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**U.S. FOOD & DRUG
ADMINISTRATION**

FDA Strategic Plan for Risk Communication and Health Literacy 2017-2019

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Strategic Plan for Risk Communication and Health Literacy, 2017 - 2019

Executive Summary

The Department of Health and Human Services and the Food and Drug Administration (FDA) aim to empower people to make informed choices for their health. FDA's mission includes helping people protect their health through informed decisions about using FDA-regulated products.

FDA aims to help patients, consumers, and health care professionals make informed decisions about FDA-regulated products using the best science and communication practices.

The purpose of this Strategic Plan for Risk Communication and Health Literacy (SPRCHL) is to clarify how FDA can more effectively communicate the benefits and risks of FDA-regulated products to our target audiences. To do so, FDA must accomplish the following four outcomes:

- I. Increased use of clear communication best practices and plain language in developing messages
- II. Increased development of messages and communications specifically for target audiences
- 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. SPRCHL is a guide by FDA staff members, for FDA staff members. This plan lays out potential action steps and methods to track FDA's progress. SPRCHL includes:

- [Strategic Framework](#): a hierarchical diagram of outcomes that FDA must achieve to meet our goal of better communication
- [Implementation Plan](#): a map of potential activities to specific outcomes in the Strategic Framework, offering a foundation to help Centers and Offices plan specific action steps for the next 1-3 years
- [Performance Indicators Phase I](#): specific indicators for outcomes in the Strategic Framework that FDA plans to monitor in the near term

We have also created a Performance Monitoring Plan, which is an internal working draft document on collecting and analyzing data for additional performance indicators.

How to Use This Document

- This document explains the connection between the SPRCHL [Strategic Framework](#), [Implementation Plan](#), and [Performance Indicators Phase I](#).
- Refer to the [Strategic Framework](#) as you read the short description in the narrative below of each outcome (each box)
- Refer to the [Implementation Plan](#) and the [Performance Indicators, Phase I](#), for next steps on activities and performance measures
- Note that the highest level outcome can be achieved by accomplishing the four Major Contributing Outcomes (I, II, III, and IV), and onward through Lower Level Outcomes. The numbers are for reference and do not imply relative importance. They are used consistently throughout the plan and appendices.

Strategic Framework Hierarchy

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

Introduction

The Department of Health and Human Services, and the Food and Drug Administration (FDA), aim to empower people to make informed choices for their health. FDA's mission includes helping people protect their health through informed decisions about using FDA-regulated products. This plan intends to help FDA staff in working toward FDA's mission by promoting risk communication and health literacy.

FDA aims to help patients, consumers, and health care professionals make informed decisions about the benefits and risks of FDA-regulated products, using the best science and communication practices. Health literacy describes the match between the information we provide and people's capacity to find, understand, and use that information for their health.

The purpose of this Strategic Plan for Risk Communication and Health Literacy (SPRCHL) is to clarify how FDA can accomplish our mission by more effectively communicating the benefits and risks of FDA-regulated products to our target audiences. For information on how SPRCHL relates to FDA's previous Strategic Plan for Risk Communication, see [Appendix 1](#).

The primary audience for this plan is FDA staff members, though the public can read it on FDA's website. SPRCHL is a guide by FDA staff members, for FDA staff members. This plan lays out potential action steps and methods to track FDA's progress along four complementary paths to promote staff understanding and use of best practices for clear communication, to strengthen social and behavioral science for better communication, increase process efficiency, and make information more easily available to the public.

Using the SPRCHL Document

SPRCHL was developed by staff members across FDA and is a broad and careful analysis of how we can achieve FDA's aim of empowering people to make informed choices about using FDA-regulated products. SPRCHL, and especially the Strategic Framework, presents an overall view of how our activities and outcomes relate to the aim. SPRCHL is not, however, an algorithm or a procedural sequence to follow.

The [Strategic Framework](#) shows how we can work toward Lower Level Outcomes that support Major Contributing Outcomes that ultimately promote FDA's aim of empowering people to make informed choices about using FDA-regulated products. Each outcome is represented by a box in the Strategic Framework, with arrows showing the connections between outcomes. The outcomes are numbered hierarchically like an outline (Roman numeral, capital letter, small letter). That system makes it easy to see how a particular outcome is situated in the Strategic Framework.

