Amendments Act of 2007), which requires summaries of FDA safety analyses be periodically prepared and posted on FDA's web site along with a brief description of the steps FDA is taking to address any identified safety issues.	Specific format but not template per se	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Drug Shortages app	To provide the public real time, new and updated drug shortage information by date, therapeutic categories in an easy-to-use format. To provide push notifications of new or updated shortages to subscribers of specific drugs.	Healthcare providers, pharmacists	Comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Free downloadable app from Apple Store, and Google Play. Notifications of updates are displayed on subscribers Android smart phones.	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Drug Trial Snapshots	Provide information about who participated in clinical trials that were done to support some new FDA-approved drugs.	Consumers and medical professionals (MDs, researchers, pharmacists, etc.)	Informal testing conducted in 2016 through the Office of the Commissioner, Office of Planning, Risk Communication Staff	FDA.gov	Yes per FDASIA 2012. Snapshots were the result of FDA Action Plan, 2014 to fulfil the transparency requirement.	Yes	Yes/Not sure

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Educational videos	Provide educational PSAs about various CDER topics of interest	Consumers, patients, and HCPs	Web metrics	FDA web site, supporter organizations, doctor's offices, media (TV, radio, print, CNN airport), external web sites	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Email list servs	Subscription based information about various CDER topics of interest	Media, Consumers, patients, and HCPs	Web metrics	Emailed to subscribers	No	Yes	Yes, it can be modified. No, it does not have to go through the rulemaking process.
FDA Drug Info Rounds	Educational training videos about FDA topics	Healthcare professionals	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, email listservs, Twitter, Facebook	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
FDA Drug Safety Podcasts	Audio Podcasts version of the Drug Safety Communications	HCPs	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, listservs, Twitter, ReachMD radio	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Index to Drug Specific Information	To provide easy access to drug safety information by brand name and active ingredient, including Drug Safety Communications, Drug Alerts and Statements.	Consumers, healthcare providers, industry, FDA and other federal agencies	Comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	New and significantly updated web pages are placed on CDER's "What's New" page, and disseminated through several email distribution lists and other social media.	Yes, Title IX, Subtitle B: Sec. 915., Postmarket drug safety information for patients and providers; Sec. 917. Risk communication; Sec. 919. Response to the institute of medicine.	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.

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Information by Drug Class	To provide easy access to drug safety information web pages, including Drug Safety Communications, Drug Alerts and Statements	Consumers, healthcare providers, industry	Comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	New and significantly updated web pages are placed on CDER's What's New page, and disseminated through several email distribution lists and other social media.	Yes, Title IX, Subtitle B: Sec. 915., Postmarket drug safety information for patients and providers; Sec. 917. Risk communication; Sec. 919. Response to the institute of medicine.	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
LinkedIn	Information about various CDER topics of interest	Consumers, patients, and HCPs	Web metrics	LinkedIn	No	Yes	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Medication Guides	Medication Guides are required to be distributed to patients for selected prescription drug products used primarily on an outpatient basis that FDA determines "pose a serious and significant public health concern requiring distribution of FDA-approved patient information" (21 CFR 208). Medication Guides provide information that FDA determines is necessary to a patient's safe and effective use of a prescription drug product.	Patients	Medication Guides are submitted to the Agency and reviewed and approved by FDA prior to distribution.	The manufacturer is responsible for ensuring that Medication Guides are available for distribution to patients by either providing Medication Guides in sufficient numbers or the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product (21 CFR 208.24).	Yes, Medication Guides are required under 21 CFR 208.	Yes. Content and format requirements for Medication Guides are found under 21 CFR 208.24	Manufacturers may modify a Medication Guide and must obtain FDA review and approval before Medication Guide may be distributed. Modifications to the requirements of 21 CFR 208 for Medication Guides would require rulemaking.

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OTC Drug Facts Labels	The Drug Facts Labeling (DFL) is intended to inform consumers what the OTC drug product is supposed to do, who should or should not take it, and how to use it.	The target audiences are primarily ordinary consumers of over-the-counter drug products in a retail setting.	Label Comprehension Studies are conducted to ensure that consumers understand key label message. A label comprehension study assesses the extent to which consumers understand the information on nonprescription drug product labeling and then apply this information when making drug product use decisions in a hypothetical situation. Data derived from a label comprehension study can identify areas on the label that would benefit from clearer or simpler presentation of important consumer information.[i]	Drug Facts labeling appears on all OTC drug products packages available for retail sale and physician samples.	Yes, the DFL is required by regulation. In the Federal Register of March 17, 1999 (64 FR 13254), the FDA published a final regulation (§ 201.66) establishing standardized content and format for the labeling of OTC drug products (Drug Facts labeling).	Yes. Content and format are required standards. The following information must appear in this order: 1) The product's active ingredients, including the amount in each dosage unit. 2) The purpose of the product. 3) The uses (indications) for the product. 4) Specific warnings, including when the product should not be used under any circumstances, and when it is appropriate to consult with a doctor or pharmacist. This section also describes side effects that could occur and substances or activities to avoid. 5) Dosage instructions (when, how, and how to often to take the product. 6) The product's inactive ingredients, important information to help information to help consumers avoid ingredients that may cause an allergic reaction.	Yes, but it is not an easy process, except that FDA on its own may revise if needed under Part 201.66. Sponsors may request exemptions, but this may be a public process (not aware if a sponsor has done, though). If so, do the modifications have to go through the rulemaking process? The type of modifications that would have to go through rulemaking would be if information essential to the use of the product can't all fit onto the DFL, for instance, using "apps" to augment the self-selection process for safe use of the OTC drug product.
PASE: Targeted stakeholder email/outreach	Drug Safety Communications and other CDER areas of interest	Industry, HCPs, Academia, Policy makers, Advocacy Groups	Comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Emails targeted to various topic/field-appropriate professional HCP organizations	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.

