



**Department of Health and Human Services
2022 Plain Writing Act Compliance Report
[Request for Information](#)**

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Background

On October 13, 2010, the Plain Writing Act (Act) was signed into law. The Act requires federal agencies to use “clear Government communication that the public can understand and use.” Communications in plain language are especially important in the context of health care and human services. The Department of Health and Human Services (HHS) recognizes that using plain language can help address the needs of those with limited literacy skills, as well as those with limited health literacy skills. Plain language helps people understand health information because the writing style is clear, concise, organized, and jargon-free. Documents written in plain language are less complex and therefore easier for everyone to understand, including people who have limited literacy skills, limited health literacy skills, or both.

In ongoing application and implementation, the Act requires agencies to “[w]rite annual compliance reports and post these reports on its plain language web page.” You can find links to HHS’s previous ten compliance reports here: <http://www.hhs.gov/open/plain-writing/>

The Department’s Exec Sec is developing our 2022 compliance report to demonstrate our continued compliance with the requirements of the Act. The report includes sections on accomplishments, best practices, innovations, continuous improvements, equity, and HHS contacts overseeing implementation of plain writing requirements.

To help us develop the Report, please provide information from your division by responding to the questions on pages 2-5, below. Please submit your information to the Secretary’s Policy System (SPS) by COB on Friday, March 11, 2022.

If you have any questions, please contact Kathy Applewhite at Kathy.Applewhite@hhs.gov.

[Food and Drug Administration]

Accomplishments

HHS seeks to reach all Americans with useful health information they can easily understand. To accomplish this goal, HHS regularly reviews new and existing reports, documents, and web content for plain writing to ensure the largest impact on the public.

From February 2021 through February 2022, please describe:

- a. The top three plain writing documents your agency published that had the largest impact on the public.*

FDA is organized into eight centers with responsibility for regulating specific product areas, as well as administrative and program offices under the Office of the Commissioner. The FDA has 223 field offices and 13 laboratories throughout the United States, in addition to international locations in China, India, Europe, the Middle East, and Latin America.

FDA's Training and Development Division, FDA University (FDAU), develops and manages innovative FDA-wide training solutions that are aligned with both FDA and HHS strategic human capital goals. FDAU manages the agency's FDA-wide plain writing training program and ensures compliance with the *Plain Writing Act of 2010*.

FDA centers submitted their top publications that had the largest impact on the public below:

Center for Biologics Evaluation and Research (CBER):

The past year continued to be one of unprecedented need for consumer-based communications as the COVID pandemic evolved. CBER met this need with many pandemic-centric documents addressing consumer information needs, as well as those not related to the pandemic:

1. [FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine](#)
2. [Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine](#)
3. [FDA Continues Important Steps to Ensure Quality, Safety and Effectiveness of Authorized COVID-19 Vaccines](#)

Center for Devices and Radiological Health (CDRH):

1. [Antibody \(Serology\) Testing for COVID-19: Information for Patients and Consumers | FDA](#) 2,062,600 page views
2. [UV Lights and Lamps: Ultraviolet-C Radiation, Disinfection, and Coronavirus | FDA](#) 701,388 page views
3. [SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests | FDA](#) 642,912 page views

Center for Tobacco Products (CTP):

CTP's Office of Health Communication and Education (OHCE):

1. [Nicotine Is Why Tobacco Products Are Addictive Web page](#)
2. [Tobacco Education Resource Library](#)

Center for Veterinary Medicine (CVM):

The following three documents were the most visited pages on the CVM Web site from February 2021 through February 2022; however, they were not originally published during this time period:

1. [Preguntas más comunes: El COVID-19 y la Ivermectina prevista para animales](#)—This is the Spanish version of the *FAQ: COVID-19 and Ivermectin Intended for Animal Use*, which discusses the inappropriate use of ivermectin intended for animals to prevent or treat COVID-19 in people.
2. [FAQ: COVID-19 and Ivermectin Intended for Animals](#)—This document explains that ivermectin is not approved to prevent or treat COVID-19 in people and the dangers of people taking animal ivermectin.

3. [Keep the Worms Out of Your Pet’s Heart! The Facts about Heartworm Disease](#)—This consumer-friendly document explains heartworm disease in dogs, cats, and ferrets and how to prevent it.

National Center for Toxicological Research (NCTR’s) primary audience is the scientific community; therefore, its top accomplishments are research publications. For the non-scientific audience, the most impactful and significant plain language documents include:

1. NCTR division one-pagers that describe the research and accomplishments for seven research divisions/office:
 - [NCTR Division of Biochemical Toxicology | FDA](#)
 - [NCTR Division of Bioinformatics and Biostatistics | FDA](#)
 - [NCTR Division of Genetic and Molecular Toxicology | FDA](#)
 - [NCTR Division of Microbiology | FDA](#)
 - [NCTR Division of Neurotoxicology | FDA](#)
 - [NCTR Division of Systems Biology | FDA](#)
 - [NCTR Office of Scientific Coordination | FDA](#)
2. NCTR’s [The 2020 Annual Report](#), issued in 2021, summarizes the key accomplishments for each research division for the reported year, including ongoing research project information, research collaboration highlights, and ongoing initiatives. The document is available to the public and shared internally.
 - b. *The types of documents, and how many of each (estimate is acceptable, please specify) that your agency wrote in plain writing. Please also specify how many of each were new and how many were substantially revised.*

FDA’s nearly 18,000 employees write a range of documents, letters, and Web and social media content for diverse audiences, including consumers, patients, health professionals, industry, scientists and researchers.

Examples include, but are not limited to, guidance documents, regulations, consumer safety alerts and updates, recall notices, warning and advisory letters, press releases, fact sheets, articles, 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 agency.

Specific data from centers and offices from February 2021 to February 2022 includes:

CDRH:

- New documents: Estimated 25 safety communications, 67 recall classification notices, 27 new device approvals, and 58 Web pages
- Revised documents: Estimated 3 updated safety communications and 27 Web pages

CTP effectively reaches various target audiences with its plain language resources through its public education efforts and other informational resources:

New Public Education Campaign Content

CTP developed and produced 11 new advertisements that aired on television and online to prevent youth tobacco use. In addition to seeing the new videos, teens interacted with the campaign social media content and the Web site. The total digital engagement with the campaign during this time was nearly 60 million likes, comments, shares and unique visits to campaign Web sites.

