



**Department of Health and Human Services  
2021 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 eight compliance reports here: <http://www.hhs.gov/open/plain-writing/>

The Department’s Exec Sec is developing its 2021 compliance report to demonstrate its continued compliance with the requirements of the Act. The report includes sections on accomplishments, best practices, innovations, continuous improvements, and HHS contacts overseeing implementation of plain writing requirements. This year, the Department is adding a new section on “new initiative for 2021” to highlight how the Department plans to use plain writing to promote equity in policies, programs, and activities.

To help develop the Report, please provide information from your division by responding to the questions on pages 2-5, below. Please submit your information to Stephanie Socgfack by 5pm Tuesday, March 23, 2021.

If you have any questions, please contact Stephanie Socgfack at [Stephanie.Socgfack@fda.hhs.gov](mailto:Stephanie.Socgfack@fda.hhs.gov).

**[Food and Drug Administration (FDA)]**

**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 March 2020 through March 2021, please describe:*

- a. *The top three plain writing documents your agency published that had the largest impact on the public.*
- 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.*
- c. *Examples of documents your agency improved through plain writing.*
- d. *How your agency updated its website devoted to plain writing, if applicable.*
- e. *Other relevant accomplishments.*

*[Enter your descriptions in paragraph format, here]*

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

From March 2020 through March 2021, FDA produced many consumer-based communications to the public in plain language addressing several different public health priorities during the COVID-19 pandemic.

Center for Biologics Evaluation and Research (CBER):

These top three reflect some of the most significant topics:

1. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine
2. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine
3. FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine

Additional CBER documents include:

- FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID-19 Treatment, Another Achievement in Administration's Fight Against Pandemic
- Coronavirus (COVID-19) Update: FDA Encourages Recovered Patients to Donate Plasma for Development of Blood-Related Therapies
- Coronavirus (COVID-19) Update: FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic
- Consumer Alert on Regenerative Medicine Products Including Stem Cells and Exosomes
- Potential Risks of Treatment with Unapproved Regenerative Medicine Products
- Vaccine Development – 101
- Emergency Use Authorization for Vaccines Explained

Center for Devices and Radiological Health (CDRH):

- N95 Respirators, Surgical Masks, and Face Masks: 11.8 million pageviews
- Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers: 715,000 pageviews

- [UV Lights and Lamps: Ultraviolet-C Radiation, Disinfection, and Coronavirus: 366,220 pageviews](#)

#### Center for Veterinary Medicine (CVM)

- [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 discussed the inappropriate use of ivermectin intended for animals to treat or prevent COVID-19 in people.)
- [FDA Alert: Certain Lots of Pet Food from Multiple Brands Recalled for Aflatoxin](#)
- [FDA Alert: Certain Lots of Sportmix Pet Food Recalled for Potentially Fatal Levels of Aflatoxin](#)  
(The 2 Alerts above discussed recalls of various pet food products because they contained toxins produced by a mold that can grow on pet food ingredients, such as corn, peanuts, and other grains. At high levels, the toxins can cause illness, liver damage, and death in pets.)

#### Center for Tobacco Products (CTP):

Three standout examples from CTP’s Office of Health Communication and Education (OHCE) are:

1. Blogs, videos, student magazine and contest, digital and in-person lesson plans, fact sheets, and posters, developed in collaboration with Scholastic, to increase awareness of youth e-cigarette prevention

FDA continues to work with Scholastic to develop [youth e-cigarette prevention materials for middle and high school students](#). A student magazine and an accompanying teacher guide educate students about the risks of e-cigarette use and nicotine addiction. Additional Scholastic materials include lesson plans, activity sheets, a guide for parents to talk to kids about e-cigarettes, and infographics. These materials are accessible online for free and are adaptable for remote instruction or independent student work.

Scholastic also launched The [“Vaping’s Not My Thing” Student Challenge](#). Students created posters that convinced teens not to vape because of the health risks.

Kathy Crosby, Director of the Office of Health Communication and Education (OHCE) at FDA’s Center for Tobacco Products, authored a [blog](#) that advises parents and teachers to be on the lookout for disposable and stealth e-cigarettes, some of which can be disguised as backpacks, smartwatches, or gaming devices. Kathy Crosby also published a second [blog](#) explaining the latest trends in youth e-cigarette use from the National Youth Tobacco Survey.