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Patient Package Inserts (PPIs)	FDA regulations require that Patient Package Inserts be developed and distributed when certain prescription drug products or classes of prescription drug products are dispensed (oral contraceptives (§ 310.501) and drug products containing estrogen (§ 310.515)). Patient Package Inserts for these products inform patients of the benefits and risks involved in their use. A manufacturer can voluntarily create and submit a Patient Package Insert to FDA for review and approval as part of a prescription drug product's labeling.	Patients	PPIs submitted to the Agency are reviewed and approved by FDA.	Distribution requirements for Patient Package Inserts for oral contraceptives and estrogen-containing products are found under 21 CFR 310.501(b) and 21 CFR 310.515(b)), respectively. The manufacturer and distributor shall provide a Patient Package Insert in or with each package of the drug product that the manufacturer or distributor intends to be dispensed to a patient.	Patient Package Inserts for oral contraceptives and drug products containing estrogens are required under §§ 310.501(a) and 310.515(a), respectively. Under the FDA Amendments Act (FDAAA), FDA can also require PPIs as part of a Risk Evaluation and Mitigation Strategy (REMS). FDAAA created a new section, section 505-1, of the FD&C Act (21 U.S.C. 355-1) that authorized FDA to require a REMS when necessary to ensure that the benefits of a prescription drug product outweigh the risks. Under section 505-1(e), Patient Package Inserts are one potential element of REMS if the Secretary determines that a Patient Package Insert may help mitigate a serious risk of the prescription drug product.	PPI content and format requirements for oral contraceptives and drug products containing estrogens are found under 21 CFR 310.501(c) and 21 CFR 310.515(c), respectively.	PPI modifications submitted to FDA are reviewed and approved by FDA. Modifications to the requirements under 21 CFR 310.501 or 310.515 would require rulemaking.
REMS@FDA	To provide approved Risk Evaluation and Mitigation Strategy (REMS) information, including REMS documents and appended materials, for FDA-approved brand name and generic prescription human drugs and biological therapeutic products.	Industry, healthcare providers, consumers, FDA and other federal agencies	The Division of Drug Info monitors for comments submitted through 'Contact Us' link on the website.	Searchable database that is updated when a REMS is approved, modified or released. New information is disseminated by distribution emails to subscribers.	Yes. Under section 505(r)(2)(B)(v) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Food and Drug Administration Amendments Act of 2007 (FDAAA).	No	Yes, it can be modified. No, it does not go through the rulemaking process.

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Safety Labeling Change Letters	There are three formal communications related to required Safety labeling changes: a) Safety Labeling Changes Notification Letter; b) Safety Labeling Changes Order Letter, and c) Approval Letter. These letters are direct communications from the FDA to an application holder of a new drug application (NDA), Therapeutic Biologic Applications (BLA), and certain abbreivated new drug applications (ANDAs). They are not a tool for communication to the public about safety issues. The purpose of the Safety Labeling Changes notification letter is to notify an application holder of the requirement to make appropriate safety related labeling changes that are based upon the new safety information. The purpose of the Safety labeling changes Order letters is to issue an "order" to the application holder to change the product labeling, if the FDA makes a determination that the application holder's proposed labeling changes do not adequately address the new safety information, or disagrees with their explanation why they believe changes are not warranted. The puurpose of the Approval letter is to approve the labeling supplement.	The specific NDA, BLA, and certain ANDA application holders to whom the letters are addressed.	The letters related to required safety labeling changes are written in a standard format, using an established template. The letters include the relevant regulatory and statutory references to support the requirements. The notification letters generally, and the order letters always include specific language to describe the new safety information that should be reflected in the labeling.	The aforementioned letters related to required Safety Labeling changes are communicated to sponsors as formal letters (sent via post and via electronic mail). FDA policies allow for posting of safety labeling changes order letters on FDA's Web site.	Under section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Food and Drug Administration Amendments Act of 2007 (FDAAA) describes the process by which safety labeling changes are required, ordered and approved. FDAAA does not state the specific types of communications that should be employed. CDER developed the aforementioned letters as tools to implement the process outlined in FDAAA.	Yes	Yes, the letter templates can be modified using CDER's internal procedures for development of new (or modification of existing) letter templates. Rulemaking is not applicable and therefore not required.
Small Business and Industry Assistance (SBIA) Chronicles Newsletter	Bi-monthly newsletter of the CDER Small Business and Industry Assistance team, provides industry with useful information to assist in all aspects of drug marketing and regulation published around the 15th each odd month)	Industry	Informally through comments to Division of Drug Info	Web, listserv	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.

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Small Business and Industry Assistance (SBIA) Regulatory Education for Industry (REdI) Conferences	Workshops and conference presentations with FDA and industry, (partner with the Center for Devices and Radiological Health on two meetings each year)	Industry	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, SBIA listserv (including specialized distribution lists (e.g., Generic Drug User Fee Act, Office of International Programs), SBIA Chronicles newsletter, Trade press (Pink Sheet; FDANews; SoCRA RAPS,)	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Small Business and Industry Assistance (SBIA) Monthly Webinars	One-hour webinars on various topics of interest to industry (e.g., new guidance)	Industry (not limited to small business)	Informally through comments to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	Web, SBIA listserv, web, and email listserv	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Twitter	All Drug Safety Communications and other CDER topics of interest	Public, Industry, HCPs, Academia, Policy makers, Advocacy/stakeholder groups, media	Comments posted on Twitter or made to Division of Drug Info (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov	FDA website and @FDA_Drug_Info Twitter	No	No	Yes, it can be modified. No, it does not have to go through the rulemaking process.
Center for Tobacco Products (CTP) – External Communications							
CTP Corporate Print Product Suite (e.g., fact sheets, backgrounders, brochures, issue snapshots, etc.)	To provide up-to-date facts and information on various regulatory tobacco topics that are primarily used for distribution for purposes and online ordering	Consumers, industry and general public	Work with subject matter experts to adjust language to target audience	Exhibits program and online ordering system	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
CTP Corporate Digital Product Suite (e.g., infographics, shareable images, GIFs, videos, etc.)	To visually illustrate regulatory tobacco topics and other public health concepts	Consumers, industry and general public	Work with subject matter experts to adjust language to target audience	Used on CTP's website and posted to CTP's social media: CTP's Twitter and Facebook	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.

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Email marketing	To communicate CTP information to various stakeholder groups, using three different e-mail lists: CTP Connect, This Week in CTP, Compliance and Enforcement, and Spotlight on Science	Public Health, researchers and the general public	Work with subject matter experts to adjust language to target audience/measure open rates	GovDelivery	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Exchange Lab	To publish CTP digital content for usage by other parties or others to increase exposure to users	Consumers, industry and the general public	Work with subject matter experts to adjust language to target audience	Used on CTP's website and syndicted to other sites	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.
Opinion Editorals (Op Eds)	To offer FDA/CTP view on policy rationale or trend in public health, etc.	Consumers, industry and the general public	Work with subject matter experts to adjust language to target audience and readership. Also, monitor social media impact.	Submitted for publication	No	No	Yes, it can be modified. No it does not have to go through rulemaking.
Perspective Pieces	To offer scientific or policy opinion on tobacco related issues	Academia, Policy Makers, Public Health and Tobacco Control Advocates	Work with subject matter experts to adjust language to target audience and readership. Also, monitor social media impact.	Submitted for publication	No	No	Yes, it can be modified. No it does not have to go through rulemaking.
Twitter (Twitter Chats)/Facebook/ YouTube (Webinars)/Flickr	To inform and engage various stakeholders around CTP-related regulations and policies	Consumers, Public Health and Tobacco Control Advocates and Industry	Work with subject matter experts to adjust language to target audience/maintain response banks/community management	Via various CTP-controlled social media channels	No	No	Yes, it can be modified. No it does not have to go through rulemaking.