New and Updated Consumer Web pages

- [Health Effects of Tobacco Use](#)
- [Nicotine is Why Tobacco Products Are Addictive](#)
- [How Smoking Affects Heart Health](#)
- [How Smoking Affects Reproductive Health](#)
- [What It's Like to Quit Smoking](#)
- [Quitting Smoking and Other Tobacco Public Health Resources](#)

New Social Media Content

CTP published about 981 Twitter posts, 118 Facebook posts, and 25 LinkedIn posts. CTP created about 167 new shareable images. Twitter engagement rate increased by 18 % in fiscal year 2021.

New Videos

- CTP created a motion-graphic, explainer [video](#) to help the general public better understand the two proposed product standards to prohibit menthol as a characterizing flavor in cigarettes and all characterizing flavors, except tobacco, in cigars.
- CTP is also producing a series of social media clips featuring CTP Director Mitch Zeller speaking on the two proposed product standards to make this information more accessible to the public.
- CTP created an [animated video](#) to encourage people to report tobacco-related health or quality problems to the *HHS Safety Reporting Portal*.
- New [video series](#)—FDA and the American Academy of Pediatrics (AAP) collaborated to develop a video series featuring pediatricians answering common questions about youth e-cigarette use.

CVM writes a range of documents, letters, and Web content for a variety of audiences. Examples include:

- Over 40 [CVM Updates](#)—These updates communicate relevant and timely information on animal health to the public (3 of the CVM Updates are also available in Spanish).
- 6 new or updated Animal Health Literacy articles—These articles provide updates to general consumers, including pet owners and food animal producers:
 1. [Paws Off! Xylitol is Toxic to Dogs](#)—This Web page is also available in 2 different sizes of printer-friendly posters (also in [Spanish](#))
 2. [Need Pet Pets? Protect Yourself and Your Pet—Be Website A.W.A.R.E.](#)—This Web page is also available as a printer-friendly brochure (also in [Spanish](#))
 3. [Snack Safely—Keep Your Pets Safe from Snack Bag Suffocation](#) (also in [Spanish](#))
 4. [Innovation in Animal Drug Development](#)

5. [How to Handle Food Products that Have Been Exposed to Filth](#)
 6. [Adequate Records Help Prevent Illegal Drug Residues and Ensure Food Safety](#)
- 9 new [Science & Research](#) articles—These articles explain the innovative applied research CVM’s Office of Research conducts to protect both human and animal health.
 - 4 Letters to Stakeholders, including food animal producers, veterinarians, retailers, and universities, on various topics.
 - Over 20 Executive Summaries of Freedom of Information Summaries for new animal drug approvals—These summaries are for veterinarians and the animal health industry.

NCTR produces research publications, NCTR annual report, NCTR division one-pagers, annual budget narratives, Congressional documents, such as issue papers, responses to various data calls, Senate and House report language, hearing prep write-ups, and initiative write-ups.

FDA’s Office of Minority Health and Health Equity (OMHHE) develops communications to help diverse communities make informed decisions about their health. During this period, OMHHE developed 12 new fact sheets, 7 new brochures, 14 new infographics, and 2 COVID-19 vaccine confidence videos available in multiple languages. OMHHE also released 116 GovDelivery e-alerts, 2 newsletters, and 256 social media graphics and messages to increase awareness of chronic diseases impacting racial and ethnic minority populations.

c. Examples of documents your agency improved through plain writing.

CDRH incorporated plain language, clear communication, and usability testing principles in redesigned key Web pages, including [Coronavirus \(COVID-19\) and Medical Devices](#) and [At-Home OTC COVID-19 Diagnostic Tests](#), and others below:

- [Philips Respironics CPAP, BiPAP, and Ventilator Recalls: Frequently Asked Questions | FDA](#)
- [Screening for COVID-19: Deciding Which Test to Use When Establishing Testing Programs | FDA](#)
- [Cochlear Implants | FDA](#)
- [Cybersecurity Awareness for Connected Medical Devices - YouTube](#)
- [COVID-19 Tests and Collection Kits Authorized by the FDA: Infographic](#)
- [CDRH 2021 Annual Report](#)
- [Dental Amalgam Infographics](#)

CTP improved many types of communications in plain writing (see those listed in the previous section), including Web pages, e-mail newsletters, videos, social media posts, infographics, factsheets, and more. For example:

- [Nicotine Is Why Tobacco Products Are Addictive Web page](#)-Since many consumers don’t fully understand the role nicotine plays in tobacco, CTP overhauled this Web page into plain language to reach the largest audience possible. The content was also updated to be easily scannable from a mobile device to increase accessibility to the content. CTP is also developing an accompanying fact sheet that will be available in English and Spanish.

- Updated [Tobacco Education Resources for Parents and Teachers | FDA](#)-CTP offers free print resources and Web content on the dangers of tobacco use to maximize the impact of its easy-to-understand materials. The *Exchange Lab* was renamed *Tobacco Education Resource Library* in February 2022 to reflect an accurate description of its contents for readers.

Some recently added print resources to the Tobacco Education Resource Library include:

- National Youth Tobacco Survey 2021 Infographic
- Six Smokeless Tobacco Education Posters
- Health Effects of Smoking Infographic
- Risks of Vaping Student Magazine
- Six LGBTQ+ Tobacco Educational Posters
- Six Multi-Cultural Youth Tobacco Education Posters
- Signs and Symptoms of Vaping Addiction Fact Sheet

CBER: COVID-19 pandemic response and recovery efforts continue to present new challenges for the entire health care community and all levels of government as children return to school and families participate in more activities. CBER continues to make decisions guided by science and the best evidence to carry out its mission during the pandemic. As such, CBER provides ongoing updates to numerous COVID-19 and other health related documents to areas of interest to the public. The material here represents a snapshot of those efforts:

- [FDA Takes Key Action by Approving Second COVID-19 Vaccine](#)
- [FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year-Olds](#)
- [FDA Expands Eligibility for COVID-19 Vaccine Boosters](#)
- [FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age](#)
- [FDA Will Follow The Science On COVID-19 Vaccines For Young Children](#)
- [FDA, NIH, and 15 private organizations join forces to increase effective gene therapies for rare diseases](#)

d. *How your agency updated its website devoted to plain writing, if applicable.*

FDAU manages the agency’s external and internal plain writing Web sites.

