



2018 Plain Writing Act Implementation Update Survey

Note: Please provide the information requested below by COB Friday, March 23, 2018. Your responses will be included in our annual compliance report. Thank you for your assistance.

1. Points of Contact:

- a. Please confirm the senior official in your OpDiv or StaffDiv responsible for plain writing. Your current senior official is listed in the chart at the bottom of the Department's plain writing webpage: <http://www.hhs.gov/open/plain-writing/>.**

Name & Title: LaKeisha M. McClendon, Chief Learning Officer
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Note: We will include the name and e-mail address of this person on the Department's plain writing webpage.

- b. Please identify any other personnel working on plain writing in your agency whom we may contact to follow up to your responses to this survey.**

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2. What steps has your agency taken since March 2017 to begin or continue implementation of the Plain Writing Act? Please describe, including:

- a. What *new* activities have you taken to further implement the Act?**

- Celebrating the anniversary of the signing of the Plain Writing Act and Health Literacy Month in October including:
 - FDA-wide message from senior staff promoting plain language awareness and training with the release of the [Strategic Plan for Risk Communication and Health Literacy](#) (SPRCHL) on FDA.gov.
 - Communication plan included rotating web banner on inside.FDA intranet promoting plain language and health literacy awareness and training resources; daily FDA Notice announcements with plain language and health literacy tips and training resources; and external social media messages.
- Redesign of Plain Language Resource Center intranet site for employees.
- Virtual FDA University (FDAU) Plain Language webinars pilot for field staff.
- Basic Plain Language Skills and Clear Communication Index Training through the Risk Communication Staff for release in HHS Learning Portal (LMS) in Spring 2018.

- b. **Since March 2017, what types of documents and how many (estimate is acceptable, please specify) of each has your agency written in plain writing? Please also specify how many of each were new and how many were substantially revised.**

FDA employees across nine centers and offices write a range of documents, letters, and web content for a variety of audiences. Examples include, but are not limited to, guidance documents, regulations, consumer safety notices and updates, recall notices, warning letters, press releases, and policies and procedures. Due to the high volume and wide range of documents FDA employees write, it's difficult to quantify and determine overall figures for the whole.

Some specific data for this time period include:

The Center for Drug Evaluation and Research (CDER) cited more than 50 documents including: response letters to stakeholders, informational materials for legislators and the public, and Federal Register notices and related documents, the majority of which were new.

The Office of the Commissioner (OC) Office of Women's Health (OWH) has made a concerted effort to ensure that all print and electronic communications comply with the Plain Writing Act. For example, OWH developed four new web pages on various health topics for women:

- [5 Health Tips College Women Need to Know](#)
- [3 Tips for Safe Medication Use on Campus](#)
- [Hispanic Women's Health: Tips for Healthy Living](#)
- [Caring for Others: Resources to Help You](#)

The OC Office of the Chief Scientist (OCS) Office of Counterterrorism and Emerging Threats (OCET) created four new web pages, ~six substantially revised web pages, and one new report.

The OC Risk Communication Staff advises other staffs on re-writing and have given plain writing advice on at least 20 documents in 2017.

Some general examples include:

The Center for Biologics Evaluation and Research (CBER) follows plain language principles in all communication. Guidance documents are written to reflect the needs of the intended audience. Press releases, web content, and all consumer information is written in simpler language to capture the widest audience possible, as are all CBER's consumer direct replies.

The Center for Drug Evaluation and Research (CDER) Office of Translational Sciences (OTS) is piloting an internal communication effort to improve internal awareness and understanding of newly issued guidance documents. They developed a prototype for a “guidance snapshot” that can be distributed internally to help reviewers quickly learn the main points of a guidance. CDER also revised its guidances according to a new format to improve readability.

The Office of the Commissioner (OC) Office of Information Management and Technology (OIMT) Privacy Office provides written guidance advising all programs submitting draft documents to the Office for review/approval to avoid jargon, and clearly define technical terms and references.

The Center for Food Safety and Applied Nutrition (CFSAN) has implemented procedures for developing public information collaboratively, with scientists, regulatory experts, and the writer-editor working together to ensure that they provide information people can access, understand, and use. The majority of its web content has been written in plain language for several years.

3. Measurement:

a. How do you track the conversion of existing documents into plain writing?

Though a global measurement is not in place in 2017, we are planning to develop metrics for tracking conversion of our numerous existing documents into plain writing through the Risk Communication Staff and Risk Communication and Health Literacy Workgroup in 2018.

b. How do you measure whether covered documents use plain writing?