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Tobacco Public Education Campaign Program	The campaigns are designed to educate consumers about the dangers of regulated tobacco products.	The campaigns target populations either at-risk for tobacco use, primarily youth, or those who currently use tobacco products.	Qualitative formative research via focus groups and individual interviews, quantitative copy testing, social listening and content analysis, and other methodologies are used to ensure comprehension of targeted audiences.	The campaigns use comprehensive dissemination approach to include websites, social media platforms, cable and broadcast television, cinema, video, radio, print, out-of-home, digital, events, and influencers.	Public education campaigns are related to several of FDA's regulatory authorities under Chapter IX of the Food Drug and Cosmetic Act or the Tobacco Control Act and contribute to carrying out those authorities, including informing consumers and the public about the risks of tobacco products, such as negative health consequences and addiction risks.	The campaigns follow an evidence-based development and implementation process.	The campaigns' strategy, messaging, and creative evolves over time. Changes do not have to go through the rulemaking process.
Videos/Webinars	To provide visual explanation of regulatory or public health concepts related to tobacco control	Policy Makers, Public Health and Tobacco Control Advocates, Industry and Consumers	Work with subject matter experts to adjust language of the script to target audience	Posted to CTP's website or links posted in social media	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.
Voice Blog	To provide first-person explanation of FDA policy or offer opinion on public health or industry issue	Academia, Policy Makers, Public Health and Tobacco Control Advocates, Industry and Consumers	Work with subject matter experts to adjust language to target audience	Posted to FDA.gov, PR Newswire and FDA email list	No	No	Yes, it can be modified. No it does not have to go through rulemaking.
Web Content	To inform various stakeholders about tobacco-related regulations and policies	Consumers, industry and the general public	Work with subject matter experts to adjust language to target audience/assess web analytics	Posted to web, SEO optimized and Google AdWords	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.
Office of the Chief Scientist (OCS), Direct Office – External Communications							
FDA Grand Rounds	To raise visibility in the scientific community of FDA's in house regulatory science research	The scientific community	The webcast Grand Rounds are talks on scientific research by scientists directed at scientists. Knowledge of technical terms is presumed for this specific audience.	Via live webcast that is archived on the web site.	No	Yes the webcast follows a format whereby the speaker talks for 50 minutes on FDA research and that is followed by 10 minutes of questions from the audience at FDA and online.	No, it cannot be modified.

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FDA Science Forum Promotional and Information Materials	The brochure is intended to describe the upcoming Science Forum—Agenda, Speaker Bios, Presentation Abstracts, Poster Sessions. The Webcast features welcoming remarks and all the speaker presentations The Summary Report provides a synopsis of the entire two-day science forum so that the visitor can decide whether to view a presentation in more detail in the webcast. Video Interviews with Forum attendees on their impressions of FDA research on the products it regulates.	Anyone who attends the Science Forum, e.g. scientists from industry, academia, government, the press, and FDA staff. Since these materials are featured on our website they are available to anyone interested in the kind of scientific research we are doing at FDA.	Our target audience is scientists even though the materials are carefully edited. We have them reviewed by an FDA editor and an appropriate scientific staff member.	Via the web site. The brochure was also printed in hard copy and handed out to Forum attendees.	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.
Progress Reports to the Science Board	To update the FDA Science Board on FDA's progress since the Science Board's 2007 Report: FDA Science and Mission at Risk so that they could advise us in a report we requested from them on what, if any changes, FDA needed to make in the direction of advancing regulatory science, including structural changes, FDA collaborations—both intramural and extramural.	The main audience for which the report was intended was the FDA Science Board. However, the report was made public by publishing it on FDA's website in July 2015: http://www.FDA.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm431539.htm. FDA wanted to be transparent in showing the enormous progress and efforts made since 2007 in advancing the science that underpins our mission.	The report was written in plain language, referencing appropriately issues raised in the Board's 2007. Acronyms were spelled out the first time and graphics and timelines were added to enhance understanding.	The report was sent to all Board members in soft copy by e-mail and later published in multiple relevant areas of FDA's web site.	No	No, we developed our own template based on the contents of the report.	No, it cannot be modified.

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Office of the Chief Scientist (OCS), Office of Counterterrorism and Emerging Threats (OCET) – External Communications							
@FDA_MCMi (MCMi Twitter feed)	FDA's Medical Countermeasure initiative (MCMi) is using Twitter as part of its communication and outreach program. MCMi's main goal for Twitter is to help consumers and stakeholders keep up-to-date on MCMi-related issues, including FDA public health emergency response efforts, and to address frequently asked questions in a convenient way. Messages on Twitter include press releases, new web postings, and highlights from FDA websites, and MCM-related information from a variety of sources.	Industry representatives, healthcare providers, other public health preparedness stakeholders (e.g., state/local/tribal/territorial health departments), media, and consumers interested in emergency preparedness/response activities	Define acronyms (as often as the 140-character format allows), use various methods to include supplementary information where possible (e.g., graphics with text explanations, and multi-part or follow-on tweets with additional info/links/background), follow plain language guidelines, respond to questions received about tweeted material as quickly as possible	Twitter	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.
MCMi annual program update	FDA's Medical Countermeasures Initiative is an agency-wide initiative to coordinate medical countermeasure development, preparedness and response to help protect the U.S. from chemical, biological, radiological, nuclear and emerging infectious disease threats. The report includes updates on activities by fiscal year including medical countermeasure-related objectives, activities and achievements (including regulatory science and regulatory policy updates), medical countermeasure product approvals, and information on Emergency Use Authorizations and other emergency response activities (recent examples include Ebola and Zika response efforts).	Congress requires the report. Additional audiences include industry representatives, healthcare providers, other public health preparedness stakeholders (e.g., state/local/tribal/territorial health depts.), media, and consumers interested in emergency preparedness/response activities	Define acronyms on first reference and provide a list, follow plain language guidelines where possible, explain technical terms as needed using footnotes and/or hyperlinks to additional information (e.g., the term "medical countermeasures" is linked to the web page: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm)	FDA.gov	Yes. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), requires FDA to issue an annual report detailing its medical countermeasure activities.	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