Internet Updates

FDA’s public plain writing Web site, [Plain Writing: It's the Law!](#) additions include:

- 2021 Annual Plain Writing Act Compliance Report
- 2021 Plain Language Award Recipients
- New examples in *Plain Writing at Work* section

Center-specific:

CVM updates their article on plain writing [In Plain English, Please](#) on FDA.gov annually.

Intranet Updates:

FDA's internal plain writing Web site [FDA's Plain Language Resource Center](#) additions include the latest compliance report, new trainings, and an article with new graphics for the *Plain Writing Act's* 11th anniversary, new events and announcements. Specific updates include the 2021 FDA *Plain Writing Act* Compliance Report, new *FDAU Plain Language* and *FDAU Technical Writing* training webinars, and the article *11 Ways to Celebrate the Plain Writing Act's 11th Anniversary at FDA*.

New Events/Announcements posted include the *2021 Plain Language Summit* and *DigitalGov* webinars, such as *Results of the 2021 Federal Plain Language Report Card*, *Using Plain Language to Tell Our Stories*, *Positioning Yourself as a Plain Language Editor*, *How Testing Your Documents Can Improve 508 Compliance*, *Plain Language and Section 508* and the 2022 Center for Plain Language *ClearMark Awards* call for nominations.

Center-specific:

Several centers created new or updated plain writing sections on their own Intranet sites:

- Office of Regulatory Affairs (ORA) Communications Toolbox [Plain Language \(sharepoint.com\)](#)- contains an overview on plain language and resources on conveying technical information.
- Center for Food Safety and Nutrition [CFSAN Training and Development Resources - Plain Language \(sharepoint.com\)](#)
- CVM Office of the Director [Plain Language \(sharepoint.com\)](#)
- [NCTR Plain Language Tips \(sharepoint.com\)](#) Web page was enhanced on NCTR's intranet section and includes a link to *FDA's Plain Language Resource Center*.

e. Other relevant accomplishments.

CDRH hosted a Patient Engagement Advisory Committee [public meeting](#) to discuss and make recommendations on *Medical Device Recalls*, which addressed factors for FDA and industry to consider to effectively communicate medical device recall information to patients and the public.

Best Practices

HHS reinforces the plain writing requirements through best practices, such as senior officials promoting plain writing and programs for tracking and measuring plain writing effectiveness.

From February 2021 through February 2022, please describe:

- a. How senior officials in your agency reinforced the plain writing requirements through Plain Writing Act-related directives.*

Senior officials prominently feature FDA's [Strategic Plan for Risk Communication and Health Literacy](#) (SPRCHL) on *FDA.gov*, emphasizing the importance of clear communications best

practices, including plain writing, use of helpful tools such as the CDC Clear Communication Index, and constructing communications for the needs of the target audience. The expected outcome of implementing the plan includes increasing the use of plain language in written documents so that audiences with limited proficiency in English or limited health literacy can understand and use them to meet their needs.

Center for Drug Evaluation and Research (CDER) senior officials support plain language requirements through their participation in plain language communications for the public. For external audiences, senior officials participate in *CDER Conversations*. For internal audiences, the monthly *CDER Connection* newsletter plain language articles update staff on center news and activities.

CTP senior officials emphasize the importance of educating new and existing staff about plain language principles in communicating important regulations, public health information, and the latest science to the public. New SOPs and resources documenting internal workflow for staff reference ensures each new written product meets plain writing requirements. Senior officials also distribute information on upcoming plain language trainings and encourage staff participation.

CVM senior officials select an employee to represent the Center on the [Plain Language Action and Information Network \(PLAIN\)](#), federal government-wide network. The employee attends monthly meetings, participates in other PLAIN activities, and is a member of the group's listserv.

NCTR management encourages its researchers to submit their PowerPoint presentations to the Communications Branch for editorial review before presenting. In fact, the Communications Branch has edited more than 100 presentations during the timeframe indicated. The Communications Branch prioritized updating all their written communications in plain language.

CDER's Strategic Communications plan incorporates plain language as a best practice.

b. How you tracked the conversion of existing documents into plain writing.

Many centers and offices across FDA use the *CDC Clear Communications Index (CCI) Tool* when revising existing documents into plain writing. The CCI Tool is available for FDA-wide use on FDA's intranet *Plain Language Resource Center*, and FDAU promotes its use during the annual *Plain Writing Act* anniversary celebration campaign.

Though all centers may not actively track the conversion of documents to plain writing, many, such as CBER, incorporate plain principles and the CCI Tool in reviews or rewrites due to new content, ensuring that new and existing content adheres to *Plain Writing Act* requirements.

CTP's regulatory and compliance staff write rules, regulations and guidance documents adhering to plain language standards, while ensuring the accuracy of highly technical scientific and legal content. When CTP's communications office prepares to announce regulatory actions, a multidisciplinary team including writers, graphic designers, and social media strategists works on creating a comprehensive suite of plain language products to reach target audiences with resonant, understandable messages.

c. How you measured whether covered documents used plain writing.

FDA centers and offices currently measure covered documents on plain writing principles through various methods, such as:

1. CDC Clear Communications Index (CCI)

FDA's [Strategic Plan for Risk Communication and Health Literacy](#) (SPRCHL) 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](#).

The tool is posted on FDA's intranet *Plain Language Resource Center* for FDA-wide use. Centers may audit their covered documents using the CCI to determine the extent that their covered documents use plain writing. The *FDA Basic Plain Language Skills and Clear Communication Index Training* is available in the HHS Learning Portal (LMS) to encourage the use of the CCI tool. FDAU promotes use of the CCI Tool throughout the year and especially during the annual *Plain Writing Act* Anniversary awareness campaign.

