

Strategic Plan for Risk Communication and Health Literacy, 2016 - 2019

Executive Summary

One of the Food and Drug Administration's (FDA's) published [Strategic Priority Goals](#) is **Goal 3: Promote Better Informed Decisions About the Use of FDA-Regulated Products**.

The **purpose** of the Strategic Plan for Risk Communication and Health Literacy (SPRCHL, or the plan) is to clarify how the Agency can communicate the benefits and risks of FDA-regulated products to target audiences more effectively to promote better informed decision making. FDA must accomplish the following four outcomes to achieve Strategic Priority Goal 3:

- I. Increased use of clear communication best practices and plain language in developing messages
- II. Increased use of more targeted messages and communications
- III. Improved efficiency of internal operations for writing and developing communications
- IV. Improved dissemination of communications and information

The **primary audience** for this plan is FDA staff members, though the public can read it on FDA's website. The plan, SPRCHL, assumes familiarity with FDA. The SPRCHL is a guide *from* FDA staff members, *for* FDA staff members, showing how FDA staff members' work connects to improve communication and decision making right now. FDA staff members are already taking steps to achieve Strategic Priority Goal 3. This plan lays out potential action steps FDA can take and methods to track the FDA's progress toward accomplishing Strategic Priority Goal 3.

FDA's SPRCHL includes:

- A [Strategic Framework](#): a diagram of over-arching and contributing outcomes that FDA must achieve to meet the Agency's Strategic Priority Goal 3
- [Performance Indicators](#): specific indicators for each outcome in the Strategic Framework that help FDA track progress towards the outcomes
- [Performance Monitoring Plan](#): details how FDA will collect, analyze, and report data for each performance indicator
- Short-Term [Implementation Plan](#): maps potential activities to specific outcomes in the Strategic Framework, offering a foundation to help Centers and Office plan specific action steps for the next 1-3 years

How to Use This Document

- Refer to Appendix 2, [Strategic Framework](#), and reference it as you read the short descriptions of each of the outcomes or contributing outcomes (each box) in the Strategic Framework
- Refer to the [Performance Monitoring Plan](#) and the [Implementation Plan](#) for next steps on performance indicators and activities
- The highest level outcome can only be achieved by accomplishing the four Major Contributing Outcomes (I, II, III, and IV), and onward through further contributing outcomes **Note: Numbers do not imply levels of importance, and are used consistently throughout the plan and appendices.**

Strategic Framework Hierarchy

- >Overarching Outcome
 - >Major Contributing Outcomes I-IV
 - >Contributing Outcomes (A, B...)
 - >Lower-level Contributing Outcomes (a, b...)
 - >Activities (1, 2...)

FDA's Risk Communication and Health Literacy Working Group will monitor the activities and performance indicators, and will revise and update these deliverables as needed. The rest of this document describes the SPRCHL in detail. For notes on background and method, see [Appendix 1](#).

Overarching Outcome:

Increased accessibility to actionable and accurate FDA communication and benefit/risk information

This outcome is the highest level outcome over which FDA risk communication, health literacy, and plain language staff members and programs have significant influence. Please refer to the Strategic Framework in Appendix 2, and note that the very top box is the Strategic Priority Goal 3, depends on the next box below it. Then below that, you will see the overarching outcome just described. This outcome is what members of the working group and other staff members can affect. When FDA accomplishes this outcome, both the Agency and the public will have ready access to actionable and accurate information about FDA-regulated products. This information will help people make informed decisions.

Access to information is key for promoting informed health care decision-making. The balance of benefits and risks of FDA-regulated products can vary, even for a single product, because a risk that might be unacceptable for one person in a given situation may be acceptable for a different person or in a different situation. Moreover, patients need information that helps them work with their health care teams to discuss their use of therapeutic products, as well as deciding about consumer products like foods. Health care professionals also need to be properly informed about products to advise patients and other team members on how best to care for individual patients. Therefore, FDA's risk communication, health literacy, and plain language staff members and programs work toward the improvement of public health by facilitating access to the actionable and accurate information needed to use FDA-regulated products.

Knowledge is integral to making informed decisions; therefore, improved knowledge of the potential benefits, risks, and important information related to FDA-regulated products directly contributes to better informed decisions on the use of FDA-regulated products.

Major Contributing Outcomes

Please refer to the Strategic Framework in Appendix 2 and see that the overarching outcome depends on four major contributing outcomes at FDA:

- I. Increased use of clear communication best practices and plain language in developing messages
- II. Increased use of more targeted messages and communications
- III. Improved efficiency of internal operations for writing and developing communications
- IV. Improved dissemination of FDA's communications and information

Please note that the outcomes are numbered for identification purposes only. The number of an outcome is the same in the Strategic Framework, the Performance Indicators, and the Implementation Plan. These numbers do not imply importance. Please keep referring to the Strategic Framework in Appendix 2 as you continue reading to see how each of these major contributing outcomes depends on more specific outcomes and activities.

I. Increased use of clear communication best practices and plain language in developing messages

This major contributing outcome will increase FDA's use and implementation of best practices and tools that promote clear communication and plain language. FDA can approach the Overarching Outcome, increased accessibility to actionable and accurate information in FDA communications, if staff members practice more effectively what is already known about clear communication and use the tools in a way that fits FDA's regulatory and public health mission.

Major Contributing Outcome I depends on three contributing outcomes, A - C:

A. Increased accountability across FDA for plain language requirements and FDA best practices

FDA could plan and track more concrete actions for plain language requirements, and make those requirements a priority. FDA can improve accountability if staff members clearly understand what actions are to be performed and by whom, then observe if they are accomplished. Accountability helps FDA staff members make progress toward FDA's Overarching Outcome and shows what such progress will look like. Currently, FDA does not uniformly observe or track the accomplishments of FDA staff members and programs as they implement best practices and plain language requirements for communications.

Some activities that support Contributing Outcome I.A. are:

- ① Developing a cross-agency approach to track health literacy actions in accord with the HHS Biennial Action Plan¹
- ② Incorporating plain language elements into PMAP² and SES³ plans
- ③ Promoting Plain Language Awards

B. Increased availability and access to FDA clear communication best practices

FDA must inform communications staff about available resources (e.g., templates, checklists, and other tools) and how to use them in developing clear communications. In some cases, FDA must tailor existing resources to meet its needs.

Some activities that support Contributing Outcome I.B. are:

- ④ Continuing to expand Plain Language Resource Center assets on the FDA intranet
- ⑤ Tailoring best practices and tools for FDA use

C. Improved knowledge across FDA of the value of communicating clearly, and how to write effectively in plain language

Hint to Readers:

- Refer to Appendix 2, [Strategic Framework](#), and see that the numbered circles match the numbered activities to the left.
- Refer next to the [Implementation Plan](#) and see that the numbered activities there also match the activities to the left.
- The activities are long-term and complex! Check the "Specific Steps" column of the Implementation Plan for some specific examples of action steps.
- The Centers and Offices will do different sorts of specific action steps. These are *examples*, not an exhaustive or permanent list.