FDA centers and offices currently test communications for inclusion of plain writing principles through various methods such as:

1. CDC Clear Communications Index (CCI)

FDA’s Strategic Plan for Risk Communication and Health Literacy recommends using the CCI for communications development. The CCI is widely recognized across HHS as a validated instrument to develop and score communications. The 20 items in the Index build on and expand plain language techniques described in the [Federal Plain Language Guidelines](#).

For example:

- The Risk Communication Staff led a group exercise in applying the CCI to evaluate and make recommendations on five draft consumer-directed drug communications.
- Center for Drug Evaluation and Research (CDER) writer-editors consider target audiences for materials and edit accordingly. A number of CDER staff members recently learned how to use the CCI and plan to incorporate the plain writing principles into their clearance process.
- The Center for Food Safety and Applied Nutrition (CFSAN) Office of Analytics and Outreach uses the CCI when developing all their external communications. Their FDA CFSAN Clear Information Tool is adapted from the CCI Score Sheet.
- The Office of Regulatory Affairs (ORA) style guide promotes using plain language and contains the Clear Communication Tool, a modified CCI, specific to ORA requirements. ORA is training senior leaders, communication staff, and regular staff on clear communication and good writing based on the style guide.
- The Office of the Commissioner (OC) Office of Women's Health (OWH) uses the CCI research-based tool to develop and assess whether covered documents use plain writing.

2. FDA's Internal and External Message Testing Network

Since 2010, the Network, led by the Risk Communication Staff, has enabled FDA communicators to test their content and documents for clear communication with FDA employees who have characteristics in common with target audiences, as well as with external public audiences.

The OC Office of Women's Health (OWH) used the FDA Risk Communications Rapid Message Testing with Consumer Panels to test messages and content with external consumer focus group panels for the [OWH Caring for Others: Resources to Help You](#) web page.

The OC Office of the Chief Scientist (OCS) Office of Counterterrorism and Emerging Threats (OCET) is in the process of message testing with FDA's internal healthcare provider group and is also working with CDER on a continuing project to assess medical countermeasure-related messages among audiences with varying education levels.

3. Digital.Gov University Usability and Message Testing

We plan to conduct an audit of covered documents across the centers in the next year using the Clear Communications Index to determine the extent that our covered documents use plain writing.

c. How do you measure (i) the effectiveness of the plain writing program for your office;

We regularly survey FDAU Plain Language class attendees to obtain feedback on class content, the instructor's delivery and teaching methods, and the instructional exercises.

Comments from 2017 evaluations include: "great material and useful subject," "great presentation, very informative," "very clear and nice presentation," "very helpful," "great content," and "one of the more useful classes in 3.5 years."

Suggestions included: providing more handouts of slides, resources and tips; using more practical examples and exercises relevant to FDA; longer and more advanced classes to allow more discussion; and offering in-person classes at more locations.

The Risk Communication Staff observes attendee numbers and responses to satisfaction surveys for their CCI trainings.

and (ii) the effectiveness of your plain writing documents (i.e., whether the public can easily understand and use them)?

We request feedback about FDA letters, reports, and information on the FDA.gov Plain Language web page through a feedback form or e-mail to FDAUniversity@fda.hhs.gov asking:

1. *Could you understand what you read?*
2. *Could you quickly find what you needed within the information you read?*
3. *Did you know what action to take or how to use the information after reading it?*

The Risk Communication Staff looks for returning request for assistance from FDA colleagues, and to the extent possible, they collect information on uptake of the clearer communication suggestions they offer.

d. What obstacles are there to measuring these aspects of your plain writing program?

- The volume and variety of content written by FDA employees;
- The size of the agency; the distribution of employees throughout the United States in field offices and laboratories, and in other countries;

- Lack of a budget allocated to plain language and health literacy;
- Lack of staff assigned to implement plain language, plain writing, and health literacy;
- The need for HHS-level support on issues such as compliance related to position descriptions, performance evaluations, and budget allocation; and
- Message testing is not always feasible, especially with emerging public health threat situations, where rapid communication is key.

4. Examples:

a. Please submit three documents that your agency has substantially altered and improved through plain writing, since March 2017.