The Center for Food Safety and Nutrition (CFSAN) has a modified *FDA CFSPAN Clear Information Tool* to measure its own documents.

CBER makes the Clear Communication Index available for use to its employees.

2. FDA's Internal and External Message Testing Network

The FDA-wide Message Testing Network enables FDA communicators to test their content and documents for clear communication with other FDA employees who have characteristics in common with message target audiences, as well as with external public audiences.

Some centers have their own message testing programs as well. CTP's Division of Research & Evaluation Message Testing helps develop every public education campaign, starting with formative research to determine which messages may have salience and credibility with youth vulnerable to tobacco use. During the copy testing process, CTP researchers share the ads with a sample of the target audience to determine if they clearly understand the main message, and if that message is relevant and authentic. CTP also designs the research to discover potential unintended consequences that could shift perceptions in the wrong direction. Finally, the team performs comprehensive evaluation research to determine the impact of the campaign.

3. Usability and Message Testing

The www.usability.gov Web site provides free and low-cost resources and services on usability and message testing for improving the user's digital experience.

4. Editing Tools

- Editing software such as *StyleWriter*, *Microsoft Word*, etc., that checks plain writing principles in documents
- FDA’s Plain Language Guide: *Putting it Plainly: Getting Started with Plain Language*
- CDRH updated a Web writing checklist for external communications that incorporates and reinforces plain language principles.
- CTP follows an Editorial Style Guide (developed for English and Spanish content) that ensures consistency in written communications

5. Center Document Clearance Processes

Individual centers may have their own document clearance process to measure whether covered documents use plain language.

- d. How you measured (i) the effectiveness of the plain writing program for your office; and (ii) the effectiveness of your plain writing documents (i.e., whether the public can easily understand and use them.)*

FDAU manages the FDA-wide plain writing program and monitors feedback from the public about the readability and usability of consumer information on the FDA.gov Web site. The questions below on FDA.gov content are posted at FDA’s plain writing Web page at <https://www.fda.gov/about-fda/plain-writing-its-law> and responses are requested through a feedback form or by a reply email to the FDAUniversity@fda.hhs.gov mailbox.

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?*

CDRH:

- Uses Web analytics, including Google analytics, heat maps, and scroll maps of new and revised Web pages, to learn how users interact with plain language content on the pages.
- Uses keyword research to incorporate plain language terms in Web content to improve readability and search engine optimization (SEO).

CVM also uses Google analytics (the number of page visits and the average time-on-page) to measure the popularity of documents; although, a high number of page visits or a long average time-on-page may not necessarily correspond to the level of plain writing in the document.

CTP:

1. CTP public education campaigns, such as *The Real Cost*, have robust resources in OHCE’s Division of Research & Evaluation to dedicate to the best practices of health communication. CTP conducts comprehensive research on the target audiences’ current knowledge, attitudes, and beliefs, and their barriers to taking action before creating campaign content.
2. CTP develops persuasive advertising designed to change the way vulnerable youth think and act toward tobacco use.

3. CTP focuses advertising on the target audience. The Division of Research & Evaluation found that most teens in the U.S. have viewed CTP ads. By tracking the same individuals over time, CTP ensures that its health communications effectively change their attitudes and beliefs about using tobacco products, resulting in decreased tobacco-use prevalence.

e. The obstacles to measuring these aspects of your plain writing program.

CDRH:

- Limited opportunities for direct feedback from audiences.
- Inability to access FDA's customer feedback survey data on FDA.gov. This survey collects user data on FDA's Web pages and the customer experience.

CTP: As mentioned above, CTP's public education campaigns are very well equipped with a Division of Research & Evaluation to test public health messages among the target audience and evaluate how well the messages change tobacco-related knowledge, beliefs, and behaviors. However, CTP faces challenges measuring the plain language program for its regulatory communications, especially with Web content. In this arena, CTP undertakes its best effort possible to measure plain writing by using Google Analytics to track certain statistics, such as page views, unique page views, and average time on page to measure top-performing Web content. CTP also relies on *ForeSee* surveys. In addition, CTP analyzes social media metrics to gain insights into audience reaction to content and conducts an annual survey of e-mail recipients to ensure messages are in plain language.

CVM sites the lack of a formal plain writing program as an obstacle to measuring the effectiveness of its plain writing documents.

f. Other relevant best practices.

1. Develop a *Plain Writing Act* implementation plan;
2. Build awareness by posting plain language events in employee-wide emails, web banner features, and digital poster displays;
3. Develop a plain language/health literacy workgroup with members from across the agency;
4. Develop an email mailbox for plain language feedback;
5. Include plain language tips in internal center/office newsletters, employee announcements, etc.
6. Use the [Federal Plain Language Guidelines](#) as a resource for best practices;
7. 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;
8. Use the *Clear Communication Index* tool to test new communications and update older templates and documents;
9. Conduct an agency-wide audit on covered documents using the *Clear Communication Index*;
10. Maintain a list of plain writing training, resources, and examples on agency's intranet, shared network drives, SharePoint sites, etc.;

11. Develop a training program- (PLAIN training presentation and example templates available at <https://www.plainlanguage.gov/training/create-your-own-class/>);
12. Develop FDA-wide pool of in-house plain language trainers to reduce reliance on external contractors; and
13. Advertise the *Center for Plain Language's* annual call for submissions for the *ClearMark* Plain Language Awards throughout the agency.

Innovations

In the past year, agencies across HHS implemented innovative strategies to promote plain writing, including web banners, webinars, external social media messages, awards, and plain writing skills in position descriptions.