¹ The Department of Health and Human Services (HHS) Biennial Action Plan for Health Literacy was developed by a cross-department working group to promote awareness of actions across HHS that promote health literacy by asking the agencies to report annually on their activities.

² Performance Management Appraisal Plan (PMAP)

³ Senior Executive Service (SES)

FDA must also ensure that all staff members understand how clear communication advances the Agency's mission and how they can demonstrate clear communication and plain language in their work.

Some activities that support Contributing Outcome I.C. are:

- ⑥ Training all staff who routinely review and clear public information
- ⑦ Implementing an FDA-adapted tool based on Clear Communication Index⁴ across all FDA Centers and Offices
- ⑧ Developing and executing internal campaigns to create awareness of plain language and best practices

II. Increased use of more targeted FDA messages and communications

This major contributing outcome will increase FDA's ability to develop communications that are effective for its target audiences. FDA communicators, subject matter experts, and any other involved staff members, need to know who their target audience is, what information they need, and how to convey the information so that the audience can use it. Therefore FDA communicators must study their audiences and apply communications science.

Major Contributing Outcome II depends on three contributing outcomes A - C:

A. Improved understanding of the knowledge, attitudes, behaviors, uses, needs, and wants of target audiences

Accurate information that is accessible and actionable for consumers, patients or caregivers often differs in the level of detail and how it is communicated from information prepared for professionals. If FDA is to create communications that are clear for target audience(s), its staff must first understand these audience members and their needs.

Contributing Outcome II.A. depends in turn on four Lower-Level Contributing outcomes a - d

a. Expanded two-way communication pathways between FDA and external stakeholders

FDA needs reliable and active communication with external stakeholders, both to obtain information about what audiences need from FDA communications and to provide stakeholders with information they need to understand FDA's information and communicate our messages to their constituents.

Some activities that support Lower-Level Contributing Outcome II.A.a. are:

- ⑨ Expanding and using additional communication pathways to encourage the public to report adverse events
- ⑩ Expanding use of social media tools to learn about stakeholder concerns
- ⑪ Conducting stakeholder meetings, public hearings, and forums with various groups (universities, professional associations, government partners, industry) to build relationships and discover opportunities to reach target populations

b. Increased access to, and leveraging of, external research related to risk communication

⁴ The Clear Communication Index is a tool for reviewing draft communications, developed by the CDC.

FDA needs to take every opportunity to learn from applicable research conducted by other organizations, e.g., academia, professional associations, and industry, so its staff members are relying on the best science.

Some activities that support Lower-Level Contributing Outcome II.A.b. are:

- ⑫ Continuing and expanding use of Special Government Employees for expert advice
- ⑬ Issuing new grants, contracts, and cooperative agreements for research

c. Increased FDA-led or championed evaluative and formative research

FDA is uniquely positioned to design and interpret, or suggest that others perform, research supporting risk communication and health literacy. This research includes 1) research with target audiences on how to best communicate specific items of information in regulatory contexts, where miscommunication can have harmful consequences and 2) research on the effectiveness of FDA programs so that communicators have data to base decisions about what to change.

Some activities that support Lower-Level Contributing Outcome II.A.c. are:

- ⑭ Conducting research studies
- ⑮ Holding focus groups to inform the development of FDA communications
- ⑯ Using social media analytics to evaluate public understanding, knowledge, attitudes, and beliefs

d. Improved intra-agency knowledge and research exchange

FDA could leverage internal communications research and expertise in the context of one type of FDA-regulated product to inform communications to similar audiences about other types of regulated products.

Some activities that support Lower-Level Contributing Outcome II.A.d. are:

- ⑰ Providing timely updates to FDA and HHS senior staff on key points of FDA actions
- ⑱ Organizing internal FDA Forums to share research in progress and research results

B. Increased skills and abilities of FDA staff to develop accurate and actionable communications

FDA staff members communicate about new scientific knowledge to target audiences. Since this information changes continually, FDA staff members' knowledge base, including skills in eliciting key points from experts and their ability to express new concepts, must likewise grow. Communication science also changes continuously, and FDA must stay current in that field as well as other scientific areas.

An activity that supports Contributing Outcome II.B. is:

- ⑲ Promoting FDA staff professional development in communications science and other sciences

C. Improved application of research evidence and feedback knowledge into operations

As FDA staff members conduct communications research and test messages, they must share the results with those involved in communications development. Staff members involved in drafting and finalizing communications must then incorporate the information about responses of target audiences.

Contributing Outcome II.C. depends on three additional Lower-Level Contributing Outcomes a - c:

a. Increased coordination with the scientific community in communication development

FDA communicators coordinate with FDA scientific staff to ensure accuracy. Communications can convey that information effectively, however, only if communicators and other involved staff members produce them using the best available knowledge on how to communicate.

An activity that supports Lower-Level Contributing Outcome II.C.a. is:

- ⑳ Examining the workflow in FDA organizations, such as development and clearance processes, to ensure that all involved staff members can effectively incorporate communications science

b. Increased use of message testing

Research and experience show that target audience members may not receive and understand a message as communicators predict, even in cases of the most carefully crafted communications. Thus, testing messages is an important step to improve communication effectiveness. There is simply no substitute for actual responses of individuals who are as close to the target audience as possible, to show whether and why a message is unclear.

Some activities that support Lower-Level Contributing Outcome II.C.b. are:

- ㉑ Maintaining an internal message testing network to test FDA's communications
- ㉒ Developing external message testing capabilities

c. Improved internal processes for moving research and knowledge into communications development

FDA communication planners must make it easier and more automatic to incorporate communications research and knowledge into staff routines. Behavior change takes time and energy, so FDA's strategy should be to make it easy and routine.

An activity that supports Lower-Level Contributing Outcome II.C.c. is:

- ㉓ Evaluating research projects for results to incorporate into communications development descriptions, including internal standard operating procedures or appropriate public guidance documents

III. Improved efficiency of internal operations for writing/developing communications

This major contributing outcome recognizes that FDA communications professionals and scientists must make the best use of their time. One way to do that is to streamline internal operations to speed production of high quality communications.

Major Contributing Outcome III depends on two contributing outcomes A and B:

A. Improved internal review and oversight process for communication

Internal review and oversight are crucial for quality and consistency with FDA policy, but the valuable time of reviewers can be used best if they know how the communication has been developed, for example, what subject matter and communications science expertise has been included. Consistency in review and oversight processes and expectations can contribute to more efficient development of communications.

An activity that supports Contributing Outcome III.A. is:

- ㉔ Reviewing and assessing FDA's communication workflow and processes to identify areas to improve efficiency

B. Improved consistency in the branding, formatting, and presentation of FDA communications

The more communications appear in a consistent format, the easier it is for audiences to find the information they need. However, different centers and offices in FDA have significant experience developing their own communication products for different types of products. Therefore, FDA staff members must consistently adhere to FDA brand guidelines, while expressing aspects unique to different centers.

Some activities that support Contributing Outcome III.B. are:

- ②5 Sharing and adopting new content publishing guidelines for FDA's external website
- ②6 Conducting a review and assessment of FDA's communication vehicles, including developing and implementing a consistent FDA visual identity

IV. Improved dissemination of FDA's communications and information

This major contributing outcome seeks to increase FDA's ability to communicate directly with target audiences, to achieve the "accessibility" element of the increasing accessibility to actionable and accurate information. FDA must make actionable, accurate information readily available to the varied audiences, either from FDA directly or through other communicators.