SPRCHL lists broad activities and specific steps that FDA's Centers and Offices can take as they work toward achieving outcomes. Please note that the Centers and Offices likely will accomplish activities in different ways. In the Strategic Framework, there are numbered circles indicating the activities associated with each of the Lower Level Outcomes. The numbers correspond to the activities listed in the Implementation Plan and in the narrative below. The particular activities that are needed to achieve the outcomes will change over time, and we may need to modify the outcomes. As a reader, you may find it helpful to review the [Strategic Framework](#) and the [Implementation Plan](#) at the same time. This narrative, starting on page 4, walks through SPRCHL's Strategic Framework in detail. It starts with FDA's communication aim and works toward the Lower Level Outcomes.

Acting on SPRCHL

In addition to the recommended activities for each Lower Level Outcome in the Strategic Framework, the Risk Communication and Health Literacy Working Group members provided examples of specific steps

that different Centers and Offices can take to engage in these activities and to achieve the associated outcomes. The [Implementation Plan](#) shows the Lower Level Outcomes, the associated recommended activities, and examples of specific steps for near term work. We list only selected examples of specific steps so that each Center and Office may take different steps, according to their specific circumstances. We will update specific steps over time.

Monitoring Progress in SPRCHL

The Risk Communication and Health Literacy Working Group monitors the progress of SPRCHL. The [Performance Indicators Phase I](#) table lists items we track. We selected this subset of potential indicators based on their feasibility and usefulness in monitoring our progress toward particular outcomes. We developed performance indicators for all the outcomes in the Strategic Framework, and plan to include additional indicators in future updates. Some indicators would provide helpful information but also would require substantial resources (personnel and financial) to monitor. We may expand monitoring to include the more resource intensive indicators at a later date.

SPRCHL Structure and FDA Structure

FDA's communications are extensive and varied across the Agency. SPRCHL shows a framework for how FDA's communications-related work supports the accomplishment of our aim of empowering people to make informed choices about using FDA-regulated products. We recognize at the same time that the outcome, better informed decisions, is affected by additional influences beyond FDA's control.

FDA is unified, but it is composed of distinct Centers and Offices with different regulatory roles. Some Centers and Offices focus on pre-market review or post-marketing surveillance, or coordinate work on products grouped by intended users (such as pediatric products) rather than by product type. Likewise, some communications are issued directly by the Center or Office most involved in the topic, while others are developed and issued by the Office of the Commissioner. FDA strives to maintain flexibility to account for the communication processes and vehicles that make most sense in the situation, either from the Center or for the Agency overall.

A Close Look at SPRCHL's Strategic Framework

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

The Overarching Outcome is the highest level outcome over which FDA risk communication, health literacy, and plain language staff members have significant influence. In the [Strategic Framework](#), each outcome is supported by the one below it. The top outcome is our aim of empowering people to make informed choices about using FDA-regulated products, which is supported by the outcome below it (improved knowledge of the risks, benefits, and important information related to FDA-regulated products by consumers, patients, providers, and professionals), and that outcome is supported by the Overarching Outcome listed above.

When FDA accomplishes this Overarching Outcome, the public will have access to actionable and accurate information about FDA-regulated products. Such information will help people become more knowledgeable about FDA-regulated products. This improved knowledge will help people make informed decisions about FDA-regulated products, FDA's aim for risk communication and health literacy. The acceptable balance of benefits and risks of FDA-regulated products can vary for several reasons. Individuals can have different risk preferences; hence a risk that is acceptable for one person may be unacceptable for another. Products that provide important and rare benefits in dire situations (such as a treatment for advanced-stage cancer) may also have high risks. Other products may be less risky, but even so, are less acceptable because effective and safer alternatives exist. Moreover, patients need information to help them discuss therapeutic products and foods with their healthcare provider. Healthcare professionals also need to be informed about products and foods to properly advise patients. These are some of the ways that FDA's communication staff works to improve public health by facilitating access to actionable and accurate information about FDA-regulated products. Regardless of what people do with the knowledge in the end, the decision making process itself can be better with accurate and actionable information.