From February 2021 through February 2022, please describe:

- a. Any innovative activities you implemented to promote plain writing.*

FDAU manages an annual communications campaign celebrating the *Plain Writing Act* October anniversary to promote awareness of the *Act* and inform employee of plain writing training and resources on the *Plain Language Resource Center* intranet site. This includes an *insideFDA* intranet homepage Web banner promoting the *Plain Language Resource Center*; an article *11 Ways to Celebrate the Plain Writing Act's 11th Anniversary at FDA* posted to the *insideFDA* homepage, the FDAU homepage and the Office of Operations blog, *FDAU Plain Language* training events, digital posters on FDA campuses, and *FDA Notice* announcements with plain language and health literacy training resources and tips. We also use this as an opportunity to encourage employees to use the *Clear Communication Index* and other tools to check their communications for plain language.

FDAU publicizes plain writing events and conferences throughout the year on the intranet and in *FDA Notice Announcements* to all employees, such as the government-wide *2021 Plain Language Summit* and *DigitalGov* webinars, such as *Results of the 2021 Federal Plain Language Report Card*, *Using Plain Language to Tell Our Stories*, *Positioning Yourself as a Plain Language Editor*, *How Testing Your Documents Can Improve 508 Compliance* and the Center for Plain Language *ClearMark Awards* call for nominations.

Center-specific:

CDRH hired new staff to implement a message testing program within the Center.

Several centers created new plain language internal Web sites on FDA's new SharePoint Online intranet platform.

In February 2022, CVM's plain writing expert and Web managers began developing an internal plain writing web page on *insideFDA* that all CVM employees will be able to access: CVM Office of the Director [Plain Language \(sharepoint.com\)](https://www.sharepoint.com).

b. Incentives or rewards you provided to employees to encourage the use of plain writing.

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

The Office of the Chief Scientist Office of Laboratory Safety (OLS) Safety Manuals Team was the 2021 Award recipient for the collaborative planning, development, and implementation of an Agency-wide Animal Exposure Program Guide.

Center Awards:

The Office of Regulatory Affairs (ORA) Honor Awards Plain Language Award is presented to recognize those employees, individuals or groups, for their significant contribution towards the improvement of existing administrative, technical, or scientific communication enhancing the design and layout of the document while minimizing technical terminology, passive voice, and unclear language

CDRH provides kudos and informal recognition as a first tier of awards, followed by more formal cash and time-off incentive awards. CDRH also nominated several documents for FDA Plain Language awards.

CTP awarded two groups for their efforts in 2021, which included a strong plain writing component. The Office of Compliance and Enforcement received an award for their work on developing a Warning Letter Response webinar, which provided a plain writing overview on the warning letter and response process in clear concise language both verbally during the webinar and on the written slides. The Office of Science received an award for their work on an Effective Deficiency Writing Training Series, aimed at scientific reviewers who write reviews of product applications and covered aspects that will help the public, including regulated industry and stakeholders, to find what they need, understand what they find, and use what they find to meet their needs.

CBER Honor Awards ceremony includes an FDA-Center-Level Honor Plain Language award.

CVM also has a Plain Language Annual Honor Award.

c. Whether you included plain writing skills in relevant job descriptions (i.e., employees who draft, edit, or clear any document). Please provide specific examples.

FDA's Office of Talent Solutions provided examples of plain writing skills included in FDA job descriptions such as:

Employees uses plain language that is free of technical jargon to:

- *develop policies and other guidance that aligns with Federal laws and regulations, Departmental policy, including job opportunity announcements, position descriptions, evaluation statements, job analysis, assessment questionnaires, etc.;*
- *edit or modify existing policies or guidance to ensure compliance;*

- *develop and modify a variety of presentations, charts, tables, executive summaries, briefings, in-house training and other materials for assigned functional specialization;*
- *draft proposed adverse actions or decisions memos, EEO decisions or settlement agreements and take the appropriate actions to clear through the appropriate person/parties within the FDA and HHS;*
- *develop documents to ensure the general public, HHS-wide employees, and FDA stakeholders can understand, interpret, and use the information conveyed to take a particular course of action.*

Center specific:

CDRH Health Communications Specialist job description includes:

- *Serves as CDRH plain language focal point.*
- *Serves as CDRH health literacy focal point.*
- *Works with multidisciplinary teams to create, deliver, and market health information about medical devices using customer-centered and science-based information.*
- *Develops and promotes strategies for obtaining, analyzing, and incorporating the views and needs of health professionals and lay device users into Center communication, policy and decision making.*

CTP Communications Specialist job description includes:

- *Plans and presents information to targeted audiences in the most understandable and easily accessible way, depending on the type of message and material being communicated.*
- *Develops new ways to communicate messages on sensitive or controversial issues where reaction has been negative or indifferent and it is essential for the targeted market to understand if the organization's mission is to be successful.*

CTP Technical Writer-Editor (Web Content Specialist) job description includes:

- *Ensures that information is presented in a logical, clear, and concise manner that can be readily understood by the target audience.*
- *Skill in gathering, analyzing and presenting facts and data in a clear and concise manner using specialized vocabulary that ensures accurate portrayal of CTP/OHCE research programs, policies, and objectives.*
- *Writing and editing health, science, and/or regulatory web content in plain language for a variety of audiences on various CTP Web platforms*

CBER employee Performance Management Appraisal Programs (PMAPs) include:

- *Work products are written at the level of the intended audience (plain language, readability, education level).*

NCTR- The four Communication Branch job descriptions include plain writing and editing requirements. Applicants for Communications Branch positions complete a writing assignment translating highly scientific content into plain language as part of the interview process.

- d. *The documents your agency nominated for recognition as recipients of ClearMark Awards by the Center for Plain Language.*

FDAU shares the *Center for Plain Language's ClearMark Awards* call for nominations with FDA centers and offices through FDA's intranet *Plain Language Resource Center* and *FDA Notices* announcements so centers and offices may self-nominate. Individual centers may also post the announcement on their own Intranet sites. Unfortunately, most centers are unable to participate due to the cost of the nomination fee required for each *ClearMark Awards* submission.

Continuous Improvement

HHS carries out a wide array of training activities to ensure that our employees fully understand the importance of plain writing and how to do it effectively. Many agencies encourage the use of plain language for both internal and external communication. Such agencies also developed trainings and materials to educate stakeholders and the general public on plain writing.