Major Contributing Outcome IV depends on four contributing outcomes A - D:

A. Improved leveraging of communication pathways with outreach partners

The Agency's outreach partners may be able to disseminate and amplify its messages in ways that are most effective for a particular audience.

Some activities that support Contributing Outcome IV.A. are:

- ②7 Educating sponsors and principal investigators in research protocols on writing better informed consent documents for prospective participants
- ②8 Supporting FDA's public affairs specialists in targeting officials and consumers in FDA's field offices
- ②9 Targeting and using external organizations to disseminate FDA messages

B. Improved response & coordination during crisis and recall situations

Communication in crisis and recall situations is even more sensitive than routine communications, and the stakes are higher. FDA can earn greater public trust if staff members prepare for crises and recalls so that they can promptly share information with the public. FDA must also be prepared to share that information efficiently with federal agencies and state and local officials, so that all sources communicate a consistent message.

Some activities that support Contributing Outcome IV.B. are:

- ③0 Developing communication strategies and research-tested messages to help ensure effective communications in the event of urgent public health situations
- ③1 Creating or adapting tools to guide communications for specific audiences in crisis and recall situations

C. Improved alignment of industry benefit and risk messages with FDA research and guidance

Manufacturers of FDA-regulated products also communicate about the benefits and risks of their products and, where applicable, comply with regulations about product labeling and promotion. Consistent

alignment of their messages with applicable results of FDA research and communications guidance will make the information from manufacturers more understandable to the target audience.

Some activities that support Contributing Outcome IV.C. are:

- ③② Reviewing, editing, and clearing Guidances for Industry on topics such as communications and involving input from stakeholder and stakeholder advocacy groups
- ③③ Considering translating regulatory documents into plain language, or providing supplementary plain language explanations for official regulatory documents

D. Improved accessibility of consumer-facing content

FDA communicators aim to make communications intended for consumers as accessible as possible. FDA should use understandable formats and accessible communication channels, and provide information in languages other than English as often as possible.

Some activities that support Contributing Outcome IV.D. are:

- ③④ Developing materials to help consumers understand the benefits and risks of FDA-regulated products
- ③⑤ Developing and expanding communications for consumers to reflect plain language and health literacy principles
- ③⑥ Administering the Language Access Plan
- ③⑦ Incorporating current, effective Web styles to develop and format current and new Web resources

Performance Indicators

The table below shows performance indicators for each outcome in the Strategic Framework. Performance indicators help FDA track progress or level of accomplishment for each related outcome. The table of performance indicators ranges from items FDA staff can monitor currently (highly feasible), items that would require more effort but still are feasible, and finally, indicators that are noteworthy but probably beyond our current scope (postpone).

Note: Items that FDA also monitors for the HHS Biennial Action Plan for Health Literacy have asterisks (*).

Legend:
Feasibility Rating

	Highly Feasible
	Feasible
	Postpone

Outcome	Feasibility	Performance Indicator
Improved knowledge of the benefits, risks, and important information related to FDA-regulated products by consumers, patients, providers, and professionals		Study, probably survey(s), of knowledge of important information on FDA-regulated products with different target audiences
		Identify any current or recent studies, including qualitative as well as quantitative methods, on beliefs about FDA and FDA-regulated products, noting any trends or retaining as baseline
Increased accessibility to actionable and accurate FDA communication and benefit/risk information		Percent of total FDA communications that are developed or revised using health literacy or plain language principles
	*	Number of FDA communications that are developed or revised using health literacy or plain language principles or tools
I Increased use of clear communication best practices and plain language in developing messages		Percent of responses where an employee reports using communication best practices "frequently" in developing messages
		Percent increase/decrease of questions into call center after revising a selected piece of communication
I.A Increased accountability across FDA for Plain Language requirements and FDA best practices		Percent of programs that have established and utilize plain language PMAP requirements
		Number/percent SES plans that reference or include plain language and best practice requirements
		Percent of responses where employees report being "encouraged/required" to use plain language
I.B Increased availability and access to FDA clear communication best practices		Percent increase in best practices published in centralized FDA location online
		Number of methods and/or venues used to distribute plain language/best practices
		Percent of responses where employees report that they "know where to find best practices"
I.C Improved knowledge across FDA of the value of communicating clearly, and how to write effectively in plain language		Percent of participants who score above X percent on post class test for classes in best practices and plain language
II Increased use of more targeted FDA messages and communications		Number of communication products whose development was informed by some inquiry of audience knowledge, attitudes, and behaviors (or from inquiries that come into FDA)
		Number of external expert consults and number of external research studies conducted for specific communication needs at FDA
		Percent of message testing where the message is found to not incorporate key plain language or communication best practices

Outcome	Feasibility	Performance Indicator
II.A Improved understanding of the knowledge, attitudes, behavior, uses, needs and wants of target audiences		Percent of large scale campaigns that undergo an effort (or specify an effort in project plan) to understand knowledge, attitudes, and behaviors using different methods
II.A.a Expanded two-way communication pathways between FDA and external stakeholders		Number of memos of understanding or other types of agreements with external stakeholder groups
		Number of patient preference meetings and information collections
		Number of participants in social media platforms (Number of twitter chats, etc.)
	*	Number of active opportunities that enable external stakeholders to communicate directly with FDA
II.A.b Increased access to, and leveraging of, external research related to risk communication		Percent or number of communication campaigns or events that received contributions from external experts (special government employee special assignments, Risk Communication Advisory Committee meetings, participation of special government employee communication experts in other advisory committee meetings)
		Number of FDA attendees at conferences where communication research is presented
		Number of conferences attended by FDA staff where communications research is presented
II.A.c Increased FDA-led or championed evaluative and formative research	*	Number of ongoing external studies related to risk communication and health literacy, including contract, co-operative agreement, or if applicable grant. (disaggregate by FDA-led and FDA-funded)
		Number of publications of FDA-led or championed research (including both peer-reviewed and FDA web-published reports)
		Number of presentations of FDA-conducted or sponsored research at scientific/professional meetings or conferences
II.A.d Improved intra-agency knowledge and research exchange		Number of FDA research presentations at an FDA venue
		Percent of communication developers that report using research conducted by others in FDA
		Percent of communication professionals that report consulting someone from a different center for advice on risk communication
II.B Increased skills and abilities of FDA staff to develop accurate and actionable communications		Number of training events offered on latest communication-related research and development techniques, and number of participants
		Percent of trainee participants who score above X percent on post-training test
		Percent change in average scores in FDA's tool (based on Clear Communication Index) scores
		Percent of respondents who score above X percent on a short knowledge "assessment" included in survey
		Number of training events offered on communications best practices
		Number of staff participating in training events on communications best practices
		Number of communication products that express clear, accurate and actionable messages, by observations other than applying the FDA's tool (based on Clear Communication Index)
II.C Improved application of research evidence and feedback knowledge into operations		Number or percent of communication projects that incorporate research results (e.g., reporting absolute risk instead of or in addition to relative risk, or using the same denominator for all ratios in a communication)
II.C.a Increased coordination with science community in communication development		Number of programs whose representatives have reviewed their workflow processes for opportunities to enhance coordination
II.C.b Increased use of message testing	*	Number or percent of messages tested with the targeted audience