Major Contributing Outcomes

The [Strategic Framework](#) shows that four Major Contributing Outcomes drive the Overarching Outcome:

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

Please continue to refer to the Strategic Framework as you read to see how each of these Major Contributing Outcomes depends on the accomplishment of lower level outcomes and activities.

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

The purpose of this Major Contributing Outcome is to increase FDA's use of best practices and tools that promote clear communication and plain language. This will contribute to increased access to actionable and accurate information in FDA communications.

Three contributing outcomes, A – C, support Major Contributing Outcome I:

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

FDA does not uniformly track the accomplishments of staff members and programs as they implement best practices and plain language requirements for communications. FDA could more systematically plan and track these best practices and requirements. FDA can improve accountability if staff members clearly understand who should perform what actions and then track their accomplishment.

To support Contributing Outcome I.A. we plan to:

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

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

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

To support Contributing Outcome I.B. we plan to:

- ④ Continue to expand Plain Language Resource Center assets (e.g., tools) on the FDA intranet
- ⑤ Adapt 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

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

To support Contributing Outcome I.C. we plan to:

- ⑥ Train all staff who routinely review and clear public information to practice plain language principles
- ⑦ Implement an FDA-adapted tool based on the Clear Communication Index⁴ across all FDA Centers and Offices
- ⑧ Develop and execute internal campaigns to create awareness of plain language and best practices

Hint to Readers:

- The numbered circles presented in this section match the numbered activities in the [Strategic Framework](#) and the [Implementation Plan](#).
- Some of 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 may take different specific action steps. These activities are examples, and may be added to or modified.

¹ The Department of Health and Human Services (HHS) Biennial Action Plan for Health Literacy was developed by a cross-departmental working group. The goal is to promote awareness of actions across HHS promoting health literacy. The group asks HHS agencies to report on their health literacy activities.

² Performance Management Appraisal Plan (PMAP)

³ Senior Executive Service (SES)

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

II. Increased development of messages and communications specifically for target audiences

FDA communicators, subject matter experts, and other staff members need to know who their target audience is, what information the audience needs, and how to convey usable information. Therefore FDA communicators must study their audiences and apply communications science to their messages. This Major Contributing Outcome will increase FDA's ability to develop communications that are effective for its target audiences.

Three contributing outcomes A – C support Major Contributing Outcome II:

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

Information that is accessible and actionable for consumers, patients, or caregivers often differs from information prepared for professionals. Different groups require different levels of detail and modes of communication. If FDA is to create communications that are clear for target audiences, its staff must first understand these audience members and their needs.

Four Lower-Level Contributing outcomes a – d promote the accomplishment of Contributing Outcome II.A.

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

FDA needs reliable and active communication with external stakeholders. This allows FDA to obtain information about what audiences need and to provide our stakeholders with information they need. Our stakeholders, in turn, will then be able to communicate our messages more effectively to other third parties.

To support Lower-Level Contributing Outcome II.A.a. we plan to:

- 9 Expand communication pathways to encourage the public to report adverse events
- 10 Expand use of social media tools to learn about stakeholder concerns
- 11 Conduct stakeholder meetings, public hearings, and forums to build relationships and discover opportunities to reach target populations

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

FDA needs to learn from applicable research conducted by other organizations, such as academia, professional associations, and industry. This will help the FDA staff to rely on the best communications science available.

To support Lower-Level Contributing Outcome II.A.b. we plan to:

- 12 Continue and expand use of Special Government Employees for expert advice
- 13 Issue new grants, contracts, and cooperative agreements for research

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

FDA is uniquely positioned to conduct or fund research on risk communication and health literacy. This research will focus on 1) how best to communicate information to target audiences and 2) how communications can improve the effectiveness of FDA programs.

To support Lower-Level Contributing Outcome II.A.c. we plan to:

- 14 Conduct research studies that evaluate and inform health literacy actions and programs
- 15 Hold focus groups to inform the development of FDA communications
- 16 Use social media analytics to evaluate public understanding, knowledge, attitudes, and beliefs

d. Improved intra-agency knowledge and research exchange

FDA should use data and expertise on communications of one type of FDA regulated product to inform communication for other types of regulated products.