From February 2021 through February 2022, please describe:

- a. *The specific number of your employees completing plain writing training.*

As FDA's Training and Development Division overseeing FDA-wide training, FDAU manages the FDA-wide plain writing training program. FDAU strives to be a learning partner that provides exceptional *competency-based* learning experiences and training services to help customers achieve their professional and or personal goals. FDAU provides FDA employees with the highest quality and most progressive education, training, and consultations to help them achieve high standards of performance.

From February 2021 through February 2022, FDAU offered plain writing training in a variety of formats to meet FDA employees' diverse needs, such as *FDAU Plain Language* virtual webinars, *FDA Basic Plain Language Skills and Clear Communication Index Training* recorded training in LMS, and *FDA Plain Language: an Introduction* online training in LMS.

During this period, FDAU offered 7 new *FDAU Plain Language* virtual webinars with a total 225 registrants. FDAU offered 4 new *FDAU Technical Writing* virtual webinars with 115 registrants. FDAU also promotes several on-demand trainings in the HHS Learning Portal (LMS): *FDA Basic Plain Language Skills and Clear Communication Index Training* recorded training, *FDA Plain Language: an Introduction* online training, as well as the *U.S. Department of Health and Human Services Plain Language Training*. In total, 391 employees completed plain writing training in all formats for this period.

Since 2013, FDAU has trained over 3,377 FDA employees in its *FDAU Plain Language* courses. (580 in 2013; 764 in 2014; 315 in 2015; 442 in 2016; 235 in 2017; 253 in 2018; 266 in 2019; 297 in 2020; and 225 in 2021)

FDA-wide Plain Writing Training

Training	Feb 2021-Feb 2022 # Offerings	Feb 2021-Feb 2022 # Registrants	Cumulative # Registrants since training release
<i>FDAU Plain Language</i>	7 webinars	225	3,377
<i>FDAU Technical Writing</i>	4 webinars	115	115
<i>U.S. Department of Health and Human Services Plain Language Training</i>	(1-hour online session in LMS)	14	173
<i>FDA Basic Plain Language Skills and Clear Communication Index Training</i>	(3-hour recorded session in LMS)	31	117
<i>FDA Plain Language: An Introduction</i>	(2-hour online course in LMS)	6	16
Total		391	3,798

Center-specific:

CDRH New communications staff are informed of the *Plain Writing Act of 2010* that requires federal agencies to use “clear government communication the public can understand and use” and take the following trainings:

- *FDA Plain Language: An Introduction*, 2-hour online course
- *FDA Basic Plain Language Skills and Clear Communication Index Training*, 3-hour recorded session
- *HHS Plain Language Training*, 1-hour session

CDRH communications staff receive updates on Plain Language tips. For additional support and training, staff is informed of the NIH Plain Language page, which includes training and a downloadable resource. Additionally, while CDRH currently does not offer a specific training course on Plain Language, the concept is incorporated in other training courses offered through its Reviewer Certification Program. Between February 2021 and February 2022, CDRH conducted a total of 35 trainings, 300 staff trained, and 634 total completions (which accounts for staff members who took multiple trainings).

CTP-182 employees completed plain language training.

CVM-A total of 375 staff members from various offices across the Center participated in their communication-related trainings.

NCTR's Jefferson Laboratories Fellows Advisory Committee offered *Lunch and Learn* sessions on plain writing and PowerPoint presentation development. FDA's virtual sessions were well advertised across the Center through a center-wide e-mail, featured on the intranet homepage, and were included in *News You Can Use* emails sent to all NCTR staff. The number of employees that completed the training was not monitored.

CBER hosted a total of 268 personnel that attended and completed plain writing training.

The FDA Office of Minority Health and Health Equity (OMHHE) developed and provided *Cultural Competency Training to Improve Health Equity* for FDA employees on strategies to create culturally tailored health education materials and resources for diverse consumers.

b. The feedback you received from those who already completed the training.

FDAU regularly surveys *FDAU Plain Language* attendees to obtain feedback on class content, the instructor's delivery and teaching methods, and the instructional exercises. From February 2021 to February 2022, over 95% of the respondents were satisfied with the overall effectiveness of the course and the instructor.

Comments from *FDAU Plain Language* 2021 evaluations:

1. Learners identified the most helpful aspects of the class including:

- *The instructor provided the general concepts and examples for plain language in addition to the realistic writing example produced from FDA. The way of teaching invited the audience to think the problem together and solve the issue by mutual communication.*
- *Discussion of the basics of structuring a document (purpose for writing, identifying the audience, purpose for reading, what the audience needs to know, and level of knowledge)*
- *It was very accessible, and the examples/instruction were helpful. This was one of the better trainings I have ever taken.*
- *Understanding the definition of plain language and why it's important. Also understanding the audience of different kinds of FDA documents.*

2. Learners identified the least useful aspects of the class including:

- *This training is very useful for everyday work and thankful to take this class. I feel duration of training is quite short and not permits enough time for self or group exercise with the document!*
- *There was a lot to be covered in a short amount of time. I wish there was more time for examples and interactivity*
- *It would be nice to receive the information on the slides as a handout or a copy of the presentation.*
- *seems like maybe we could have had the manuals sent to us prior to the class*

FDAU offered four total *FDAU Technical Writing* courses since the course debut in March 2021. Over 98% of the learners responded that they were satisfied with the course.

Center-specific:

CDRH Examples of Level 1 Evaluation feedback:

- Master Technical Writing: A Plain Writing Workshop - 82% of participants rated the overall course as “very good” or “excellent.”
- Effective Communication Skills for Scientific & Technical Professional - 66% of participants rated the overall course as “very good” or “excellent.”
- Master Four-Party Harmony – 60% of participants rated the overall course as “very good” or “excellent.”

CTP:

- Three Technical Writing courses- average evaluation score 4.57/5
- Two Practical Grammar courses- average evaluation score 4.55/5
- Three Proofreading Skills courses- average evaluation score 4.60/5

CVM Technical Writing and Practical Grammar courses received very strong positive feedback from CVM staff that the courses met their needs. Participants rated content and overall organization favorably for both courses. The top driver of attendance was a belief that the courses would help participants become more effective in their jobs.