Outcome	Feasibility	Performance Indicator
II.C.c Improved internal processes for moving research and knowledge into communications development		Number of research projects identified as related to risk communication or health literacy, for which concrete suggestions for FDA use are also identified
III Improved efficiency of internal operations for writing & developing communications		Average length of time from a communication project's concept to draft
		Average length of time from a communication project's draft to completed clearance
		Percent of communication projects where drafting is complete within planned timeline
		Percent of communication projects where clearance is complete within planned timeline
		Percent of respondents who report that getting communications approved for dissemination is a "highly efficient process"
III.A Improved internal review and oversight process of communication messages		Average length of time from entering clearance to completed clearance
III.B Improved consistency in the branding, formatting, and presentation of FDA communications		Percent of reviewed (or published) messages returned for branding and formatting corrections
IV Improved dissemination of FDA's communications and information		Average length of time from clearance to dissemination (planned vs actual)
		Number of different dissemination channels used for same message
		Percent of communications that are tailored to more than one audience
IV.A Improved leveraging of communication pathways with outreach partners		Number of retweets/likes/sharing of FDA social media messages
		Number of referring links to FDA messages
IV.B Improved response and coordination during crisis and recall situations		Number of exercises conducted with partner communication offices
		Average time from detection of crisis to first release of communication to public or stakeholders
		Number of communication plans developed for different potential crisis situations
IV.C Improved alignment of industry benefit/risk messages with FDA research and guidance		Number of industry documents that show improved quality or are associated with an evaluation plan
		Success factors related to patient medication information project
IV.D Improved accessibility of consumer-facing content		Percent of messages translated into another language by FDA and released
		Percent of 508 compliance, based on a DHHS scan of FDA's website

Performance Monitoring Plan

FDA's Performance Monitoring Plan is in Appendix 3. The Performance Monitoring Plan provides more details about how FDA staff will collect and analyze the performance indicator data, and with what frequency. It will be updated as needed, for example if FDA staff members find a need to adjust how to collect data.

Implementation Plan

The Implementation Plan (below) reviews the recommended potential activities for each of the lowest level outcomes in the Strategic Framework, with numbers matching Strategic Framework and the descriptions above. The Implementation Plan goes into greater detail, however, suggesting some more specific steps to be taken over the near term. The Implementation Plan offers a foundation for more tailored preparations in Centers. Although the working group agreed that these action steps would of value to the Agency, it recognizes that these steps may need to be revised or amended over time.

Implementation Plan			
Lowest level Outcomes	Number	Recommended Activities	Examples of Specific Steps
I.A Increased accountability across FDA of Plain Language requirements and FDA best practices	1	Develop a cross-agency approach to track health literacy actions in accord with HHS Biennial Action Plan	<ul style="list-style-type: none"> • Complete annual Plain Writing Act reports • Develop a process for retrieving annual documents for preparation of Plain Language Annual Reports. • Ensure that HHS health literacy measures are included in FDA's; collect throughout the year
	2	Incorporate plain language elements into PMAP and SES plans	<ul style="list-style-type: none"> • Research a method to insert Plain Language elements into SES plans • Develop model Plain Language elements that can be added to Agency staff PMAP elements
	3	Promote Plain Language Awards	<ul style="list-style-type: none"> • Encourage nominations for Center-Level awards, publicize winners • Propose new Agency-level honor award for plain language • Research costs and benefits of pursuing funding and nominations for Clear Mark awards

Lowest level Outcomes	Number	Recommended Activities	Examples of Specific Steps
I.B Increased availability and access to FDA clear communication best practices	4	Continue to expand Plain Language Resource Center assets on the FDA intranet.	<ul style="list-style-type: none"> • Add information and resources writers-editors need to improve published information • Add social media policy and practices • Add how to make documents and messages accessible to people with disabilities • Develop a one page Fact Sheet (with justifications) of why using Plain Language is important • Complete YouTube policy and disseminate within FDA • Update resources from other agencies and add any missing links
	5	Tailor best practices and tools for FDA use	<ul style="list-style-type: none"> • Compile a list of communication platforms across the Agency and develop communication materials appropriate for each • Evaluate and establish standardized templates for frequently used communication types (e.g. information advisories) • Conduct an inventory of Center and Office specific editorial style guides • Produce FDA-oriented plain language editorial guide plus dictionary of words commonly used in FDA writing, including regulatory and medical terms • Develop a drug-specific plain language glossary or dictionary that can be used for communications materials • Adapt Clear Communication Index to address FDA needs identified through the pilot project • Create easy to use FDA best-practices guidelines using information on various FDA web sites; include CDC guidelines; spin off a laminated sheet for new hires and as a refresher for current staff members
I.C Improved knowledge across FDA of the value of communicating clearly, and how to write effectively in plain language	6	Train all staff who routinely review and clear public information	<ul style="list-style-type: none"> • Encourage use of plain language training (already developed and provided through FDA University and consider new ways to promote the training Agency-wide)
	7	Implement an FDA-adapted Clear Communication Index across all FDA Center(s)	<ul style="list-style-type: none"> • Conduct training on using the FDA-tailored tool based on Clear Communication Index • Showcase a comparison of Foresee survey results for communications developed using FDA tool (based on Clear Communication Index) against non-scored communications
	8	Develop and execute internal campaigns to create awareness of plain language and best practices	<ul style="list-style-type: none"> • Establish a project to explore most effective ways to promote the use of plain language across FDA • Develop posters and videos on use of plain language for distribution in the White Oak campus lobby • Create information sheet containing real-life examples of the impact of <i>not</i> using plain language • Conduct brown bag presentations on effective writing techniques and formatting, include writing for web • Publish monthly articles demonstrating how to write complex, critical information in plain language