2. New web feature and infographic with tips for safe disposal of nicotine hazardous waste

CTP continually works on updating its website and is always mindful of making the

content as clear and easy to understand as possible. CTP also creates engaging, plain language content to directly answer the information needs of its key audiences and public health stakeholders. As a result of receiving many questions and requests from school teachers and administrators for guidance on the safe storage and disposal of e-cigarette waste that they confiscate from students, CTP published the [Tips for Safe Disposal of E-Cigarettes and E-Liquid Waste](#) web feature article and infographic. People can order free copies of the print infographic in English and Spanish. CTP also engaged in a yearlong paid social media campaign to raise awareness of this issue among consumers, parents and educators, and to drive increased traffic to the website.

### 3. *CTP Connect Newsletter*

CTP's monthly *CTP Connect* email newsletter uses clear terminology to summarize recent CTP actions to protect public health. For example, the [February 2021 issue](#) contains very short descriptions to communicate highlights, with links to longer-form stories on the web that are also written in plain language. For those interested in additional detail on a topic, links direct readers to further information.

CTP maintains a list of 41,000 unique subscribers who have signed up to receive *CTP Connect* or other documents such as the *Spotlight on Science* newsletter for a target audience of researchers and *CTP News* with regulatory announcements for industry and others.

*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 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 across the United States, in addition to international locations in China, India, Europe, the Middle East, and Latin America. 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, and 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 March 2020 to March 2021 includes:

CDRH:

- **New documents:** Estimated 11 safety communications, 29 recall notices, 57 new device approvals, 25 web pages
- **Revised documents:** 1 updated safety communication, 20 web pages

CTP effectively reaches various target audiences with its plain language resources through its public education efforts and other informational resources. These efforts progressed greatly in the March 2020–March 2021 time frame, and below are some examples of new documents along with associated numbers.

**1. *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 website. The total digital engagement with the campaign during this time was nearly 60 million likes, comments, shares and unique visits to campaign websites.

**2. *New Scholastic Resources***

In a collaboration with Scholastic, CTP recently developed clearly, simply written new resources designed to help educate 12- to 18-year-olds through youth e-cigarette prevention efforts. New materials include five innovative videos, two new lesson plans for middle- and high-school teachers, two new worksheets, a teacher guide, a student magazine, a student contest, and two new blogs. In addition, during this time period, CTP translated all the educational materials into Spanish.

**3. *New Exchange Lab Resources***

To maximize the impact of its easy-to-understand materials, CTP offers free print resources and web content on its [Exchange Lab](#) to communicate the dangers of tobacco use. From March 2020–March 2021, CTP disseminated about 75,678 print materials through the Exchange Lab and conferences and events. CTP also disseminated 1,348 digital calendars to military bases to help tobacco retailers calculate if customers are of the legal age to buy tobacco products.

**4. *New Exchange Lab Print Materials***

Some recently added print resources to the Exchange Lab include:

- Vaping Misperceptions Infographics ([English](#) and [Spanish](#))
- [Minimum Legal Age Stickers for Tobacco Retailers](#)
- [Minimum Legal Age Poster for Tobacco Retailers](#)
- National Youth Tobacco Survey 2020 Infographic ([English](#) and [Spanish](#))
- [Tips for the Safe Disposal of E-Cigarettes and E-Liquid Waste Infographic](#)
- Spanish Language Posters about Chemicals in Vaping ([Nickel](#), [Nicotine](#), [Chromium](#), [Formaldehyde](#), [Lead](#))
- Spanish Youth E-Cigarette Prevention ([1](#), [2](#))
- [Tips for Safe E-Cigarette and Nicotine Disposal Fact Sheet](#)

**5. *New Social Media Content***

CTP published about 774 Twitter posts, 105 Facebook posts, and 9 LinkedIn posts from March 2020 to March 2021. CTP created about 250 new shareable images. Twitter engagements increased by 47% in fiscal year 2020.

## 6. *New Videos*

- CTP created two new innovative animated videos: one on how to report tobacco product problems to the Safety Reporting Portal and another about the new virtual exhibit booth on CTP’s Exchange Lab.
- In addition, CTP created three new video interviews with leading pediatricians that answer common questions about vaping addiction among youth.

## 7. *New Web Feature Articles*

Feature stories are another format for communicating information in clear, concise language. These are examples of completely new content from a wide range of feature stories explaining regulatory, compliance, and science actions taken by CTP toward reducing death and disease from tobacco products. (A “[Feature Stories](#)” webpage provides a more comprehensive view of all recent articles.)