CBER surveyed its learners on training and how it contributes to work that supports the center’s mission. The following are some examples of feedback:

- *Excellent instructor!*
- *Exercises and group discussions were very valuable.*
- *All aspects of the course were valuable to my learning including seeing and hearing Dr. Turner, visual aids (slides, handouts), and active participation (ability to ask questions and group exercises).*
- *Most valuable = learning about the language to use to effectively communicate risk. Least valuable = length of time of course, too long*

c. The plain writing training programs you used.

FDAU manages the FDA-wide plain writing training program and offers training in several formats:

- *FDAU Plain Language-* This 2-hour plain writing workshop is designed to assist the learner to write in a clear, concise and well-organized manner appropriate for the intended audience. Such writing avoids jargon, redundancy, ambiguity and obscurity. Experienced instructors encourage class participation in the workshop with hands-on exercises.
- *FDA Basic Plain Language Skills and Clear Communication Index Training-* This 3-hour recorded training features Dr. Cynthia Baur from the CDC who provides an overview of basic plain language skills, tailored to a public health government agency’s needs. She uses relevant examples to illustrate plain language principles and provides a demonstration on using the Clear Communication Index to develop a public health communication.

- *FDA Plain Language: an Introduction*- This 2-hour online course in LMS provides the tools to clearly communicate your message by teaching the basics of plain language-what it is, why we need it, and how to use 7 principles of plain language. The course consists of an overview, a summary, and the following lessons:
 - Lesson 1: Identify Your Primary Audience
 - Lesson 2: Logically Organize Your Content
 - Lesson 3: Short Sentences and Paragraphs
 - Lesson 4: “You” and Other Pronouns
 - Lesson 5: Active vs. Passive Voice
 - Lesson 6: Choosing the Best Words
 - Lesson 7: Testing Your Document and Web Content
- *FDAU Technical Writing*- This 2-hour technical writing seminar teaches a proven system to produce better documents faster. The techniques work for the simplest e-mail to complex technical documents. Through course instruction and group exercises with FDA documents, participants learn how to analyze audience and purpose; ensure the document gets to the point; organize content for the audience; use standard formats for introductions and executive summaries; revise content and organization to catch logical fallacies; edit for coherence, including key words, transition words, and vertical lists; edit for clarity to remove the ambiguity that causes risk; edit for conciseness and readability to meet plain language standards.

The *U.S. Department of Health and Human Services Plain Language Training*, as well as other federal agency and private training is listed on FDA’s *Plain Language Resource Center* intranet site such as:

- [Plainlanguage.gov Online Training](http://Plainlanguage.gov)
- [NIH Plain Language: Getting Started or Brushing Up](#)
- [DigitalGov Plain Language Video Playlist](#)
- [Simon Fraser University Plain Language Certificate \(Fee\)](#)

Center-specific:

CDRH Provided training and support for writing clear and plain messages to staff members responsible for writing external communications. Plain writing techniques are covered in five courses as part of the Reviewer Certification Program:

Core Coursework:

- Basics of Four-Part Harmony in Lead and Consult Reviews (1.0)
- Basics of Writing Consult Request and Consult Reviews (1.0)

Advanced Coursework:

- Master Technical Writing (7.0)
- Master Four-Part Harmony (4.0)
- Effective Communication Skills for Technical/Scientific Personnel (6.0)

In the CDRH plain writing courses, there is a total of 19.0 hours of training in the areas of

communication, four-part harmony, plain writing, and technical writing.

CDRH also offers one Technical Writing Skills course (14.0 hours), including plain writing skills, Center-wide without restrictions.

CTP refers employees to FDAU for plain writing training. While CTP hasn't offered its own plain language training since 2015, they do offer Technical Writing, Practical Grammar and Proofreading Skills courses. Specifically:

- The Technical Writing course aligns with the 2011 Federal Plain Language Guidelines. It provides instruction and leads exercises on techniques for analysis, writing, and editing that reinforce the principles in these guidelines.
- The Practical Grammar Review and Proofreading Skills courses do not focus on plain language specifically but include techniques that align with plain language principles, such as techniques to simplify grammar for clarity and conciseness.

In CVM's plain writing trainings, participants review the *Plain Writing Act of 2010* and discuss how to write using the *Federal Plain Language Guidelines*. Participants also practiced plain writing in sample documents. CVM also encourages its staff to attend plain writing training through FDAU.

CBER continues to have a robust writing program for its employees. Besides the LMS Plain Writing training, the following courses were available to CBER employees:

- *How to Write Clear and Concise Reviews: A Plain Writing Workshop*
- *Individual Writing Coaching*
- *Clear and Concise Email Writing*
- *Practical Grammar and Proofreading Skills*
- *Technical Writing for Reviewers*
- *Introduction to Risk Communications for Biologics*

d. Examples of trainings and materials you developed to educate stakeholders and the general public on plain writing.

FDA's plain writing Web site [Plain Writing: It's the Law! | FDA](#) describes the *Plain Writing Act of 2010* requirements, provides the *Federal Plain Language Guidelines*, summarizes plain language principles and the benefits of using plain language. It also provides plain language usage tips and Web writing tips for the general public and other stakeholders.

CVM has an article [In Plain English, Please](#) on the importance of plain writing on its external Web site for the general public and all stakeholders.

e. Ways in which you improved or focused your plain writing efforts.

During the pandemic, FDAU successfully transitioned its FDA-wide in-person *FDAU Plain Language* classes to virtual Adobe Connect and Zoom webinars. FDAU emphasized more on-demand training options and publicized *Digital.gov* webinar events on the *Plain Language*

Resource Center intranet and *FDA Announcements*. FDAU continued to offer new *FDAU Technical Writing* courses as well. As the pandemic eases and the federal workforce begins to return onsite, FDAU is exploring options to transition to a hybrid training environment in the future.

Center-specific

CDRH *Master Technical Writing* participants receive a training workbook and course slides with tips on plain writing, technical writing and proofreading for reference. Additionally, participants may contact the instructor directly to engage in individualized sessions to practice and improve their writing skills. Practice activities and exercises are also made available digitally to participants of the *Master Four-Part Harmony* course.