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MCMi email update	To share news, events, reports and other information related to public health emergency preparedness and response from FDA and our partners, including other federal agencies in the Public Health Emergency Medical Countermeasures Enterprise.	Industry representatives, healthcare providers, other public health preparedness stakeholders (e.g., state/local/tribal/territorial health depts.), media, and consumers interested in emergency preparedness/response activities	Follow plain language guidelines, define acronyms on first reference, explain technical terms as needed. We also use graphics to help simplify messages and enhance user comprehension and experience (recent example: https://content.govdelivery.com/accounts/USFDA/bulletins/14df104), and are currently collecting reader feedback via survey.	GovDelivery	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Office of External Affairs (OEA) – External Communications							
Consumer Updates	Consumer Updates are "feature-style" articles that include quotes from FDA experts and: provide practical wellness and prevention tips; feature the latest safety information; cover all FDA-regulated products and agency-related public health issues; show FDA regulatory science at work to protect and promote public health; and improve transparency	Consumers and other lay audiences who may or may not be steeped in FDA activities and terminology.	Through the writing and review process, we strive to make the language of the Consumer Updates as "plain language" and accessible as possible, paying particular attention to technical terms and lingo that may not resonate with are key audiences. We also seek to limit the length of the pieces, in both written and visual forms, in order to more effectively convey key messages and keep audience interest.	Consumer Updates are distributed via several methods, including: a GovDelivery email list (signups are through FDA.gov), PIER/PR Newswire (for media and other stakeholders), and social media channels.	No	The communication follows a rough template in that we strive to have each Consumer Update piece be 750 words or fewer, with at least one piece of art (which can be a graphic, infographic, illustration, animation, video, or other visual element). Typically we create a PDF for each Consumer Update for those who might want to print the piece, although we may or may not post the PDF to the website. We have recently begun experimenting with shorter pieces.	Yes, it can be modified. No, it does not have to go through rulemaking.

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E-Lists: FDA CardioBeat, FDA Diabetes Monitor, Hepatitis B and C Updates and HIV/AIDS Updates	Informational updates to subscribers on disease specific conditions	Subscribers who self-select to receive communications on cardiology, diabetes, hepatitis or HIV/AIDS	We have relied on using cleared language from other FDA source documents, such as drug safety communications, safety communications and advice from relevant review divisions.	GovDelivery	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Facebook page (the FDA only has one)	Communicate agency-priority and other consumer related information to target audiences. With over 400 million global users and 100 million U.S. users Facebook is important social media channel to disseminate information. FDA's Facebook account has approximately 427,000 likes.	The primary audience for Facebook is consumers. Secondary audiences include health professionals, scientists, and industry.	We monitor the engagement level and shares with our posts to ensure they are being effective. We also share best practices with other Centers who contribute content for this account. One example is the use of images to accompany posts for maximum engagement.	Through posts on our Facebook page	No	We only have this one main agency Facebook page.	Not applicable
FDA.gov	FDA.gov is FDA's online home for critical, agency-priority information. The site strives to provide the information our visitor's need anytime, from any device. Current statistics show that approximately 45% of all traffic to FDA.gov is from mobile devices (tablets and phones). This number has increased significantly over the last three years and will continue to go. The agency works to ensure all visitors have access to the information they need, when they need it.	Consumers, health professionals, scientists/researchers, and industry.	We closely track a full array of analytics associated with the site, including a customer satisfaction tool, Google analytics, and heat map tools showing where visitors are clicking. We use all of this information to implement iterative changes to improve the site to be more customer-centric.	FDA.gov	No	Yes, the entire site uses cascading style sheets which are similar to templates.	Not applicable
FDA Media Advisory	A tool used to announce media events surrounding major actions and accomplishments	News media (assignment editors)	We use plain language, AP Style and HHS style.	PR Newswire (wire), PIER (email)	Our regulations state that the agency communicates agency actions. This is also spelled out in the HHS Media Policy here: http://www.hhs.gov/sites/default/files/media_policy.pdf	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

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FDA MedWatch Learn	Teaches students, health professionals, and consumers how to complete the forms necessary to report problems to FDA. Individuals have the opportunity to practice filling out the FDA MedWatch Form 3500 (for health professionals) or FDA Form 3500B (for consumers).	Students, health professionals, and consumers	We used the services of a contractor to assist with the content development of the case studies. The contractor has experience in communications and with plain language.	FDA.gov	No	Yes, web content management system.	Yes, it can be modified. No, it does not have to go through rulemaking.
FDA News Release	A tool to announce major agency actions and accomplishments. Note, some news releases are translated into foreign languages.	News media (if release is translated into foreign language then audience is targeted), public	We use plain language, AP Style and HHS style.	FDA.gov, GovDelivery, PR Newswire (wire), PIER (email)	Our regulations state that the agency communicates agency actions. This is also spelled out in the HHS Media Policy here: http://www.hhs.gov/sites/default/files/media_policy.pdf.	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
FDA's Patient Network Newsletter	A bi-weekly email newsletter that provides information about product safety, drug shortages, product approvals, upcoming meetings, and more.	Patients	We have relied on using cleared language from other FDA source documents, such as MedWatch Safety Alerts, News Releases and Federal Register Notices.	GovDelivery	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
FDA Statement	A tool used to officially comment on important actions that may not necessarily be an agency action but an outside organization that has a nexus to the agency	News media and the general public	We use plain language, AP Style and HHS style	FDA.gov, GovDelivery, PR Newswire (wire), PIER (email)	Our regulations state that the agency communicates agency actions. This is also spelled out in the HHS Media Policy here: http://www.hhs.gov/sites/default/files/media_policy.pdf.	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
FDA Updates for Health Professionals	A bimonthly newsletter with recent announcements, medical product approvals, opportunities to comment on proposed rules, upcoming public meetings, and other information of interest to health professionals.	Health professionals	We have relied on using cleared language from other FDA source documents, such as MedWatch Safety Alerts, News Releases and Federal Register Notices.	GovDelivery	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
FDA Voice	This communication vehicle functions somewhat like an "op-ed." They are used to highlight explain and defend FDA policy or actions and to do so in a conversational format.	They vary – industry, health care professionals, Congress, other policymakers, scientist and the news media.	We conduct a survey every six months. We are right on target with comprehension, topics frequency of posts and the audience.	Through our GovDelivery subscriber list, via release to the media, to targeted stakeholder lists, on social media (Facebook and Twitter). FDA Voice is also posted on FDA's Home Page, on its own dedicated page and on FDA's intranet. Blogs are frequently reposted by stakeholders.	No	We follow the same visual template for every blog using Wordpress. We also aim to keep the blog at approximately 500 words, although that is often exceeded. We also urge authors to write in Plain English as much as possible and if technical language is used, we go to great strides to define what we mean.	Yes. All it takes is going back in to Wordpress and making the changes. But blogs are considered a snapshot in time, modifications are rarely made unless we've encountered an error of some kind.
For Health Professionals (Health Professional website)	Contains the most recent version of the Health Professional Newsletter, MedWatch reporting information, MedWatch Safety Alerts, MedWatch Monthly Safety Labeling Changes, Medscape interviews with FDA experts and resources for health professionals.	For Health Professionals webpage (includes MedWatch web pages) – health professionals	The Health Professional pages do not use a comprehension tool. These pages are developed for a health professional audience.	FDA.gov	No	Yes, web content management system.	Yes, it can be modified. No, it does not have to go through rulemaking.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
For Patients (Patient Network Website)	Created in 2012, the FDA Patient Network is a comprehensive program that works to expand and sustain communication with patients and their community. The FDA Patient Network also helps educate patients, patient advocates, and their healthcare professionals about medical product regulations and we continue to look at ways to involve patients more effectively in regulatory decisions related to medical product safety and approval. The website include information includes information about clinical trials, human product regulations, expanded access, the opportunity to comment on guidance documents, the most recent version of the Patient Network Newsletter, links to cancer, cardiovascular disease, diabetes, hepatitis B and C webpages, HIV/AIDS and web pages, public meeting information, social media information, FDA patient specific e-mail list serves, resources	Patients	The Patient Network website uses the readability tool in Microsoft Word to determine the reading level of the web content pages.	FDA.gov	No	Yes, web content management system.	Yes, it can be modified. No, it does not have to go through rulemaking.
Google AdWords campaigns	Google AdWords are a very effective, proactive communication tool used to drive traffic to FDA's digital content. There are two ways to do this through AdWords: through keywords on the Google search appliance and through the Google network of web sites. For a limited budget (approximately $3K) these campaigns are a very effective tool for driving traffic.	The primary audience for AdWords is consumers. Our campaigns have proven that consumers are definitely our most effective audience for these campaigns.	We carefully work to set up these campaigns based on the keywords that our audience uses – this ensures they are finding our ads when they are searching on Google. We also have the ability to modify campaigns on the fly if we see certain ads/keywords not performing well.	Through ads on Google and through ads on web sites in Google's network.	No	Not applicable	Not applicable