- [Get the Latest Facts on Teen Tobacco Use](#)
- [Tips for Safe Disposal of E-Cigarettes and E-Liquid Waste](#)
- [CTP’s Exchange Lab Offers Free Tobacco Education Materials](#)
- [CTP Expands Hiring To Meet Regulatory Goals](#)
- [Q&A with CTP’s Director of Communications](#)

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

- Over 60 [CVM Updates](#) to communicate relevant and timely information about FDA and animal health to the public.
- 2 FDA Alerts listed above in (a)
- 3 Animal Health Literacy Articles to communicate to general consumers, mainly pet owners.
  - [Aflatoxin Poisoning in Pets](#)
  - [Save Your Pet Food Lot Number!](#)
  - [Who Do You Call If You Have A Pet Emergency?](#)
- 2 FDA Letters to Stakeholders
  - [Do Not Use Chloroquine Phosphate Intended for Fish as Treatment for COVID-19 in Humans](#) (also in [Spanish](#))
  - [Do Not Use Ivermectin Intended for Animals as Treatment for COVID-19 in Humans](#) (also in [Spanish](#))
- [1 FAQ: COVID-19 and Ivermectin Intended for Animal Use](#) (also in [Spanish](#))
- 1 New Webpage—[Animal Drugs @ FDA Explained](#)



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

Examples of documents FDA centers improved through plain writing during this time period include:

CBER: The COVID-19 pandemic presented new challenges for the entire health care community and all levels of government, including CBER. To carry out its mission during the pandemic, CBER continued to make decisions guided by science and the best evidence, even when the complete safety and efficacy information of a given product may not yet be known or available at the time. CBER also continued to revise its policies based on the rapidly evolving data on this previously unknown, highly contagious virus. CBER continually updates numerous documents related to COVID-19. For example:

- [Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions](#)

CDRH:

- [N95 Respirators, Surgical Masks, and Face Masks](#)
- [Dental Amalgam Fillings and Infographic](#)
- [Automated External Defibrillators \(AEDs\)](#)
- [CDRH's Response to COVID-19 Infographic](#)

Center for Devices Evaluation & Research (CDER)'s Office of Communications (OCOMM) made plain language improvements by redesigning [Drug Safety Communications \(DSC\)s](#) in a more reader-friendly format based on research. OCOMM also routinely translates DSCs to Spanish, which outlines information for patients, consumers, and health care professionals on new drug warnings, drug label changes and other safety information.

During 2020, CTP vastly improved the plain language content on its [Safety Reporting Portal](#) for consumer reports of problems with tobacco products. This includes web pages and evergreen social media content informing consumers how to report safety problems, such as e-cigarette explosions, accidental nicotine poisonings of kids, and burns or seizures. CTP created a very engaging [social media animated video](#) to improve consumer reporting. CTP also promoted the portal through paid social media advertisements.

CVM:

- [CVM eSubmitter Programs](#)
- [CVM eSubmitter Resource Center](#)
- [Approved Animal Drug Products \(Green Book\)](#)
- [Animal Drug Shortage Information](#)



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

**FDA.gov Plain Writing: It's the Law!** updates:

- 2020 Annual Plain Writing Act Compliance Report
- 2020 Plain Language Award Recipients
- Updated examples in *Plain Writing at Work* section

**FDA Plain Language Resource Center intranet** updates:

Compliance:

- 2020 FDA *Plain Writing Act* Compliance Report

Training:

- New *FDAU Plain Language* in-person and webinar offerings
- New *FDAU Technical Writing* webinars

Events:

1. Plain Language Summit 2020
2. Access for All: Plain Language is a Civil Right Virtual Conference 2020
3. Plain Language and Section 508
4. Virtual Teaching: Plain Language
5. Plain Language Basics: Online Workshop
6. 2020 ClearMark Plain Language Awards Nomination link

CTP: Due to the COVID-19 pandemic and the subsequent transition to virtual conference platforms, CTP recently launched a [virtual exhibit booth](#), which features an innovative new video and provides visitors an opportunity to explore [CTP resources on the Exchange Lab](#). This virtual platform provides a “site within a site” series of carefully curated and tailored landing pages (with a unique URL) designed for several of CTP’s targeted stakeholder audiences - public health practitioners, health care providers, school nurses, educators, and tobacco retailers.