Lowest level Outcomes	N u m b e r	Recommended Activities	Examples of Specific Steps
II.A.a Expanded two-way communication pathways between FDA and external stakeholders	9	Expand and use additional communication pathways to encourage the public to report adverse events	<ul style="list-style-type: none"> • Create online tutorials targeted to different audiences to help navigate reporting adverse events related to tobacco • Develop Pinterest and 50-state call, as well as additional webinars working with the Office of Health and Constituent Affairs and the Office of Regulatory Affairs' District Directors to improve reporting of adverse events • Use Consumer Updates, Web page, webinars, Twitter, Facebook, and presentation to public affairs specialist at district offices, Google AdWords, CFSAN Educators Newsletter, WebMD interview, and distribution of handouts at conferences to improve reporting of adverse events related to cosmetics • Create a list of FDA communication platforms centrally available
	10	Expand use of social media tools to receive input/information about stakeholder concerns	<ul style="list-style-type: none"> • Continue to use and promote the Apprio/Brandwatch social media dashboards to identify influential social media posts to which FDA can respond, and trends of interest or concern about emerging issues (safety, new technology, etc.)
	11	Conduct stakeholder meetings, public hearings, and forums with various groups (universities, professional associations, government partners) to build relationships and discover opportunities to reach target populations	<ul style="list-style-type: none"> • Conduct stakeholder meetings and activities through the Public Affairs and Stakeholder Engagement (PACE) group • Conduct meetings with Patient Liaison Program/ Office of Health and Constituent Affairs to gather input of the patient perspective (CDER Patient Focused Drug Development Initiative) • Hold public hearings to provide and gather public info (e.g., Generic Drugs User Fee Act regulatory science), external stakeholder meetings during user fee agreement negotiations • Use the Office of Health and Constituent Affairs' Health Professional Liaison Program to get perspectives from health professional stakeholders
II.A.b Increased access to, and leveraging of, external research related to risk communication	12	Continue and expand use of Special Government Employees (SGEs) for expert advice	<ul style="list-style-type: none"> • Hold Risk Communication Advisory Committee meetings • Expand use of SGEs for special projects related to enhancing communication effectiveness • Appoint permanent or temporary members (when appropriate) with communications expertise to other advisory committees
	13	Issue new grants, contracts, and cooperative agreements for research	<ul style="list-style-type: none"> • Issue new grants and contracts for research on post-market evaluation of drug safety, equivalence of complex products and locally-acting products, therapeutic equivalence evaluation and standards, and any computational and analytical tools related to communications • Issue Generic Drug User Fee Act regulatory science grants and contracts on post-market safety of generic drugs, including attention to collaborative communication development requirements • Administer cooperative agreements, e.g., with University of Chicago and Auburn University to study knowledge gaps about generic drugs among influencers of generic drug use • Issue grants and contracts supporting regulatory science goals related to communication (e.g., tobacco regulation)

Lowest level Outcomes	N u m b e r	Recommended Activities	Examples of Specific Steps
II.A.c Increased FDA-led or championed evaluative and formative research	14	Conduct research studies	<ul style="list-style-type: none"> • Conduct a series of studies on consumer understanding of quantitative information in prescription drug promotion (e.g. <i>Experimental Study of Format Variations in the Brief Summary of DTC Print Advertisements, Communication of Effectiveness Information in DTC Print Ads+B20, and Presentation of Quantitative Benefit Information in DTC Television and Print Advertisements for Prescription Drugs</i>) • Conduct <i>Studies to Enhance FDA Communications Addressing Opioids and Other Potentially Addictive Pain Medications: a Comprehensive Risk Communication Research Program</i> • Collect and publish data on <i>Understanding Consumer Perceptions of Modified Risk Tobacco Product Claims</i> • Develop a paper to examine existing counseling practices, techniques and tools, as well as identifying opportunities to provide more effective standardized counseling by healthcare providers to their patients to improve effectiveness of communicating serious risks vs benefits for patients considering or taking those drugs with a Risk Evaluation and Mitigation Strategy
	15	Hold focus groups to inform the development of FDA communications	<ul style="list-style-type: none"> • Hold focus groups to inform development of targeted educational messages about FDA's restaurant menu labeling requirements • Establish focus groups to inform the development of, and cognitive interviews to refine the wording of, messages about biosimilars to increase prescriber and pharmacist knowledge in order to increase mainstream acceptance of the products
	16	Use social media analytics to evaluate public understanding, knowledge, attitudes, and beliefs	<ul style="list-style-type: none"> • Continue to use and promote FDA's social media contract with Apprio/Brandwatch to monitor consumers' online conversations about FDA-regulated products to assess public understanding, knowledge, attitudes, and beliefs around relevant issues
II.A.d Improved intra-agency knowledge and research exchange	17	Provide timely updates to FDA and HHS senior staff on key points of FDA actions	<ul style="list-style-type: none"> • Write and publish Information Advisories to summarize key points of FDA actions such as drug approvals, advisory committee meetings, and guidance announcements to brief FDA and HHS Senior Staff
	18	Organize internal FDA forums to share research in progress and research results	<ul style="list-style-type: none"> • Hold Office of Generic Drugs Science forum • Hold an annual Health Literacy Poster Session where everyone at FDA can present ongoing research related to health literacy • Provide a forum for working group members educate one another on their respective center's research agendas
II.B Increased skills and abilities of FDA staff to develop accurate and actionable communications	19	Promoting FDA staff professional development in communications science and other sciences	<ul style="list-style-type: none"> • Identifying areas for increasing knowledge of frequent subject matter for communications • Locating educational opportunities such as conferences and symposia

Lowest level Outcomes	Number	Recommended Activities	Examples of Specific Steps
II.C.a Increased coordination with science community in communication development	20	Examine workflows in FDA organizations, such as development and clearance processes, to ensure that all involved staff members can effectively incorporate communications science	<ul style="list-style-type: none"> Identifying opportunities for enhancing coordination with subject matter experts specifically about characterizing the target audience Developing communications to provide the scientific information specifically needed and usable by that target audience.
II.C.b Increased use of message testing	21	Maintain an internal message testing network to test FDA's communications	<ul style="list-style-type: none"> Advertise message testing services across Agency Conduct message testing Solicit more message testing volunteers from within Agency
	22	Develop external Agency message testing capabilities	<ul style="list-style-type: none"> Develop proposal for funding to contract with external internet panel access to perform message testing
II.C.c Improved internal processes for moving research and knowledge into communications development	23	Evaluate research projects for results to incorporate into communications development descriptions, including internal standard operating procedures or appropriate public guidance documents	<ul style="list-style-type: none"> Gather and catalog all research projects relevant to risk communication/health literacy Scan external literature to update FDA's communication best practices on an ongoing basis Develop before/after materials to show internal colleagues the value of incorporating research results into communications
III.A Improved internal review and oversight process of communication messages	24	Review and Assess FDA's communication workflow and processes to identify areas to improve efficiency.	<ul style="list-style-type: none"> Members of Risk Communication and Health Literacy Working Group who are involved in clearance processes discuss how to observe their own organization's workflow, identifying areas for potential streamlining, and bringing suggestions to attention of supervisors for consideration.
III.B Improved consistency in the branding, formatting, and presentation of FDA communications	25	Share and adopt new content publishing guidelines for FDA web	<ul style="list-style-type: none"> Complete migration to Drupal web content management system
	26	Conduct a review and assessment of FDA's communication vehicles, including developing and implementing a consistent FDA visual identity	<ul style="list-style-type: none"> Develop and disseminate in FDA a graphic standards manual and design templates and examples for key products Provide education as needed throughout FDA, explaining the role of consistency in branding, formatting, and other aspects of communication to promote target audience understanding