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GovDelivery	GovDelivery is a government to citizens communications solution that allows FDA to reach audiences through email marketing to drive traffic to our digital pages.	Target audiences include consumers, health professionals, scientists, researchers, and industry. This tool enables different administrators to create custom groups (users opt in) to receive specific information they are interested in. When new or updated information is available, administrators have the ability to quickly share this information with their user group.	We have the ability to track the number of visitors to web pages that are coming from our Govdelivery tool. We can also create custom surveys to ensure users are getting the information they want and expect.	Emails	No	There is a custom GovDelivery template that OEA created and shared but offices can also customize their own solution.	Not applicable
MedWatch Safety Alerts	MedWatch alerts provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. The alerts contain actionable information that may impact both treatment and diagnostic choices for healthcare professional and patient.	Subscribers who self-select to receive MedWatch Safety Alerts. Historically, the target audience was health professionals.	MedWatch Safety Alerts are written based on cleared language from drug safety communications or safety communications	GovDelivery	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
News and Notes - Weekly Media Tip Sheet	Weekly media tip sheet of upcoming events, meetings, congressional testimony, etc.	News media	We use plain language, AP style and HHS style	FDA.gov, GovDelivery, PR Newswire (wire), PIER (email)	Our regulations state that the agency communicates agency actions. This is also spelled out in the HHS Media Policy here: http://www.hhs.gov/sites/default/files/media_policy.pdf.	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

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Speech, keynote, remarks by the commissioner	The commissioner is typically invited by an organization to deliver remarks on an issue of interest to the group. FDA will discuss the agency's point of view on that issue and what the agency is doing to address it. Speeches can be used to educate the public, explain the agency's point of view on an issue or issues and to publicize what FDA is doing to address them.	It varies depending upon the organization, but typically industry, patient advocacy groups or health care professionals.	The speechwriter and others meet with the event organizers ahead of time to discuss what subjects to discuss and in what way. The speech is also vetted with experts within the agency and with OCC. Sometimes slides accompany a speech to add additional information and interest.	Speeches are posted on FDA's website on a page devoted to speeches by the commissioner.	No	Not really, although speeches do have a natural flow. The speaker will always begin by thanking the moderator and the organization, and then offer up some sort of anecdote that connects the speaker to the audience but there is no official template.	Rarely, only in the event of a factual mistake. Then the online text may be modified.
Twitter	Communicate agency-priority and "news-worthy" information to target audiences quickly. Overall, the agency has approximately 17 Twitter accounts. OEA manages this primary account. The primary account focuses on agency priority announcements and news-worthy information. Account has approximately 137,000 followers.	The primary audience for Twitter is health professionals and scientists/researchers. Secondary audience is consumers.	We monitor our followers, retweets, and comments/engagement levels with our posts to ensure they are being effective	Through posts on our main Twitter account.	No	All posts on our main Twitter account	Not applicable
YouTube Channel	YouTube is used as a hosting platform for all FDA videos. Playlists can be developed to organize the videos and the channel is utilized for both external and internal audiences.	Most videos are for external audiences (consumers, health professionals, scientists, industry) but the tool is also utilized for internal-only audiences. Videos can be listed or unlisted based on target audience. This listing determiones who can see the videos.	We closely monitor metrics/analytics for our videos and share best-practices with those around the agency who are producing videos. We are also developing an updated YouTube policy document to assist others with developing videos.	Generally disseminated through links on web pages and through social media channels. GovDelivery email distribution is also utilized.	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.