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

e. *Other relevant accomplishments.*

CDRH:

- Conducted a virtual public meeting on [FDA's Communications About the Safety of Medical Devices](#), which included moderated discussions and recommendations about plain language in safety communications.
- Updated communication templates for safety communications, *Letters to Health Care Providers*, as well as email templates, to incorporate plain language best practices.
- Developed a web writing checklist for external communications that incorporates and reinforces plain language principles.
- Incorporated plain language, clear communication, and UX principles in redesigning key webpages, including navigation pages, for Medical Devices and Radiological Health

content.

- Provided training and support for writing clear and plain messages to staff members responsible for writing external communication.
- Shared for public comment a new discussion paper, *Communicating Cybersecurity Vulnerabilities to Patients: Considerations for a Framework*, to provide best practices to consider when communicating with patients and caregivers about cybersecurity vulnerabilities, which included plain language principles.

CTP successfully created an innovative mini communications campaign – including a branded web, email marketing and social media – to inform affected parties about the incredibly nuanced process of submitting a premarket tobacco application to FDA by a court-ordered deadline of Sept. 9, 2020. The effort, known as “FDA Tobacco Application Tips,” quickly delivered comprehensive information, specific and targeted tips, and helpful resources to stakeholders trying to meet the deadline. This included rapidly evolving circumstances, such as a late August court decision changing the requirements at hand for manufacturers of premium cigars and final decisions on matters such as extensions. CTP posted 101 social media messages with tips, resources, or reminders across 3 social media channels and initial results demonstrate great success as the social message alone resulted in over 571,000 views, 1,000 engagements (likes, shares, and comments) and over 1,300 link clicks.

### **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 March 2020 through March 2021, please describe:*

- a. How senior officials in your agency reinforced the plain writing requirements through Plain Writing Act-related directives.*
- b. How you tracked the conversion of existing documents into plain writing.*
- c. How you measured whether covered documents used plain writing.*
- 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.)*
- e. The obstacles to measuring these aspects of your plain writing program.*
- f. Other relevant best practices.*

*[Enter your descriptions in paragraph format, here]*

- 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 (CCI), and constructing communications for the needs of the target audience. The expected outcomes 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.

CDER senior officials support plain language requirements through their participation in plain language documents aimed at the public. For external audiences, this includes their participation in *CDER Conversations*. For internal audiences, CDER follows plain language best practices through the monthly publication *CDER Connection* newsletter for staff. This newsletter's articles provide updates on center news and activities in plain language.

CTP senior officials reinforced the plain writing requirements by setting a goal for the 2021 calendar year to update the CTP editorial style guide and create an internal communications plan to educate new and existing staff about incorporating plain language principles to communicate important regulations, public health information, and the latest science to the public.

CVM senior officials reinforced the plain writing requirements with representation by a center employee on the government-wide [Plain Language Action and Information Network \(PLAIN\)](#). The employee attends monthly meetings, participates in other PLAIN activities, and is a member of the group's listserv.

*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 reviewing existing documents as part of their conversion process into plain writing. The CCI Tool is available for FDA-wide use on FDA's intranet *Plain Language Resource Center* and we promote its use during the annual *Plain Writing Act* anniversary celebration campaign.

Though all centers may not actively track conversion of documents to plain language, many, such as CBER, incorporate plain writing principles and the CCI Tool in reviews or rewrites due to new content.

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 of writers, graphic designers, and social media strategists works on creating a comprehensive suite of plain language products to reach its target audiences with resonant, understandable messages.

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

FDA centers and offices currently test communications 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. *FDA Basic Plain Language Skills and Clear Communication Index Training* is available in LMS to encourage the use of the CCI tool. FDA 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 CFSAN Clear Information Tool* for its own documents.

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. For example, CTP does comprehensive research on the target audience. Before creating campaign content, CTP researches the target audience's current knowledge, attitudes, and beliefs, to identify their barriers to taking action. Second, CTP develops persuasive advertising designed to change the way vulnerable youth think and act toward tobacco use. Third, CTP laser targets its audience through advertising in their market. The Division of Research and Evaluation has found that most teens in the U.S. see CTP ads. By following this same group over time, CTP can measure their impact on changed attitudes and beliefs for tobacco products use by tracking reduced prevalence in their age group.

## 2. FDA's Internal and External Message Testing Network

The Network 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.