Lowest level Outcomes	Number	Recommended Activities	Examples of Specific Steps
IV.A Improved leveraging of communication pathways with outreach partners	27	Educate sponsors and principal investigators in research protocols on writing better informed consent documents for prospective participants	<ul style="list-style-type: none"> Disseminate resources and recommendations to sponsors and principle investigators that improve understandability of informed consent documents, recruitment tools, questionnaires and surveys
	28	Support FDA's Public Affairs Specialists to target officials and consumers FDA's field offices	<ul style="list-style-type: none"> Make presentations to local groups, answer queries, and interact with state, local, tribal, and non-governmental organization partners
	29	Target and use external organizations to disseminate FDA messages	<ul style="list-style-type: none"> Maintain relationships, e.g., through current memoranda of understanding, with professional societies and other groups Expand relationships with external groups, for example, by holding public meetings with patients, patient organizations and healthcare professional to discuss health literacy on our website and how to improve FDA's message delivery
IV.B Improved response and coordination during crisis and recall situations	30	Develop communication strategies and research-tested messages to help ensure effective communications in the event of urgent public health situations	<ul style="list-style-type: none"> Catalog the most likely and serious difficulties that may complicate emergency administration of medical countermeasures (MCMs) Maintain and expand the MCM issues page in providing a centralized list of issue-specific resources for a variety of topics, linking to the various center pages, news releases, guidance, and external links Institute an FDA wide MCM communicators round-table
	31	Create or adapt tools to guide communications for specific audiences in crisis and recall situations	<ul style="list-style-type: none"> Create message library to use during crisis situations (e.g., pandemic influenza), with messages audience-tested and pre-cleared to the extent possible, to help FDA communicate more rapidly to the public with effective crisis messages Project likely target audiences (e.g., message mapping)
IV.C Improved alignment of industry benefit and risk messages with FDA research and guidance	32	Review, edit, and clear Guidances for Industry on topics such as communications and involving input from stakeholder and stakeholder advocacy groups	<ul style="list-style-type: none"> Complete and implement patient medication information project with guidance, education, etc. Continue developing Guidances for Industry in an order prioritized by needs of stakeholders
	33	Consider translating regulatory documents into plain language, or providing supplementary plain language explanations for official regulatory documents	<ul style="list-style-type: none"> Create a list of highest priority documents

Lowest level Outcomes	Number	Recommended Activities	Examples of Specific Steps
IV.D Improved accessibility of consumer-facing content	34	Develop materials to help consumers understand the benefits and risks of FDA regulated products	<ul style="list-style-type: none"> • Continue releasing and promoting health safety and other relevant information to the public through FDA Consumer Updates • Develop materials on cosmetic ingredients, such as the different uses of formaldehyde • Develop additional tools to broaden outreach efforts for alerting consumers to safety issues (e.g. cosmetics) • Develop webinar series accessible to low-literacy audiences (e.g. similar to "Get to Know ClinicalTrials.gov") • Identify high priority documents to be rewritten in plainer language, e.g., at eighth grade level. • Produce CBER-oriented blogs and research article summaries for posting on CBER's Innovation and Regulatory Science web site • Produce CBER-oriented posters on the center's research for display in Building 1 for viewing by FDA staff and visitors; poster images also put on Innovation web site
	35	Develop and expand communications for consumers to reflect plain language and health literacy principles	<ul style="list-style-type: none"> • Examples include: Consumer Updates, webpages for a patient audience, and FDA 101's to new patient representative recruits Standardize external email communications as much as possible to make more succinct, compelling, and plain language as appropriate for intended audiences • Expand the translation of FDA conducted science in readily accessible formats (e.g. Posters based on published research) • Summarize GDUFA research results for the public • Publish materials that tell the story of Agency's scientific activity in plain language • Update and promote the Consumer Update about health literacy
	36	Administer the Language Access Plan	<ul style="list-style-type: none"> • Standardize the language translation processes • Develop use of internal volunteer network to check translations • Continue updating the Language Access Plan Steering Committee SharePoint site, to serve as a central location for Language Access Program • Plan inter-agency multi-lingual workshop, based on successful pilot in which Office of Minority Health (OMH) partnered with FDA Office of External Affairs (OEA), USAGov, and Department of Justice • Plan multi-lingual outreach activities, based on successful pilot in which OMH, OEA and the Office of Regulatory Affairs' Office of Health Fraud launched a multilingual campaign during Consumer Health Protection Week on dangers of some imported dietary supplement products.
	37	Incorporate current, effective Web styles to develop and format current and new Web resources	<ul style="list-style-type: none"> • Evaluate high level sections of the FDA website (e.g. the "Report a Problem") to identify areas for improvement • Eliminate link farms and consolidate information on the FDA website • Evaluate and ensure that all consumer-facing content is accessible by smart phone • Review and revise older documents to adapt to current effective Web style and placement of search terms • Share new content publishing guidelines developed for migration to Drupal web content management system

Appendix 1

Background and Method

The **purpose** of the Strategic Plan for Risk Communication and Health Literacy (SPRCHL, or the plan) is to clarify how the Agency can communicate the benefits and risks of FDA-regulated products to target audiences more effectively to promote better informed decision making. The plan, SPRCHL, lays out an approach to achieve FDA's [Strategic Priority Goal 3](#), *Promote better informed decisions about the use of FDA-regulated products*.

The **primary audience** for this plan is FDA staff members. The SPRCHL is a guide *from* FDA staff members, *for* FDA staff members, showing how our work connects to improve communication and decision making right now.

FDA's previous working groups on risk communication, health literacy, and plain language merged at the beginning of plan development to tap into the communications and social science expertise and practical experiences of members of all these groups. The resulting Risk Communication and Health Literacy Working Group developed the plan and will monitor FDA's progress.

The cross-agency working group first reviewed the FDA's previous [Strategic Plan for Risk Communication](#) (SPRC). For SPRC, the FDA's Risk Communication Advisory Committee's (RCAC) had recommended that FDA plan for risk communication as a strategic activity. Acting on the RCAC's recommendation, FDA's Risk Communication Staff collaborated with a cross-agency group and developed a draft of the SPRC, which the RCAC reviewed and endorsed in April 2009. The SPRC presented three goals with corresponding strategies including:

- Strengthen the science that supports effective risk communication
- Expand FDA capacity to generate, disseminate, and oversee effective risk communication
- Optimize FDA policies on communicating risks and benefits