To support Lower-Level Contributing Outcome II.A.d. we plan to:

- 17 Provide timely updates to FDA and HHS senior staff on key FDA actions
- 18 Organize 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 must likewise grow. Staff development is a critical building block in improving FDA's communications.

To support Contributing Outcome II.B. we plan to:

- 19 Promote 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 the developers of the communications. The developers of the communications must then incorporate the information about responses of target audiences.

Three Lower-Level Contributing Outcomes a – c support Contributing Outcome II.C.:

a. Increased coordination with the scientific community in communication development

FDA communicators coordinate with FDA scientific staff to ensure accuracy of communications. Communicators should apply the best available knowledge on how to communicate effectively without compromising scientific accuracy.

To support Lower-Level Contributing Outcome II.C.a. we plan to:

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

b. Increased use of message testing

Research shows that target audience members may not receive and understand a message as communicators predict, even for the most carefully crafted communications. Thus, testing messages is an important step to improve communication effectiveness. The best way to understand how a message is perceived is to seek feedback from individuals who are as close to the target audience as possible.

To support Lower-Level Contributing Outcome II.C.b. we plan to:

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

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

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

To support Lower-Level Contributing Outcome II.C.c. we plan to:

- ②3 Evaluate research projects for best practices. These will then be incorporated into internal standard operating procedures or appropriate public guidance documents

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

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 up the production of high quality communications.

Two Lower Level Outcomes support Major Contributing Outcome III:

A. Improved internal review and oversight processes for communication

Internal review and oversight of communications are crucial for quality and consistency with FDA policy. The valuable time of reviewers can be used best, however, if they know how the communication has been developed. For example, if they know what subject matter and communications science expertise has been applied, then they may have more confidence in the communication and approve it quickly. Consistency in expectations of review and oversight processes can contribute to more efficient development of communications.

To support Contributing Outcome III.A. we plan to:

- ②4 Identify areas to improve efficiency in FDA's communication process through review and assessment

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. Therefore, FDA staff members must consistently adhere to FDA brand guidelines, while retaining the flexibility to express what is unique about different programs and the products they communicate about.

To support Contributing Outcome III.B. we plan to:

- ②5 Share and adopt new content publishing guidelines for FDA.gov
- ②6 Ensure implementation of a consistent FDA visual identity

IV. Improved dissemination of FDA's communications and information

FDA needs to communicate directly with target audiences to increase accessibility to actionable and accurate information. FDA must make this information readily available to their audiences. This information may be distributed from FDA directly or through other communicators.

Four Lower Level Outcomes A – D support Major Contributing Outcome IV:

A. Improved leveraging of communication pathways with outreach partners

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

To support Contributing Outcome IV.A. we plan to:

- 27 Educate research sponsors and principal investigators on improving informed consent documents for prospective participants
- 28 Support FDA's public affairs specialists in reaching stakeholders in FDA's field offices
- 29 Target and use external organizations to disseminate FDA messages

B. Improved response and coordination during crisis and recall situations

Communication in crisis and recall situations is even more sensitive than routine communications, as 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 in an emergency. 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.

To support Contributing Outcome IV.B. we plan to:

- 30 Develop communication strategies and research-tested messages to help ensure effective communications in the event of urgent public health situations
- 31 Create or adapt 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 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 FDA research and communications guidance will make manufacturers' communications more understandable to the target audience.

To support Contributing Outcome IV.C. we plan to:

- 32 Complete Guidances for Industry on communications, and involve input from stakeholder and stakeholder advocacy groups
- 33 Translate regulatory documents into plain language, or provide supplementary plain language explanations for official regulatory documents

D. Improved accessibility of consumer-facing content

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

To support Contributing Outcome IV.D. we plan to:

- 34 Develop materials to help consumers understand the benefits and risks of FDA-regulated products
- 35 Develop and expand communications for consumers to reflect plain language and health literacy principles
- 36 Administer the [Language Access Plan](#)
- 37 Incorporate current, effective Web styles to develop and format Web resources

Implementation Plan

The [Implementation Plan](#) reviews the recommended potential activities for each of the Lower Level Outcomes in the [Strategic Framework](#). Each activity in this document and the Strategic Framework is consistently numbered. The Implementation Plan suggests some specific steps for the near term in the Centers and Agency-wide. Although the working group agreed that these action steps are valuable to the Agency, it recognizes that these steps may need to be revised or amended over time. Therefore we expect to update the Implementation Plan in future years.