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Office of Foods and Veterinary Medicine (OFVM) – External Communications							
Constituent Updates	To send updates and new information to stakeholders and interested parties. Also, to direct recipients to important information on FDA.gov	All external/internal CFSAN/CVM stakeholders and those who have opted in to receiving updates from FDA.	Metrics from online visits, feedback from Public Affairs Specialists, newsletter/feature distribution, and FDA surveys and other data on consumer knowledge and attitudes.	Email and web page updates	No	Yes, to an extent.	Yes, it can be modified. No, it does not have to go through rulemaking.
Consumer Advisory Notices	To provide links to safety alerts, consumer advisories, and other safety information about the following FDA-regulated products: • Food and beverages • Dietary supplements • Infant formula	External/internal stakeholders involved in relevant activities/issues and those who have opted in to receive updates of this nature from FDA.	Metrics from online visits/downloads, number of orders received from warehouse, feedback from Public Affairs Specialists, newsletter/feature distribution, and FDA surveys and other data on consumer knowledge and attitudes.	Email and web page updates	No	Yes, it follows a similar form.	Yes, it can be modified. No, it does not have to go through rulemaking.
CORE Web Posts	To send breaking news, provide new and updated information related to food safety and outbreaks to stakeholders, and reassure consumers that FDA is doing everything it can to protect public health	External/internal stakeholders with an interest/stake in food safety and outbreaks and those who have opted in to receive updates about outbreaks from the FDA.	Metrics from online visits/downloads, feedback from Public Affairs Specialists, and FDA surveys and other data on consumer knowledge and attitudes.	Email and web page updates	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
CVM Updates	To send updates and new information related to the Center for Veterinary Medicine (CVM) to stakeholders.	External/internal stakeholders involved in CVM-related activities/issues and those who have opted in to receive updates from CVM.	Metrics from online visits, feedback from Public Affairs Specialists, newsletter/feature distribution, and FDA surveys and other data on consumer knowledge and attitudes.	Email and web page updates	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
Educational Fact Sheet - Food	To provide, in non-technical language, succinct information on topics related to food safety, nutrition (including labeling and dietary supplements), and cosmetics.	Public health educators, teachers, dietitians, and public health professionals, as well as general consumers.	Metrics from online visits/downloads, number of orders received from warehouse, feedback from Public Affairs Specialists, newsletter/feature distribution, and FDA surveys and other data on consumer knowledge and attitudes.	Electronic media (website, social media promotion, newsletters, etc.), print publications, conference exhibits, other federal agencies, and public health organizations' platforms and listservs	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Education Campaigns	To inform and educate stakeholders and the public on topics related to food safety, nutrition (including labeling and dietary supplements), and cosmetics.	Public health educators, teachers, dietitians, and public health professionals, as well as general consumers.	Metrics from online visits/downloads, number of orders received from warehouse, feedback from Public Affairs Specialists, newsletter/feature distribution, and FDA surveys and other data on consumer knowledge and attitudes.	Electronic media (website, social media promotion, newsletters, etc.), print publications, conference exhibits, other federal agencies, and public health organizations' platforms and listservs	No	No	Yes, it can be modified. No, it does not have to go through rulemaking.
Education Resource Library	This webpage is intended to be a one-stop shop that provides printable, educational materials on topics related to food safety, nutrition (including labeling and dietary supplements), and cosmetics. Materials are available in PDF format for immediate download and may also be ordered in larger quantities.	Public health educators, teachers, dietitians, and public health professionals, as well as general consumers.	Metrics from online visits/downloads, number of orders received from warehouse, feedback from Public Affairs Specialists, newsletter/feature distribution, and FDA surveys and other data on consumer knowledge and attitudes.	Electronic media (website, social media promotion, newsletters, etc.), print publications, conference exhibits, other federal agencies, and public health organizations' platforms and listservs	No	Some materials within the Education Resource Library follow a template, but not all. There are a many different types of educational materials there.	Yes, it can be modified. No, it does not have to go through rulemaking.

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FDA Voice Blog	To humanize FDA's message by explaining what the agency does and why. The blog provides updates, shares information, and tells stories to stakeholders in a narrative format that's attributable to a specific person within the agency. It gives a voice and a face to topics that might otherwise seem complex, intangible or unimportant.	External/internal stakeholders involved in CFSAN-related activities/issues, industry, academia, consumers, and those who have opted in to receiving updates from FDA.	Online metrics and feedback and data on consumer knowledge and attitudes.	Email and web page updates	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
FSMA Updates	To send updates and new information related to the FDA Food Safety Modernization Act (FSMA) to stakeholders.	External/internal stakeholders involved in FSMA-related activities/issues and those who have opted in to receive updates about FSMA from the FDA.	Metrics from online visits/downloads, feedback from Public Affairs Specialists, and FDA surveys and other data on consumer knowledge and attitudes.	Email and web page updates	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Nutrition Facts Label Materials	To provide concise information, in plain language, on the Nutrition Facts label and how to use it.	Public health educators, teachers, dietitians, and health professionals, as well as general consumers.	Metrics from online visits/downloads, feedback from Public Affairs Specialists, and FDA surveys and other data on consumer knowledge and attitudes.	Electronic media (website, social media promotion, newsletters, etc.), print publications, conference exhibits, other federal agencies, and public health organizations' platforms and listservs	No	No. There are a many different types of Nutrition Facts label educational materials. However, some of those types of materials are similar in format.	Yes, it can be modified. No, it does not have to go through rulemaking.
Office of Global Regulatory Operations and Policy (OGROP) - External Communications							
Speeches	Communicate OGROP and FDA news and policy to outside stakeholders	Generally, but not limited to, industry, association, academics, foreign regulatory partners, and U.S. government officials involved with food and medical product regulatory matters	Concise, precise remarks, delivered well	In addition to the speaking venue, placed on FDA website and promoted through GO Presentation Library.	No	Yes, speeches follow a basic speech structure.	No, it cannot be modified.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
Office of Minority Health (OMH) – External Communications							
Brochures	To educate consumers on health issues affecting minority groups. Brochures are created on an ad-hoc basis and are translated into other languages, as appropriate.	Minority consumers, health professionals and FDA and Health and Human Services (HHS) staff	The materials are written according to the Plain Language Writing Act and translated to address the needs of Limited English Proficiency consumers.	Communication is disseminated through social media, FDA website, in-person meetings, conferences, listserv, community events and the OMH newsletter.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Fact Sheets	To educate consumers on health issues affecting minority groups. Fact Sheets are created on an ad-hoc basis and are translated into other languages, as appropriate.	Minority consumers, health professionals and FDA and HHS staff	The materials are written according to the Plain Language Writing Act and translated to address the needs of Limited English Proficiency consumers.	Communication is disseminated through social media, website, in-person meetings, conferences, listserv, community events and the OMH newsletter.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Infographics	To educate consumers on health issues affecting minority groups. Infographics are created on an ad-hoc basis and are translated into other languages, as appropriate.	Minority consumers, health professionals and FDA and HHS staff	The materials are written according to the Plain Language Writing Act and translated to address the needs of Limited English Proficiency consumers.	Communication is disseminated through social media, website, in-person meetings, conferences, listserv, community events and the OMH newsletter.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Lecture series or webinars	OMH host thought leaders from across the United States to discuss current trends in minority health research and programs. The lectures and webinars are posted online for viewing.	Minority consumers, health professionals and FDA and HHS staff	The materials are written according to the Plain Language Writing Act and translated to address the needs of Limited English Proficiency consumers.	Communication is disseminated through social media, website, in-person meetings, conferences, listserv, community events and the OMH newsletter.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Newsletters	A quarterly newsletter along with regular email updates (e-Updates) to announce the latest FDA information on health and safety that are important to minority communities.	Minority consumers, health professionals and FDA and HHS staff	The materials are written according to the Plain Language Writing Act.	Communication is disseminated quarterly through GovDelivery.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