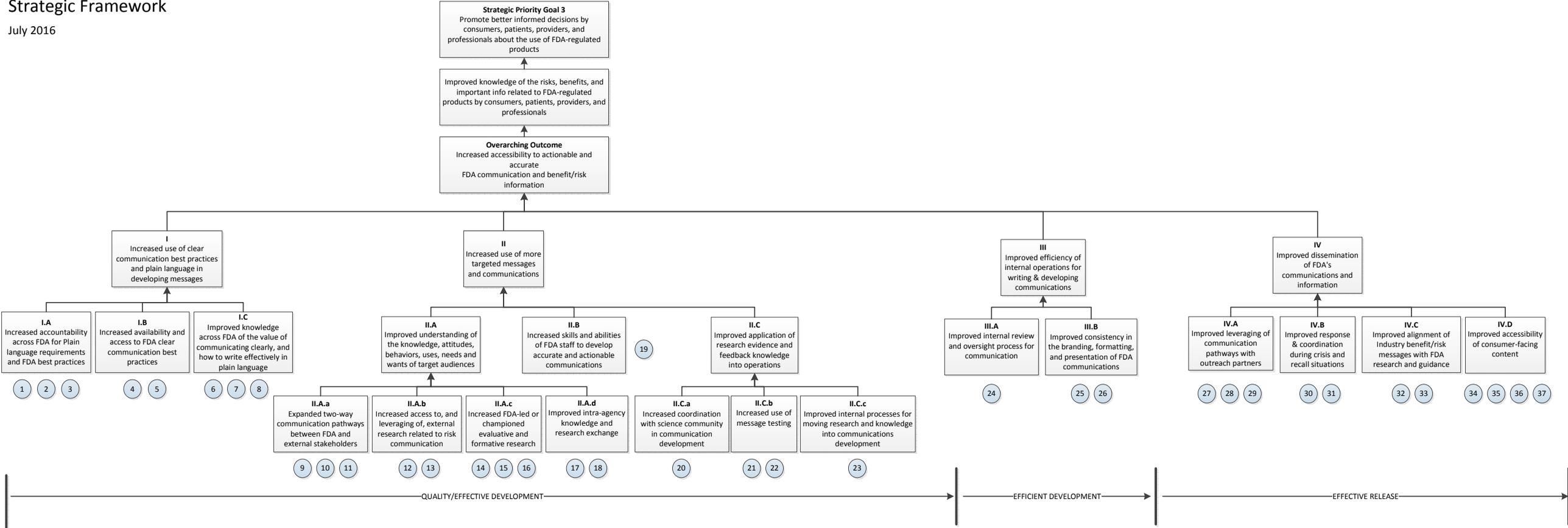
After publishing the SPRC in 2009, FDA monitored progress, finally publishing an update listing 32 strategy-level accomplishments.

To meet FDA's need for an updated plan, the cross-agency working group developed a new plan using the Strategic Program Planning method. The plan is titled *Strategic Plan for Risk Communication and Health Literacy, 2016-2019*, abbreviated *SPRCHL* [pronounced "sparkle"].

The SPRCHL presents the basic connections between risk communication, health literacy, and plain language to address the FDA's Strategic Priority Goal 3. It also offers practical action steps that can be implemented in 1-3 years.

Risk Communication and Health Literacy Strategic Framework

July 2016



Corresponds to Activity

Outcome	Measure/Indicator	Unit of Measure	Data Source	Baseline	Target	Data Collection			Notes
						Method	Who	When	
Improved knowledge of the risks, benefits, and important information related to FDA-regulated products by consumers, patients, providers, and professionals	Study, probably survey(s), of knowledge of important information on FDA-regulated products with different target audiences								
	Identify any current or recent studies, including qualitative as well as quantitative methods, on beliefs about FDA and FDA-regulated products, noting any trends or retaining as baseline								
Increased accessibility to actionable and accurate FDA communication and benefit/risk information	Percent of total FDA communications that are developed or revised using health literacy or plain language principles	# of total FDA communications or campaigns # of FDA communications/campaigns that use HL or PL principles	Centers track internally and report	CY 2015 report to HHS: 4 tools + 29 examples of communications		Sum counts of program activities entered in CY 2016 HHS spreadsheet by RC & HL WG members	RC & HL WG members	Monthly	
	* Number of FDA communications that are developed or revised using health literacy or plain language principles or tools	# of FDA communications/campaigns that use HL or PL principles							
I Increased use of clear communication best practices and plain language across FDA in developing messages	Percent of responses where an employee reports using communication best practices "frequently" in developing messages	# of total survey responses # of total survey responses that indicate "frequently"	Survey to be developed						
	Percent increase/decrease of questions into call center after revising a selected piece of communication	# of calls to call center for period of time before release of message # of calls to call center for same period of time after release of message	Call center data						
I.A Increased accountability across FDA of Plain Language requirements and FDA best practices	Percent of programs that have established and utilize plain language PMAP requirements	# of programs # of programs that incorporate plain language into PMAP							
	Number/percent SES plans that reference or include plain language and best practice requirements	# of total SES plans # of SES plans that include plain language references							
	Percent of responses where employees report being "encouraged/required" to use plain language	# of total survey responses # of total survey responses that indicate "encouraged/required"	Survey to be developed						
I.B Increased availability and access to FDA clear communication best practices	Percent increase in best practices published in centralized FDA location online	# of best practices published in specified location on X day # of best practices published in specified location on X day + X day	Plain language resource center on intranet						
	Number of methods and/or venues used to distribute plain language/best practices	# of methods/venues on X day # of methods/venues on X day + X day							
	Percent of responses where employees report that they "know where to find best practices"	# of total survey responses # of total survey responses that indicate "know where to find best practices"	Survey to be developed						
I.C Improved knowledge across FDA of how to communicate clearly, and how to write effectively in plain language	Percent of participants who score above X percent on post class test for classes in best practices and plain language	# of total class participants* # of class participants that score >X%	# participants is available from FDAU, and is published in PWA report	CY 2015 report to HHS: 525 total participants					Post class test/exam needs to be developed
II More targeted messages and communications	Number of communication products whose development was informed by some inquiry of audience knowledge, attitudes, and behaviors (or from inquiries that come into FDA)	# of total communication products # of communication products informed by inquiry of audience KABs	Survey to be developed						
	Number of external expert consults and number of external research studies conducted for specific communication needs at FDA	# of external expert consults and number of external research studies conducted for specific communication needs at FDA	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Percent of message testing where the message is found to not incorporate key plain language or communication best practices	# of total messages tested # of messages tests found not to incorporate plain language	Annual sub-study			A sub-study would need to be established that looks samples and assesses FDA messages across Centers. Sub-study could be used for several performance indicators			Definition and criteria for "key" best practices will need to be defined (e.g. clear purpose, target audience, action, etc.).
II.A Improved understanding of the knowledge, attitudes, behaviors, uses, needs and wants of target audiences	Percent of large scale campaigns that undergo an effort (or specify an effort in project plan) to understand knowledge, attitudes, and behaviors using different methods	# of total campaigns # of campaigns that use a method to understand KABs	Survey to be developed						