1. Center for Veterinary Medicine (CVM)

- Revised content:

Before: [Animal Drug Safety Frequently Asked Questions](#)

After: [Frequently Asked Questions about Animal Drugs](#)
(see attachment)

- New content:

- Vet-LIRN (Veterinary Laboratory Investigation & Response Network):
Protecting Human & Animal Health (see attachment)

Additional:

- Video on Antiparasitic Resistance in Cattle & Small Ruminants in the U.S.
(<https://www.youtube.com/watch?v=kn1NE-vmhr4>)
- [FDA Approves First Drug to Control Pain in a Food-Producing Animal](#)

2. Center for Drug Evaluation and Research (CDER) Office of Translational Sciences (OTS)

- FDA guidance for industry [Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease](#) (the new bulleted format of this guidance is expected to be widely used to improve readability and comprehension of CDER guidances, and additional guidances using this format are currently under development or in clearance) (see attachment)
- A prototype for a “guidance snapshot” to help reviewers understand the main points of a guidance: Biomarker Qualifications: Evidentiary Framework Draft Guidance (see attachment)

Additional:

- [Grapefruit and Some Drugs Don't Mix](#), in the [Consumer Safety Update](#) series featured on FDA.gov

3. The OC Office of the Chief Scientist (OCS) Office of Counterterrorism and Emerging Threats (OCET)

- <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMiProfessionalDevelopmentActivities/ucm400029.htm> (see attachment)

Additional:

- <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMRegulatoryScience/ucm391318.htm>

b. Please submit three documents that your office intends to revise or rewrite.

1. Questions and Answers on the Proper Use of Monensin in Dairy Cows
2. Pet Food Labels – General
3. <https://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/UCM434314.pdf>

c. Please provide the top three documents using plain writing from your office that have had the largest impact on the public.

1. Zika response web page and related content:
<https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm>
2. Ebola response web page and related content:
<https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm410308.htm>
3. FDA Pregnancy Portal (www.fda.gov/pregnancy): Highlights FDA resources women can use to make good choices about medicines, foods, and other products for women and their baby.

Additional examples include:

OC Office of the Chief Scientist (OCS) Office of Counterterrorism and Emerging Threats (OCET):

What are Medical Countermeasures?

<https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm>

OC Office of Women's Health (OWH):

Pregnancy Initiative: Resources for You and Your Baby:

- **Fact Sheets:** Medicines and Pregnancy fact sheet. Available in [English](#), [Spanish](#), [Chinese](#), [French](#) and [Haitian Creole](#).

- **Video:** Resources For You and Your Baby. Available in [English](#) and [Spanish](#).
- [5 Health Tips College Women Need to Know](#)
- [3 Tips for Safe Medication Use on Campus](#)
- [Hispanic Women's Health: Tips for Healthy Living](#)
- [Caring for Others: Resources to Help You](#)

Center for Biologics Evaluation and Research (CBER):

- <https://www.fda.gov/biologicsbloodvaccines/resourcesforyou/consumers/ucm345587.htm>
- <https://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228.htm>
- <https://www.fda.gov/forconsumers/consumerupdates/ucm048368.htm>
- <https://www.fda.gov/forconsumers/consumerupdates/ucm286155.htm>

Center for Veterinary Medicine (CVM):

- [Get the Facts about Pain Relievers for Pets](#)
- [Keep the Worms Out of Your Pet's Heart! The Facts about Heartworm Disease](#)
- [All About BSE \(Mad Cow Disease\)](#)
- [Get the Facts! Raw Pet Food Diets can be Dangerous to You and Your Pet](#)
- [How Cows Eat Grass](#)

5. Training

a. Has your agency been using the LMS Plain Writing training?

<https://lms.learning.hhs.gov/Saba/Web/Main/goto/GuestOfferingDetails?offeringId=dowbt00000000025313>

Yes, since its release.

b. How do you determine who should take it?

- This training is available to all FDA federal employees and contractors with access to the LMS. A link to the HHS Plain Language Training is featured on inside.FDA's intranet Plain Language Resource Center at: <http://inside.fda.gov:9003/ProgramsInitiatives/Communications/PlainLanguage/default.htm>.
- The Risk Communication Staff uses the HHS Plain Language Training as a prerequisite to their training on the Clear Communications Index.

c. What percentage of employees completed the training?

Though less than 1%, over 100, of FDA's 16,000 employees, have completed the training, we hope to start marketing it more aggressively, as an alternative to in-person training that fills up quickly.

d. What specific feedback have you received from those who already completed the training?

We have received feedback that the training is very helpful and useful information and provides a good foundation on plain language principles.

e. How do you expect to use this training this year?

We plan to advertise the HHS Learning Portal (LMS) Plain Language Training in conjunction with the celebration of the anniversary of the Plain Writing Act in October in a message from the Commissioner, as well as throughout the year.

f. If you do not use the LMS Plain Writing training, please describe, in detail, any plain writing training/programs you did use.

FDA University (FDAU) Plain Language classes:

FDAU has trained over 2,336 FDA employees (580 in 2013, 764 in 2014, 315 in 2015, 442 in 2016, and 235 in 2017) in plain language.