Performance Indicators

Performance indicators are measures related to outcomes in the Strategic Framework. By observing these measures and noting changes over time, we can track progress toward the related outcomes. Potential performance indicators vary widely in how easily we can track them, and in how directly they reflect the related outcome. Information that is more easily collected, such as the number of trainings staff attends, may not directly reflect improved FDA communications. In contrast, information that is more difficult to collect, such as a national survey of public understanding of FDA messages, would more directly reflect improved FDA communications. This survey, however, would be so costly that FDA could not undertake the project immediately.

Performance Monitoring Planning

The [Performance Indicators Phase I](#) table shows indicators that FDA can track in the near term. We will update our monitoring plans to include more indicators in later phases of monitoring.

Appendix 1: SPRCHL and Previous Strategic Plan

Background and Method

Risk communication and health literacy are ongoing concerns for FDA. FDA's previous plan for risk communication needed revising and updating. To meet FDA's need for an updated plan, a 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, 2017-2019, abbreviated SPRCHL [pronounced "sparkle"]. SPRCHL presents the basic connections between risk communication, health literacy, and plain language to address FDA's aim of empowering people to make informed choices about using FDA-regulated products. It also offers practical action steps that we can implement in 1-3 years.

The purpose of SPRCHL is to clarify how FDA can communicate the benefits and risks of regulated products to target audiences more effectively to promote better informed decision making. SPRCHL lays out an approach to achieve FDA's aim of empowering people to make informed choices about using FDA-regulated products.

Who developed SPRCHL? And who is it for?

FDA's working groups on risk communication, health literacy, and plain language merged at the beginning of plan development. The resulting Risk Communication and Health Literacy Working Group developed the plan and will monitor FDA's progress. The primary audience for this plan is FDA staff members. SPRCHL is a guide by FDA staff members, for FDA staff members, showing how our work connects to improve risk communication and support for health literacy at FDA.

How does SPRCHL relate to earlier strategic planning for risk communication?

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

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

After publishing SPRC in 2009, FDA monitored its progress and published an update listing 32 accomplishments. Many of the underlying ideas from SPRC are still important in SPRCHL.

Continuities between SPRC and SPRCHL

a. SPRC noted (p. 3) that:

FDA takes the approach that risk communication:

- is integral to carrying out FDA's mission effectively;
- is a two-way process;

- must be adapted to the various needs of the parties involved; and
- must be evaluated to ensure optimal effectiveness.

The current SPRCHL continues to recognize that clear communication is integral to FDA’s mission, is two-way and must be audience-appropriate, and that evaluation is critical.

- b. SPRC mentioned health literacy is important to reach audiences with limited health literacy and to build awareness of health literacy among FDA Staff members. SPRCHL does so as well, but highlights health literacy more directly, in accord with the Department of Health and Human Services approach in its Biennial Action Plan for Health Literacy:

Health literacy results from the match between the health information and services created for the public and people’s capacity to find, understand and use them.

- c. SPRC explained that FDA communication is produced by FDA but also communicated through our partners. SPRC pointed out that FDA works to provide information directly to consumers, patients, and health care professionals, and to provide guidance to regulated industry on communication that is clear and not misleading:

FDA Risk Communication is interactively sharing risk and benefit information to enable people to make informed judgments about use of FDA-regulated products and providing guidance to industry about how to most effectively communicate the risks and benefit of regulated products. (SPRC p.8)

SPRCHL likewise includes both direct and indirect communications. Both plans were developed through a cross agency group of communicators and related staff members, and both benefitted from advice from FDA’s RCAC.