## 3. DigitalGov Usability and Message Testing

GSA's Digital.gov website provides free and low-cost resources and services for improving the user's digital experience

## 4. Editing Tools

- Editing software such as *StyleWriter*, *Microsoft Word*, etc., that check plain writing principles in documents
- FDA's Plain Language Guide: *Putting it Plainly-Getting Started with Plain Language at FDA*

## 5.Center Document Clearance Processes

- For example, the ORA Communications Toolbox contains plain language overview and resources on conveying technical information

*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.)*

FDA requests feedback from the public about FDA letters, reports, and information on its plain writing webpage at <https://www.fda.gov/about-fda/plain-writing-its-law> by a reply email to [FDAUniversity@fda.hhs.gov](mailto:FDAUniversity@fda.hhs.gov) or through a feedback form asking the questions:

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?*

CBER's Consumer Affairs Branch (CAB) handles all consumer contact and identifies any posted information that is not clearly understood. CAB members then work with the consumer until all concerns are addressed.

CDRH uses:

- Web analytics, particularly heat maps and scroll maps of new and revised pages, to learn how users interacted with and reacted to plain language content on the pages.
- Keyword research to incorporate plain language terms in web content to improve readability as well as search engine performance.

CTP's Division of Research and Evaluation helps develop every public education campaign, starting with formative research to determine which messages might have 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 on the campaign's potential impact.

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

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

- 1) The size of the agency; the distribution of employees throughout the United States in field offices and laboratories, and in other countries;
- 2) The volume and variety of content written by FDA employees;
- 3) Lack of a budget allocated to plain language and health literacy;
- 4) Lack of staff assigned to implement plain language, plain writing, and health literacy;

- 5) The need for HHS-level support on issues such as compliance related to position descriptions, performance evaluations, and budget allocation; and
- 6) Message testing is not always feasible, especially with emerging public health threat situations, where rapid communication is key.

Center-specific obstacles include:

CDRH:

1. Limited opportunities for direct feedback from audiences.
2. Lack of funding and staffing for message testing and other related testing, such as usability testing.
3. 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's Division of Research and Evaluation tests public health messages among their target audiences and evaluates how well the messages change tobacco-related knowledge, beliefs, and behaviors for its public education campaigns. 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 its audience reaction to its content and conducts an annual survey of email recipients to ensure its plain language messages are understood.

CVM:

The lack of a formal plain writing program at CVM is 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 including 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 related to plain writing;
- 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* tool;
- 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/>); and
- 12) Plans to develop FDA-wide pool of in-house plain language trainers to reduce reliance on external contractors.

Center-specific best practices include:

CVM's plain writing expert shares a monthly tip for plain writing in the Center's "CVM News," which is emailed to all staff.

## **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 March 2020 through March 2021, please describe:*

- a. *Any innovative activities you implemented to promote plain writing.*
- b. *Incentives or rewards you provided to employees to encourage the use of plain writing.*
- 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.*
- d. *The documents your agency nominated for recognition as recipients of ClearMark Awards by the Center for Plain Language.*

*[Enter your descriptions in paragraph format, here]*

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

FDA celebrates the *Plain Writing Act* anniversary annually in October with a communications campaign that includes: FDA intranet homepage web banner promoting plain language and health literacy awareness and training resources; Office of Operations (OO) blog *10 Ways to Celebrate Plain Writing Act Anniversary in October*, digital posters, 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. We publicize plain writing events and conferences throughout the year on FDA's intranet and in *FDA Notice Announcements* to all employees, such as the government-wide *Plain Language Summit 2020*, *Access for All: Plain Language is a Civil Right Virtual Conference*



2020, and DigitalGov webinars, such as *Plain Language and Section 508*, and the Center for Plain Language *ClearMark Awards* call for nominations.