Since March 2017, FDAU has offered 17 two-hour, in-person Plain Language classes for 235 employees with 10 more classes scheduled for the remainder of 2018. FDAU is piloting 19 virtual plain language webinars for field staff in the remainder of 2018.

OC Office of Planning's Risk Communication Staff (RCS) Clear Communication Training:

The Risk Communication Staff trained over 100 employees to use the Clear Communication Index (CCI), with a prerequisite of the LMS HHS Plain Writing Training or other plain language class from the resources listed on the Plain Language Resource Center at insideFDA. The Risk Communication Staff also arranges for specialized training with one of its Special Government Employees. The Risk Communication Staff engaged one of the developers of the Clear Communication Index to serve as a trainer. The Staff then facilitated her providing targeted training for several offices.

Center for Drug Evaluation and Research (CDER) staff members also participated in a session about the Clear Communication Index and worked through examples

of how to implement CCI principles. CDER editors meet monthly to discuss a variety of issues, including ways to continue implementing use of plain language.

The OC Office of Women's Health (OWH) has used both the CDC Clear Communication Index and LMS HHS Plain Writing Training for employees to develop print and electronic materials. OWH encourages all employees who author, edit, or clear FDA documents to receive FDA internal and external plain writing and health literacy training.

The OC Office of the Chief Scientist (OCS) Office of Counterterrorism and Emerging Threats (OCET) uses both the Clear Communication Index and LMS HHS Plain Writing Training.

The Basic Plain Language Skills and Clear Communication Index recorded training through the Risk Communication Staff is scheduled to be released in the LMS in Spring 2018.

Several centers offer their own plain writing training as well. For example:

- Center for Veterinary Medicine (CVM) Talent Development Learning Center Plain Writing Training.
- Center for Biologics Evaluation and Research (CBER) has a robust writing program. The following courses are available to CBER employees:
 - How to Write Effective Comments to Sponsors: A Plain Writing Workshop
 - Clear and Concise E-mail Writing (How to Write & Manage Effective Emails that Get Results)
 - Individual Writing Coaching
 - Practical Grammar and Proofreading Skills
 - Technical Writing for Reviewers
- Center for Food Safety and Applied Nutrition (CFSAN) Staff College offers courses in plain language.
- Center for Drug Evaluation and Research (CDER) Office of Executive Programs (OEP) conducted plain language training for staff.

6. Agency Support, Incentives, and Recognition

- a. **How have senior officials in your agency reinforced the requirements to write documents in plain writing? Has your agency's leadership issued Plain Writing Act-related directives? If no, what is your plan to do so?**

Yes, in commemoration of the seventh anniversary of the signing of the Plain Writing Act of 2010 and Health Literacy Month, the Deputy Commissioner for Policy, Planning, Legislation, and Analysis, Anna Abram, sent an FDA-wide message:

- emphasizing FDA's commitment to increasing its use of clear communication best practices and plain language in communications to the public; and
- encouraging employees to leverage training opportunities and resources at FDA and review the Strategic Plan for Risk Communication and Health Literacy (SPRCHL) released on FDA.gov, and apply its principles to their everyday work.

The SPRCHL emphasizes the importance of clear communications best practices, including plain writing, use of helpful tools such as the Clear Communication Index, and constructing communications for the needs of the target audience. Expected outcomes include increased use of plain language and documents written so that they are understood by audiences with limited proficiency in English or limited health literacy.

- b. **(If applicable): How has your agency updated its website devoted to plain writing over the past year?**

1. Public FDA.gov web page
(<https://www.fda.gov/AboutFDA/PlainLanguage/default.htm>):

Updates include adding:

- New Plain Writing Examples from FDA communications;
- FDA Plain Language Award Recipients to Spotlight section; and
- 2017 FDA Annual Plain Language Compliance Report.

2. inside.FDA's Plain Language Resource Center web page
(<http://inside.fda.gov:9003/ProgramsInitiatives/Communications/PlainLanguage/default.htm>):

Redesigned site with additional resources from Risk Communication Staff including:

1. Plain Language Training
 - Clear Communication Training
 - Digital.Gov Plain Language Video Playlist

- Simon Fraser University Plain Language Certificate

2. Plain Language Tools

- *FDA Plain Language Guide* printable resource, consolidates all the “Plain Language Tips,” “The Plain Writing Act of 2010”, “Plain Language Principles”, and “Federal Plain Language Guidelines”
- [CDC Clear Communication Index Score Sheet](#)
- [Plain Language Web Writing Tips](#)
- FDA CFSAN Clear Information Tool
- NIH Plain-Language Checklist
- Commonly Misused Words
- Watch Your Words
- NIH Making Health Communication Programs Work
- CDC Everyday Words for Public Health Communications

3. Other Plain Language

- Added [FDA Plain Language Award Recipients](#) web page
- New Plain Writing Examples

4. Health Literacy

- Added new resources to Health Literacy section
- Created new Health Literacy Training section

c. Please describe incentives or rewards you provide to employees to encourage the use of plain writing.