- d. SPRC recognized communication and understanding does not automatically cause a particular behavior:

[E]ven if people are getting direct FDA recommendations, it is ultimately an individual’s personal choice to, for example, purchase a prescription drug and take or give it to their pet, pick the right food choice for their health, use a medical device appropriately for a particular patient, or avoid unnecessary exposure to radiation. It is critical that individuals receive information that is adequate to ensure that they make informed choices. (SPRC p. 9)

FDA communication remains multifaceted in its aims. In some cases, FDA aims to ensure that decision makers, whether consumers, patients, or health care professionals, have complete and up to date information. We recognize that the right decision can differ from one individual or circumstance to another. In other cases, we have advice that is specific, for example, to locate any product of a recalled lot and discard it. In those cases, we aim to persuade as well as inform. It is critical that FDA communications make the aim of the communication clear. That means identifying who is the audience and what is the key message.

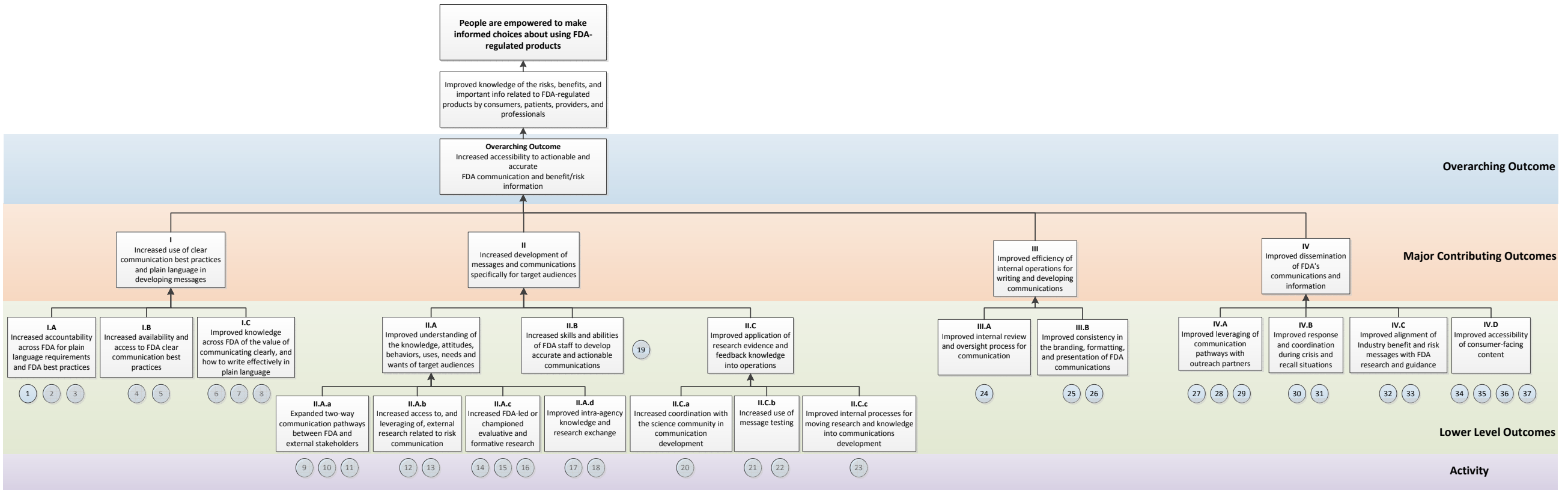
Advances from SPRC to SPRCHL

- a. Actionability: The previous plan SPRC explained the concept of risk communication, argued for the importance of risk communication, and gave examples of how FDA’s mission depends on risk communication for success. The current plan SPRCHL simply assumes all that, plus health literacy, to be foundational to FDA’s communication aim. The previous plan SPRC ended with specific actions

FDA could take. The current plan SPRCHL starts with what we want to accomplish and what actions we can take to achieve our aim.

- b. Method of Development: SPRC was developed in a strategic planning process that had been used before, but did not follow the latest best practices in strategic planning. The current plan SPRCHL was developed through disciplined application of the Strategic Program Planning method, starting with desired outcomes and working back through what we must accomplish to bring about those outcomes, what activities we can do, and how we can track progress.

FDA's Strategic Framework for Risk Communication and Health Literacy



Corresponds to Activity

Appendix 3: Implementation Plan

The Implementation Plan below reviews the recommended potential activities for each of the Lower Level Outcomes in the Strategic Framework. Each activity in this document and the Strategic Framework is consistently numbered. The Implementation Plan suggests some specific steps for the near term in the Centers and Agency-wide. 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. Therefore we expect to update the Implementation Plan in future years.