CTP focused on revising its external Web pages to improve the plain language readability and accessibility for the public on the topics on quitting smoking and smoking health effects.

CVM shares plain writing tips in its monthly *CVM News* for employees, and plain writing materials and resources will now be available on CVM's new plain writing Web page on the *insideFDA* intranet.

CBER focused on improving its plain language training by increasing interactivity within the training events and providing post-training reference resources. Instructors added more hands-on exercises, check point evaluations, and quizzes to reenforce learning objectives and ensure a successful transfer of knowledge.

Equity

The President issued Executive Order (EO)13985 on *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* on January 20, 2021.

The term “equity” provided in EO 13985 means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. EO 13985 further provides that the term “underserved communities” refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of “equity.”

Promoting equity is essential to the Department’s mission of protecting the health of Americans and providing essential human services.

From February 2021 through February 2022, please describe:

- a. *How your agency used plain writing to promote equity in your agency's policies, programs, and activities.*

In 2021, the FDA Office of Minority Health and Health Equity (OMHHE) launched the [Enhance Equity Initiative](#) that supports research projects and highlights communication resources to enhance:

[EQUITY in clinicals](#) trials by supporting efforts to advance diversity in clinical trials.

[EQUITABLE data efforts](#) by increasing data available on diverse groups.

[EQUITY of voices](#) by amplifying the FDA's communication with diverse groups and to ensure stakeholders, including consumers, are informed about the FDA's efforts and to understand diverse patient perspectives, preferences, and unmet needs.

The OMHHE developed several resources for racial and ethnic minorities and tribal communities available in different formats including print and digital fact sheets, brochures, infographics, videos, and social media messages in multiple languages.

Center specific:

[CDRH](#) uses plain language and inclusive language and incorporates 508 compliance standards in all internal and external communication. Whenever possible, they collaborate with third-party disseminators, such as patient advocacy groups, physicians' societies, and FDA field staff who work for and in communities around the United States, to help its messages reach underserved populations and patient communities.

[CTP](#) greatly revised its public health Web content regarding health and gender. CTP decreased binary language where it did not serve a public health purpose, including incorporating a men's health Web page and a women's health Web page, and creating a brand new [How Smoking Affects Reproductive Health](#) Web page. The language on this page is much more inclusive of the LGBTQ+ communities.

FDA is developing a tobacco prevention campaign designed to reach American Indian and Alaska Native (AI/AN) youth, ages 13-17, who are at-risk for using e-cigarettes. The native youth population demonstrates higher tobacco susceptibility and tobacco use than their non-native peers, and a tendency toward earlier initiation. Based on formative research, there are roughly 400,000 native teens in the United States who are aged 13-17, and more than half of them are at-risk for tobacco use. The campaign is tentatively scheduled to launch in May 2022.

Also, as part of the agency's ongoing efforts to reduce the enormous public health burden of tobacco use, FDA will release new smoking cessation education posters. The posters use a positive, motivational tone to support adult smokers on their journey to quit for good, while underscoring the health benefits of quitting cigarettes. The posters will be available in English and Spanish and are tailored for diverse audiences, including LGBTQ+ smokers, and will be available for stakeholders for free in *FDA's Tobacco Education Resource Library*. The posters send people to *EveryTryCounts.gov* - developed in collaboration with the National Cancer Institute (NCI) and in consultation with a relevant dissemination partner, - they feature quitting tips, cessation text

messaging programs, and online cessation counseling. The site will be available in English and Spanish.

CTP updated its editorial style guide per updates to Associated Press style. CTP now prefers more gender-neutral language, such as “spokesperson” or “representative” rather than “spokesman” or “spokeswoman.” CTP also improved its language about ethnicity and race in this year’s editorial guide.

CVM has a long-standing commitment to diversity, equity, and inclusion to harness the power of diversity of thought, background, and experience that is essential for the organization's ability to innovate and maintain high performance. In support of this commitment, CVM offers a robust diversity and inclusion curriculum that includes six high-quality courses aimed at defining diversity, and how to leverage diversity to create a more dynamic and inclusive workplace.

Additionally, as part of CVM’s diversity, equity, and inclusion initiative, all staff complete unconscious bias training to help identify potential blind spots, as well as a harassment prevention training to raise awareness.

In these trainings, participants discuss the importance of inclusive language and ways to incorporate this language in documents in accordance with the *Federal Plain Language Guidelines*.

Some CVM stakeholders have limited proficiency in English, and therefore, may have difficulty reading and understanding Web site content. CVM continues to expand its Spanish outreach program by translating selected Web site content into Spanish for pet owners, animal producers, veterinarians, and other groups in the animal health industry. From February 2021 through February 2022, CVM posted 21 new Spanish documents, updated three Spanish documents, and posted two new Portuguese documents, with many more to come in 2022.

NCTR encouraged its staff to attend Diversity, Equity, and Inclusion and Compassionate Inclusion training offered in April 2021. NCTR established a *Faces of NCTR* section on *insideFDA* that features interviews/Q’s & A’s with NCTR staff representing “underserved communities” as described above.

CBER:

- New CBER Diversity, Equity, Inclusion, and Accessibility (DEIA) Web page with CBER specific information as well as links to FDA’s EEO and DEIA Web sites.
- Expanded communication surrounding Heritage Months and events to CBER workforce from the CBER Center Director.
- CBER works with the FDA’s Office of Minority Health and Health Equity to develop materials that promote equity and access to CBER-regulated products. This is especially critical throughout the ongoing pandemic with the crucial need for its information to be available to all consumers.
- CBER continues to translate its materials to about 30 languages. CBER also has multiple foreign language translator volunteers willing to assist with about seven different languages.

Contacts

The Act requires each department to designate one or more senior officials to oversee implementation of plain writing requirements. A list of such HHS agency officials can be found on the HHS website here: <https://www.hhs.gov/open/plain-writing/>

Please confirm the senior official in your Operating or Staff Division responsible for plain writing.

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Note: We will include the name and e-mail address of this person on the Department's plain writing webpage.