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

**The Office of the Commissioner (OC) 2020 FDA Plain Language Award**

*The Plain Language Award recognizes FDA writers who succeed in making our documents easier to read, i.e., communicating clearly by using the tools and techniques of Plain Language.*

**Office of the Chief Scientist**

**Office of Laboratory Safety (OLS) Safety Manuals Team**

*For the collaborative planning, development, and implementation of an Agency-wide Animal Exposure Program Guide.*

**Center for Drug Evaluation and Research (CDER) 2020 FDA Plain Language Award**

**Biosimilar Basics Team**

*For excellence in communicating complex concepts about biosimilarity into an easy-to-read infographic and website with basic information for patients.*

**Office of Regulatory Affairs (ORA) 2020 Plain Language Award**

*This honor 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, hard-to-follow language.*

**ORA Office of Training Education and Development (OTED)**

**Training Officer Handbook Implementation Team**

*For creating a user-focused handbook completely explaining how training officers coordinate the delivery of instructor-led training.*

**Center for Veterinary Medicine (CVM) 2021 Plain Language Award**

Stuart C. Jeffrey, DVM, MS

CTP's Office of Compliance Enforcement gave a group award to members of its Division of Promotion, Advertising, and Labeling (DPAL) for developing template language for letters to industry informing applicants of deficiencies in their applications. The team created letter-ready comments to make reviews of tobacco products more efficient and ensure consistency within the application reviews. These activities enabled CTP to support the protection of public health by ensuring that tobacco product labeling and advertising are not false or misleading.

CBER routinely recognizes communication skills at the CBER Honor Awards ceremony. There is an FDA-Center-Level Honor award that recognizes Plain Language that is presented at the CBER Honor awards ceremony.

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

- 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.*

Yes. Relevant job descriptions are included below:

Writer-Editor:

- *Mastery of grammar, and plain language writing and editing principles.*
- *Ability to edit and or make plain language scientific, regulatory or technical information.*

Communications Specialist:

- *Edits, writes and proofreads materials using Federal plain language guidelines.*

CDRH Health Communication Specialist:

- *Serves as CDRH plain language focal points.*

Many CBER employees have plain language included in their Performance Management Appraisal Programs (PMAPs):

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

CDER Office of Communication job descriptions routinely mention plain language writing skill requirements for its employees.

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

FDA 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. 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 March 2020 through March 2021, please describe:*

- The specific number of your employees completing plain writing training.*
- The feedback you received from those who already completed the training.*
- The plain writing training programs you used.*

- d. *Examples of trainings and materials you developed to educate stakeholders and the general public on plain writing.*
- e. *Ways in which you improved or focused your plain writing efforts.*

*[Enter your descriptions in paragraph format, here]*

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

See Table below:

<b>FDA-wide Plain Writing Training</b>			
<b>Training</b>	<b>3/20-3/21 # Offerings</b>	<b>3/20-3/21 # Registrants</b>	<b>Cumulative # Registrants since training release</b>
<i>U.S. Department of Health and Human Services Plain Language Training</i>	(1-hour online session in LMS)	27	159
<i>FDAU Plain Language</i>	1 in-person 1 virtual 9 webinars	297	3,152
<i>FDA Basic Plain Language Skills and Clear Communication Index Training</i>	(3-hour recorded session in LMS)	55	86
<i>FDA Plain Language: An Introduction</i>	(2-hour online course in LMS)	4	10
<i>FDAU Technical Writing</i>	2 new webinars	29	(New in 2021)

*FDAU Plain Language: 297 total in-person, webinar, and virtual offerings*  
 FDA University (FDAU) has trained over 3,152 FDA employees (580 in 2013; 764 in 2014; 315 in 2015; 442 in 2016; 235 in 2017; 253 in 2018; 266 in 2019; 297 in 2020)

Center-specific training:

CBER: From March 2020 through March 2021, CBER hosted a total of 330 personnel that attended and completed plain writing training.

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 in LMS*

- *FDA Basic Plain Language Skills and Clear Communication Index Training*, 3-hour recorded session in LMS
- *U.S. Department of Health and Human Services Plain Language Training*, 1-hour session in LMS
- NIH Plain Language webpage, 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 (RCP) Program. Between March 2020 and 2021, CDRH conducted a total of 26 trainings and trained 335 employees.

CTP: From March 2020 to March 2021, 146 CTP employees completed plain language training.

CTP refers employees to FDA University for free Plain Language courses held annually. CTP does offer Technical Writing, Practical Grammar and Proofreading Skills classes. Specifically:

- The Technical Writing course aligns with the Federal Plain Language Guidelines. It does provide instruction and lead 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.

CVM: A total of 96 staff members from various offices across the center participated in the communication-related trainings provided at CVM.

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

FDA University (FDAU) regularly surveys FDA-wide *FDAU Plain Language* in-person and webinar class attendees to obtain feedback on class content, the instructor's delivery and teaching methods, and the instructional exercises.