Implementation Plan

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
I.A Increased accountability across FDA for 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; collection 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 elements of FDA staff's PMAP
	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
I.B Increased availability and access to FDA clear communication best practices	4	Continue to expand Plain Language Resource Center assets (e.g., tools) 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 procedures for 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 document and disseminate within FDA • Update resources from other agencies and add any missing links to these resources

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
	5	Adapt 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 a 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 study • 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 to practice plain language principles	<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 tool based on the Clear Communication Index across all FDA Centers and offices	<ul style="list-style-type: none"> • Conduct training on using the FDA-adapted 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 campaign research 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 communications • Publish monthly articles demonstrating how to write complex, critical information in plain language

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
II.A.a Expanded two-way communication pathways between FDA and external stakeholders	9	Expand communication pathways to encourage the public to report adverse events	<ul style="list-style-type: none"> • Create online tutorials, specifically for different target 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 presentations to public affairs specialists 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 learn 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 from stakeholders 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 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
	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

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
II.A.b Increased access to, and leveraging of, external research related to risk communication	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)
II.A.c Increased FDA-led or championed evaluative and formative research	14	Conduct research studies that evaluate and inform health literacy actions and programs	<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 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

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
II.A.d Improved intra-agency knowledge and research exchange	17	Provide timely updates to FDA and HHS senior staff on key FDA actions	<ul style="list-style-type: none"> • Produce briefings in preferred formats when needed by 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	Promote 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
II.C.a Increased coordination with science community in communication development	20	Examine workflow in FDA organizations, such as development and clearance processes, to ensure that all involved staff members can collaborate effectively to incorporate communications science in FDA information	<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 message testing capabilities to test FDA's communications	<ul style="list-style-type: none"> • Develop proposal for funding to contract with external internet panel access to perform message testing

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
II.C.c Improved internal processes for moving research and knowledge into communications development	23	Evaluate research projects for best practices. These will then be incorporated into 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 to newer standards 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 processes for communication	24	Identify areas to improve efficiency in FDA's communication process through review and assessment	<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.gov	<ul style="list-style-type: none"> • Complete migration to Drupal web content management system
	26	Ensure implementation of 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
IV.A Improved leveraging of communication pathways with outreach partners	27	Educate research sponsors and principal investigators on improving informed consent documents for prospective participants	<ul style="list-style-type: none"> • Disseminate resources and recommendations to sponsors and principal investigators that improve understandability of informed consent documents, recruitment tools, questionnaires and surveys
	28	Support FDA's Public Affairs Specialists in reaching stakeholders in FDA's field offices	<ul style="list-style-type: none"> • Make presentations to local groups, answer questions, 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 FDA website and how to improve message delivery

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
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 a message library to use during crisis situations (e.g., pandemic influenza), with audience tested and pre-cleared messages 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	Complete Guidances for Industry on communications, and involve 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 Guidelines for Industry in an order prioritized by needs of stakeholders
	33	Translate regulatory documents into plain language, or provide 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 more plain language, e.g., at an 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.

Lowest Level Outcomes	Number	Recommended Activities	Examples of Specific Steps
	37	Incorporate current, effective Web styles to develop and format 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 • Consolidate information and reduce the number of links 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 4: Performance Indicators – Monitoring – Phase I

Outcome	Performance Indicator – Phase I Tracking
I Increased use of clear communication best practices and plain language in developing messages	Percent increase/decrease of questions into call center after revising a selected piece of communication
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
II Increased development of messages and communications specifically for target audiences	Number of external expert consults Number of external research studies conducted for specific communication needs at FDA
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.)
II.A.b. Increased access to, and leveraging of, external research related to risk communication	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
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 Number of training events offered on communications best practices Number of staff participating in training events on communications best practices
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
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 Number of communication plans developed for different potential crisis situations
IV.D Improved accessibility of consumer-facing content	Percent of messages translated into other languages by FDA and released Percent of 508 compliance, based on a DHHS scan of FDA's website