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Postcards	To educate consumers on health issues affecting minority groups. Post cards are created on an ad-hoc basis and are translated into other languages, as appropriate.	Minority consumers, health professionals and FDA and HHS staff	We follow the Plain Language Writing Act and translate our materials to address the needs of Limited English Proficiency consumers.	Communication is disseminated through social media, website, in-person meetings, conferences, listserv, community events and the OMH newsletter.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Social Media Cards	OMH prints social media cards to be distributed at conferences and meetings. The cards have OMH's social media contact information.	Minority consumers, health professionals and FDA and HHS staff	The materials are written according to the Plain Language Writing Act and translated to address the needs of Limited English Proficiency consumers.	Communication is disseminated through social media, website, in-person meetings, conferences, listserv, community events and the OMH newsletter.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Videos	To educate consumers on health issues affecting minority groups. Videos are created on an ad-hoc basis and are translated into other languages, as appropriate.	Minority consumers, health professionals and FDA and HHS staff	The materials are written according to the Plain Language Writing Act and translated to address the needs of Limited English Proficiency consumers.	Communication is disseminated through social media, website, in-person meetings, conferences, listserv, community events and the OMH newsletter.	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Office of Regulatory Affairs (ORA) – External Communications							
Advisory Letters	This table alerts consumers to companies illegally marketing products for the treatment or prevention of serious diseases. The table does not include every website that is illegally marketing products for serious diseases.	The general public, news organizations, industry as well as other government agencies that would have interest in such in the protection of public health.	Information is provided in a straight forward format. Not aware of any issues of comprehension.	Via the FDA.gov website with text and pdf documents and searchable and exportable database in Excel, CVS formats or viewers have the capability to “Copy” the displayed information presented in five columns.	Yes, as basis information of the actions of a regulatory agency as per: CFR - Code of Federal Regulations Title 21.	Yes, the database does provide five columns of information: Date, Firm, Examples of Products, Website, Compliance Status.	Yes, it can be modified. No, it does not have to go through rulemaking.

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Clinical Investigators - Disqualification Proceedings	FDA regulates scientific studies that are designed to develop evidence to support the safety and effectiveness of investigational drugs (human and animal), biological products, and medical devices. Physicians and other qualified experts ("clinical investigators") who conduct these studies are required to comply with applicable statutes and regulations intended to ensure the integrity of clinical data on which product approvals are based and, for research involving human subjects, to help protect the rights, safety, and welfare of those subjects. In certain situations in which FDA alleges a clinical investigator has violated applicable regulations, FDA may initiate a clinical investigator disqualification proceeding. The Clinical Investigator - Disqualification Proceedings database (http://www.accessdata.FDA.gov/scripts/sda/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings) provides a list of clinical investigators who are or have been subject to an administrative clinical investigator disqualification action and indicates the current status of that action. For each clinical investigator who is listed, links to related FDA regulatory documents (e.g., NIDPOEs, NOOHs, Presiding Officer Reports, Commissioner's Decisions) are provided, when available.	The general public, universities and industries involved in medical and public health research as well as other government agencies that would have interest in such clinical investigator disqualification.	Information is provided in a straight forward format. Not aware of any issues of comprehension.	Via the FDA.gov website with text and pdf documents and searchable database in Excel format.	Yes as basis information of the actions of a regulatory agency as per: CFR - Code of Federal Regulations Title 21 and via agreement with the Department of Justice	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
Import Alerts & Import Alert Database	This page provides information on what an import alert is and how to interpret it. For information on how to be removed from an import alert, please see the import alert removal page. Import alerts inform FDA field staff and the public that the agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of FDA laws and regulations. These violations could be related to the product, manufacturer, shipper and/or other information. Before importing into the United States, importers should know if their products are subject to DWPE. DWPE allows the agency to detain a product without physically examining it at the time of entry. Viewers to the Import Alert Data base can browse by country/area, by industry, by number assigned to each alert and by last published date.	The general public, news media, and the import industry.	Information is provided in a straight forward format. Not aware of any issues of comprehension.	Via the FDA.gov website and people can subscribe to a weekly summary which is delivered via GovDelivery platform to subscribers' email.	Yes, as basis information of the actions of a regulatory agency as per: CFR - Code of Federal Regulations Title 21.	No.	Yes, it can be modified. No, it does not have to go through rulemaking.
FDA Data Dashboard	This is a tool to share inspectional, compliance and enforcement related data in various, easily understood graphical formats. The tool allows users to drill down on elements within the graphical formats for a more detailed view and to export the graphs and underlying data.	The general public and in particular it is used by public health professionals, journalists, students and industry while conducting research.	Based upon feedback and or questions submitted to FDADataDashboard@fda.hhs.gov	Via the FDA.gov website at page displaying data using graphical formats.	Yes, as basis information of the actions of a regulatory agency as per: CFR - Code of Federal Regulations Title 21	No	No, this is basically the reporting of publicly releasable information in a graphical format.