Outcome	Measure/Indicator	Unit of Measure	Data Source	Baseline	Target	Data Collection			Notes	
						Method	Who	When		
II.A.a Expanded two-way communication pathways between FDA and external stakeholders	Number of memos of understanding or other types of agreements with external stakeholder groups	# of active MOUs or other types of agreements with external stakeholder groups								
	Number of patient preference meetings and information collections	# of patient preference meetings and information collections								
	Number of participants in social media platforms (Number of twitter chats, etc.)	Number of followers on Facebook, Twitter, and other social media platforms, reported by Center	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives	
	* Number of active opportunities that enable external stakeholders to communicate directly with FDA	# opportunities for public input on health or safety communications	Survey to be developed	# opportunities in CY 2015 reported to HHS: 7 examples						
II.A.b Increased access to, and leveraging of, external research related to risk communication	Percent or number of communication campaigns or events that received contributions from external experts (special government employee special assignments, Risk Communication Advisory Committee meetings, participation of special government employee communication experts in other advisory committee meetings)	# of total campaigns # of campaigns where an expert provided contributions	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives	
	Number of FDA attendees at conferences where communication research is presented	# of FDA attendees at a conferences where communications research is presented	Survey to be developed							
	Number of conferences attended by FDA staff where communications research is presented	# conferences attended where communications research is presented	Survey to be developed							
II.A.c Increased FDA led or championed evaluative and formative research	* Number of ongoing external studies related to risk communication and health literacy, including contract, co-operative agreement, or if applicable grant. (disaggregate by FDA-led and FDA-funded)	# of external studies ongoing during any part of covered calendar year (disaggregate by FDA led and FDA funded)	Centers track internally and report	# of studies in CY 2015 reported to HHS: 19		RC and HL members leading or aware of studies in their programs note on-going projects on CY 2016 spreadsheet	Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives	
	Number of publications of FDA-led or championed research (including both peer-reviewed and FDA web-published reports)	# of publications of FDA led or championed research	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives	
	Number of presentations of FDA-conducted or sponsored research at scientific/professional meetings or conferences	# of presentations of FDA conducted or sponsored research at scientific/professional meetings or conferences	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives	
II.A.d Improved intra-agency knowledge and research exchange	Number of FDA research presentations at an FDA venue	# of FDA research presentations at an FDA venue	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives	
	Percent of communication developers that report using research conducted by others in FDA	% of communications developers that report using research conducted by others in FDA	Survey to be developed							
	Percent of communication professionals that report consulting someone from a different center for advice on risk communication	% of communication professionals that report consulting someone from a different center for advice on Risk Communication	Survey to be developed							
II.B Increased skills and abilities of FDA staff to develop accurate and actionable communications	Number of training events offered on latest communication-related research and development techniques, and number of participants	# of training events offered on latest communication-related research and development techniques # or participants								
	Percent of trainee participants who score above X percent on post-training test	# of total trainee participants # of trainee participants that score >X%				Disaggregate by course			Post class test/exam needs to be developed Acceptable test score % needs to be defined	
	Percent change in average Clear Communication Index scores	# of sampled CCI scores Score for each sampled CCI	Bi-annual sub-study				A sub-study would need to be established that looks samples and assesses FDA messages across Centers. Sub-study could be used for several performance indicators			
	Percent of respondents who score above X percent on a short knowledge "assessment" included in survey	# of total survey responses # of responses that score X% or higher	Survey to be developed							
	Number of training events offered on communications best practices	# of training events offered on communications best practices								
	Number of staff participating in training events on communications best practices	# of staff participating in training events on communications best practices								
	Number of communication products that express clear, accurate and actionable messages, by observations other than applying the Clear Communication Index		Annual sub-study				A sub-study would need to be established that looks samples and assesses FDA messages across Centers. Sub-study could be used for several performance indicators			

Outcome	Measure/Indicator	Unit of Measure	Data Source	Baseline	Target	Data Collection			Notes
						Method	Who	When	
II.C.a Increased coordination with science community in communication development	Number of programs whose representatives have reviewed their workflow processes for opportunities to enhance coordination								
II.C.b Increased use of message testing	* Number or percent of messages tested with the targeted audience	# of total messages/communications # of messages tested with target audience	Message Test administrators	# messages tested in CY 2015 was reported to HHS: 11 examples		Test administrators record monthly on CY 2016 spreadsheet			Disaggregate by messages tested by FDA and those tested by external contractor
II.C.c Improved internal processes for moving research and knowledge into communications development	Number of research projects identified as related to risk communication or health literacy, for which concrete suggestions for FDA use are also identified	# research projects with suggestions identified							
III Improved efficiency of internal operations for writing & developing communications	Average length of time from a communication project's concept to draft	# of total communication projects Date of concept Date of draft	Centers track internally and report						Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Average length of time from a communication project's draft to completed clearance	# of total communication projects Date of draft Date of completed clearance	Centers track internally and report						Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Percent of communication projects where drafting is complete within planned timeline	# of total communication projects # of communication projects that complete draft within planned timeline	Centers track internally and report						Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Percent of communication projects where clearance is complete within planned timeline	# of total communication projects # of communication projects that complete clearance within planned timeline	Centers track internally and report						Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Percent of respondents who report that getting communications approved for dissemination is a "highly efficient process"	# of survey responses # of responses that report "highly efficient process"	Survey to be developed						
III.A Improved internal review and oversight process for communication	Average length of time from entering clearance to completed clearance	# of communications that complete clearance Date of entering clearance Date of completing clearance	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
III.B Improved consistency in the branding, formatting, and presentation of FDA communications	Percent of reviewed (or published) messages returned for branding and formatting corrections	# of total reviewed messages # of reviewed messages returned for correction	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
IV Improved dissemination of FDA's communications and information	Average length of time from clearance to dissemination (planned vs actual)	# of communications that complete clearance Date of entering clearance Date of dissemination	Centers track internally and report				Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Number of different dissemination channels used for same message	# of different dissemination channels used for same message	Centers track internally and report			This indicator could also look and track the % of project plans that include and execute multiple dissemination channels	Center representative reports annually		Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Percent of communications that are tailored to more than one audience	# of communications disseminated	Annual sub-study or Centers track internally and report			A sub-study would need to be established that looks samples and assesses FDA messages across Centers. Sub-study could be used for several performance indicators			If tracked by Centers, a tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
IV.A Improved leveraging of communication pathways with outreach partners	Number of retweets/likes/sharing of FDA social media messages	# of retweets/likes/sharing of FDA social media messages	Brandwatch and other tools being used by Centers				Center representative reports annually		
	Number of referring links to FDA messages	# of referring links to FDA messages	FDA Web Analytics				Center representative reports annually		
IV.B Improved response and coordination during crisis and recall situations	Number of exercises conducted with partner communication offices	# of exercises conducted with partner communication offices	Centers track internally and report				Center representative reports annually		Term 'exercise' needs to be defined with criteria for what constitutes an 'exercise' Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives

Outcome	Measure/Indicator	Unit of Measure	Data Source	Baseline	Target	Data Collection			Notes
						Method	Who	When	
IV.C Improved alignment of industry benefit/risk messages with FDA research and guidance	Number of industry documents that show improved quality or are associated with an evaluation plan								Could be another sub-study of industry messages, however this may be too complex and beyond the scope of FDA. Also, if industry didn't improve their alignment, it might be more of an indicator that they are not complying with FDA rather than an indicator that we are communicating poorly with them. Consider removing?
	Success factors related to patient medication information project								
IV.D Improved accessibility of consumer-facing content	Percent of messages translated into another language by FDA and released	# of total communications # communications translated into at least 1 additional language	Centers track internally and report					Center representative reports annually	Tool or survey to be designed to support the standardization of tracking and reporting by Center Representatives
	Percent of 508 compliance, based on a DHHS scan of FDA's website	% of HHS assessed 25 top web sites	HHS report of Accenture Scan, Dec of CY, to FDA IT	over 90%	100% for scanned sites	OEA Web & Digital Media Staff supplied results of HHS scan of 25 FDA sites			

* reported to HHS
 Highly Feasible
 Feasible
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Below is an image of the FDA's Strategic Priorities table of contents, showing Goal #3. For the full document, visit the FDA website here: [FDA Strategic Priorities](http://www.fda.gov/strategic-priorities)

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