- The Plain Language Award is presented at the Office of the Commissioner (OC) Honor Awards Ceremony to formally recognize FDA writers who succeed in making our documents easier to read, i.e. communicating clearly by using the tools and techniques of plain language.

2017 Plain Language Award Recipients:

Office of the Chief Counsel, April L. Finnen, M.B.A., for outstanding and creative contributions to FDA’s public health emergency communications.

Office of the Chief Counsel, OWH Pregnancy Initiative: Resources for You and Your Baby, for outstanding achievement in providing pregnant women with plain language resources on medication and food safety.

Office of External Affairs, Multilingual Health Fraud Pilot, for creating and launching a multilingual communications program pilot around

fraudulent dietary supplements to reach the populations most at-risk for using them.

- The Center for Biologics Evaluation and Research (CBER) presents a Plain Language Award at its annual CBER Honor Awards for significant contribution toward improving administrative, technical, or scientific communications. The award is based on the development of documents that: provide complete and helpful information; have an easy-to-read design and layout, using headings, readable type and white space; and meet the needs of its readers.

d. Do you include plain writing ability in relevant job descriptions (i.e., employees who draft, edit, or clear any document)? Please provide examples.

The language included in position descriptions for writing/written communication varies based on the position and duties to be performed. While the term *plain writing ability* may not be mentioned specifically, certain components of plain writing are included:

- *Skill developing or preparing a variety of documents [examples are typically given] in a clear, concise manner to [enter what the skill will be used to accomplish].*

- Many Center for Biologics Evaluation and Research (CBER) employees have plain language included in their PMAP's:
 1. *".....correspondence is logical, clear, follows plain language guidelines....."*
 2. *"Work products are written at the level of the intended audience (plain language, readability, education level)."*
- OC Office of Information Management and Technology (OIMT) Privacy staff performance plans include a requirement that staff follow plain language guidelines when drafting communications.

e. Do you nominate documents for recognition as recipients of ClearMark Awards by the Center for Plain Language? If so, what documents? If not, why not?

Since nominating documents for the ClearMark Awards also requires the nomination fee, we've submitted a budget request so we may nominate one of FDA's Plain Language Award winners next year. We can also share the Center for Plain Language's ClearMark Awards call for nominations with FDA centers and offices through FDA Employee News announcements, inside FDA's Plain Language Resource Center, and the Risk Communication and Health Literacy Working Group, so they may self-nominate.

7. Please provide any Plain Writing-related best practices used by your OpDiv/StaffDiv to comply with the Plain Writing Act.

- Develop a Plain Writing Act implementation plan.
- Build awareness by posting plain language events in employee-wide e-mails, Web banner features, and digital display.
- Develop a plain language/health literacy workgroup including members from across the agency.
- Develop an e-mail inbox for plain language feedback.
- Include plain language tips in internal center/office newsletters; employee announcements, etc.
- Use the [Federal Plain Language Guidelines](#) as a resource for best practices related to plain writing.
- Establish agency-wide representatives to attend the monthly meetings of the [Plain Language Action and Information Network \(PLAIN\)](#), participate in other PLAIN activities, and become members of the group's listserv.
- Use Clear Communication Index to rate communications and provide advice on improvement.
- Maintain a list of plain writing training, resources, and examples on shared network drives, SharePoint sites, or intranet.
- Start a training program.

8. What support from the Department and or other HHS organizations would be most helpful in continuing to make your plain writing program stronger?

- Hold regular meetings with other agencies' plain language representatives to share best practices.
- Initiate regular correspondence with agency leaders reminding them of the importance of a plain language program and their support. Encourage completion of the HHS Plain Language Training, possibly including it as mandatory training.
- Encourage all agencies to include plain language initiatives and training in budgets.
- Initiate and add plain language statements to position descriptions and performance evaluations at the HHS level and encourage it at the agency level.
- Work with PLAIN to develop a pool of HHS-wide and agency-wide Plain Language Trainers who are federal employees.
- Provide dedicated funds available to OpDivs for nomination fees for ClearMark Awards.
- Incorporate Plain Writing Act compliance and implementation into Reimagine HHS.

9. Other. Please provide any additional comments, suggestions, or materials concerning plain writing.

Please extend survey response time deadline from 2 to 3-4 weeks to allow adequate time to gather complete responses to questions from all centers.