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The Imports Program	General information about the FDA's Import Program. This includes Import Basics, Entry Process, Actions and Enforcement and Resources. All products regulated by the Food and Drug Administration must meet the same requirements, whether imported from abroad or produced domestically. The job of protecting consumers includes an ever-increasing need to oversee imports, which have been increasing by 10-15 percent per year for the last decade, and those percentages expect to keep rising. Links are provided to assist an importer in How to Submit an Entry, Examination and Sample Collection, Actions and Enforcement, Import Alerts, Import Refusal Report.	The general public and the import industry.	Information is provided in a straight forward format. Not aware of any issues of comprehension.	Via the FDA.gov website	Yes, as basis information of the actions of a regulatory agency as per: CFR - Code of Federal Regulations Title 21.	No	Yes, it can be modified. No, it does not have to go through rulemaking.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
ORA Electronic Reading Room	The ORA Electronic Reading Room displays copies of ORA records. We are making these records publicly available either (1) proactively at our discretion or (2) because they are "frequently requested" per the Electronic Freedom of Information Act Amendments of 1996. Some records may be redacted to remove non-public information (see 21 CFR Part 20). Records are in a searchable database with the fields of: Record Date, FEI Number, Firm Name, Record Type, State, Establishment Type and Date Posted. Record Types include the following sortable fields: FDA Form 483 (Inspectional Observations), 483 Response, Adverse Determination Letter, Adverse Determination Response, Consent Decree, Consent Decree Correspondence, Consumer Complaint Record, Investigation Memo, establishment Inspection Report (EIR), Exhibits and Attachments, FDA Requested Recall Letter, Memo, Other Correspondence, Recall Record, Receipt of Payment Letter, Response, Resumption of Authorization Letter, Sample Record, State Referral Letter, Warning Letter Response, and Workplan.	The general public, news organizations, industry as well as other government agencies that would have an interest.	Information is provided in a straight forward format. Not aware of any issues of comprehension.	Via the FDA.gov website and also available via RSS Feed.	Yes, as basis information of the actions of a regulatory agency as per: CFR - Code of Federal Regulations Title 21.	Yes, the database does provide five columns of information: Record Date, FEI Number, Firm Name, Record Type, State, Establishment Type and Date Posted.	Yes, it can be modified. No, it does not have to go through rulemaking.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
Warning Letters	To provide information in the best interest of public health pertaining to the FDA's Inspections, Compliance, Enforcement and Criminal Inspections.	The general public, news organizations, industry as well as other government agencies that would have interest in such in the protection of public health.	Information is provided in a straight forward format available to be viewable via nine different readers/viewers. Not aware of any issues of comprehension.	Via the FDA.gov website with text and actual image of the letter sent to the company/organization. Information posted covers the years from 2005 to 2016. Warning Letters can be sorted by: Tobacco Retailer Warning Letters, General FDA Warning Letters, and Drug Marketing and Advertising Warning Letters and Untitled Letters to Pharmaceutical Companies. Viewers to this site can browse Warning Letters by Company, by Issuing Office, by Subject, by with Response Letters and by with Closeout Letters.	Yes, as basis information of the actions of a regulatory agency as per: CFR - Code of Federal Regulations Title 21.	Yes, the database does provide five columns of information: Letter Issue Date, Company Name, Issuing Office, Subject, Close Out Date.	Data can be added and modified as required. No to rulemaking process.
Office of Women's Health (OWH) – External Communications							
Consumer fact sheets and brochures	Provide consumers with basic information at a glance about health issues impacting women and general tips for the safe use of FDA-regulated products.	Women: Consumers, Patients	The materials are written in a plain language format and the reading level is assessed. Select materials are also tested using qualitative focus groups with the target audience to assess readability, comprehension, and layout.	The fact sheets and brochures are posted in PDF and html format on the FDA website. Free print copies are also made available in bulk to the public (consumers, health professionals, community-based organizations, colleges) via the Federal Citizen Information Center and USA.gov. The publications are also disseminated at OWH-supported conference exhibits and outreach events.	No	Yes, there is a general template for the type of information and the layout.	Yes, it can be modified. No, it does not have to go through rulemaking. However, publication updates may need to be submitted to the HHS Strategic Communications Platform for clearance.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
Consumer Medication Booklets	Provide consumers with information FDA-approved products used in the treatment of common health conditions impacting women (depression, hypertension, high cholesterol, menopause, smoking cessation, HIV, and birth control). The booklets list brand and other names for approved products, questions to ask the healthcare provider and general safety warnings. The booklets do not list all side effects and risk information. Links are provide to access full product information on the FDA website.	Women: Consumers, Patients	The materials are written in a plain language format and the reading level is assessed. Select materials are also tested using qualitative focus groups with the target audience to assess readability, comprehension, and layout.	The medication booklets are posted in PDF and html format on the FDA website. Free print copies are also made available in bulk to the public (consumers, health professionals, community-based organizations, colleges) via the Federal Citizen Information Center and USA.gov. The publications are also disseminated at OWH-supported conference exhibits and outreach events.	No	Yes, there is a general template for the type of information and the layout.	Yes, it can be modified. No, it does not have to go through rulemaking. However, publication updates may need to be submitted to the HHS Strategic Communications Platform for clearance.
e-blasts or email alerts	Provide women's health stakeholders with information on FDA program activities, public meetings, safety communications and other regulatory actions impacting the health of women. The e-blasts are sent on an "as-needed basis" to respond to emerging issues.	Public: Consumers, Patients, Health Professionals, Women's Health Advocates, Representatives from National and Community-Based Organizations.	The updates are written in a plain language format.	The e-blasts are sent via email using GovDelivery or Outlook. The GovDelivery listserv is open to the public and anyone can sign up for one of the women's health distribution lists.	No	Yes, there is a general template for the type of information and the layout.	The e-blasts can be modified prior to being sent. Once e-blasts are sent, changes to the content can only be addressed in a new email. Modifications do not require rulemaking.
e-Updates	Provide women's health stakeholders with information on FDA program activities, public meetings and regulatory actions impacting the health of women.	Public: Consumers, Patients, Health Professionals, Women's Health Advocates, Other Government Agencies, Representatives from National and Community-Based Organizations.	The updates are written in a plain language format.	The e-Updates are sent via email using GovDelivery. The listserv is open to the public and anyone can sign up for one of the women's health distribution lists. Since 2015, the e-Updates are sent monthly. Prior to that date, e-Updates were sent on a quarterly basis. There is also a website where the e-Updates for the current year are posted.	No	Yes, there is a general template for the type of information and the layout.	Yes, it can be modified. No, it does not have to go through rulemaking.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
FDA For Women Website	Provide women and women's health stakeholders with FDA health and safety information.	Women: Consumers, Patients, Women's Health Stakeholders seeking information to distribute to women (consumers)	The information is written in a plain language format and made Section 508 compliant.	Website and social media and outreach cards are used to drive traffic to the website	No	Yes	Yes, it can be modified. No, it does not have to go through rulemaking.
Take Time to Care Program (TTTC)	Provide women and women's health stakeholders with FDA health and safety information.	Women: Consumers, Patients	The materials are written in a plain language format and the reading level is assessed. Select materials are also tested using qualitative focus groups with the target audience to assess readability, comprehension, and layout.	Communications are disseminated via multiple channels including web, Twitter, Pinterest, outreach events, and partnerships. Through the TTTC Program, OWH collaborates with national and community-based organizations, other government agencies, health professional associations, women's organizations, faith-based institutions, businesses, insurers, and health/ disease groups to disseminate FDA women's health resources and messages.	No	The communication template varies depending on the outreach channel and target audience.	Information distributed through the Take Time to Care Program can be modified. Modifications do not require rulemaking. However, publication updates may need to be submitted to the HHS Strategic Communications Platform for clearance.
FDAWomen on Twitter	Provide women and women's health stakeholders with FDA health and safety information.	Women: Consumers, Patients Women's Health Stakeholders: Health Professionals, Advocates, Women's Health Organizations, Disease Groups, National and Community based organizations	The tweets are written in a plain language format.	The 140 character messages are sent via the Twitter platform.	No	No, there is no template. The messages much fit within the 140 character limit set by Twitter.	Messages cannot be modified after they are sent. Messages can only be deleted.

How the agency refers to the communication	Describe the intended purpose	Target Audience	How do you ensure comprehension?	How is the communication disseminated?	Is it required by regulation?	Does it follow a template?	Can the communication be modified? If so, do the modifications go through a rulemaking process?
Videos or public service announcements (PSAs)	Provide women and women's health stakeholders with general FDA health and safety information.	Women: Consumers, Patients Women's Health Stakeholders: Health Professionals, Advocates, Women's Health Organizations, Disease Groups, National and Community based organizations	The scripts are written in a plain language format.	The videos are posted on the FDA website and the FDA YouTube Channel. In some cases, the videos are compiled on a DVD and made available to women's health stakeholders for use in the health programs and outreach. The videos are also promoted via the OWH Twitter account.	No	No, there is no template. The videos are designed to meet the communication objectives for the target audience.	Yes, videos can be edited for length and content. The modifications do not have to go through the rulemaking process