Since March 2020, nearly 95% of the respondents were satisfied with the overall effectiveness of the course and the instructor.

Comments from 2020 evaluations:

1. Learners identified the most helpful aspects of the class including:
  - *Editing for clarity, conciseness, readability*
  - *Identified key plain writing tips for us to apply immediately*
  - *Writing in active voice*
  - *The examples were pertinent and the discussion surrounding the exercises was very useful*
  - *The level of participation on all participants and the instructor given that the class was online.*

2. Learners identified the least useful aspects of the class including:
  - *Using examples that were not relevant to what I do*
  - *It went over the allotted time*
  - *Just a suggestion, it would be helpful to have the slides ahead of time*
  - *The audio was hard to listen to the speaker*
  - *It was hard to engage with other participants*

FDAU began offering a new *FDAU Technical Writing* course in March 2021. Nearly 95% of the learners responded that they were satisfied with the course.

Center-specific feedback:

CDRH: Examples of Level 1 Evaluation feedback:

- *Master Technical Writing: A Plain Writing Workshop:* 73% of participants rated the overall course as “very good” or “excellent.”
- *Effective Communication Skills for Scientific & Technical Professional:* 74% of participants rated the overall course as “very good” or “excellent.”
- *Master Four-Party Harmony:* 58% of participants rated the overall course as “very good” or “excellent.”

CTP: From March 2020 to March 2021, CTP held the following classes and received the following scores on a scale of 0 to 5 (excellent):

- *Technical Writing:* 3 courses with average evaluation score of 4.04.
- *Practical Grammar:* 2 courses with average evaluation score of 4.65.
- *Proofreading Skills:* 3 courses with average evaluation score of 4.52.

CVM:

CVM evaluates its courses to ensure that it offers high-quality training to all staff. The Technical Writing and Practical Grammar courses received very strong positive feedback from CVM staff:

- 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.
- Participants also indicated that the courses met their needs.

*c. The plain writing training programs you used.*

FDA-wide training:

- *U.S. Department of Health and Human Services Plain Language Training*
- *FDAU Plain Language-in-person and webinars*
- *FDA Basic Plain Language Skills and Clear Communication Index Training-recorded training in LMS*
- *FDA Plain Language: an Introduction-online training in LMS*
- *FDAU Technical Writing*

- Other agency and private training listed on FDA’s *Plain Language Resource Center*:
  - NIH *Plain Language: Getting Started or Brushing Up*
  - USDA *Plain Language Training Course*
  - FAA *Plain Language Course: The Basics*
  - DigitalGov *Plain Language Video Playlist*
  - Simon Fraser University *Plain Language Certificate (Fee)*

Center-specific training:

CBER continues to have a robust writing program for its employees. Besides the *U.S. Department of Health and Human Services Plain Language Training* in LMS, the following courses were available to CBER employees:

- *How to Write Effective Comments to Sponsors*
- *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*

Many CDER employees have taken FDA University plain language classes. In addition to the agency-wide plain language training, CDER staff members take writing and editing courses on an ongoing basis as part of their career development.

CDRH: Plain writing techniques are covered in 5 courses as part of the *Reviewer Certification Program*. They include:

**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)

Core courses are taught in the first 60 days of employment, while Advanced courses (also required) are offered in the reviewers’ first full year of employment. In the 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.

CTP:

- Technical Writing
- Practical Grammar
- Proofreading Skills

CVM offers several communication-related trainings for all staff. For example, courses in Technical Writing and Practical Grammar are both part of the Center’s robust Core Curriculum. CVM encourages its staff who are interested in plain writing to attend training programs offered through FDA or HHS. A list of upcoming plain writing training programs is included in the monthly tip for plain writing in “CVM News.”

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

*The Office of the Commissioner (OC) Office of Minority Health and Health Equity develops innovative methods to reach diverse communities, and supports implementing [FDASIA Section 1138](#) (2012) to address low literacy by:*

- Reviewing FDA communication plans to help ensure public resources are clear, culturally appropriate, and available in other languages as needed.

CDRH:

- Live classes and pre-recorded instruction (teaching)
- Power point slides (teaching points)
- Writing exercises [how to] write concisely, in plain language (group and individual exercises)
- Critique of reviewers’ “real time” writing samples (individual feedback)
- 1x1 time with Instructor, if requested (focused learning)

CVM

- “CVM News” monthly newsletter for internal stakeholders shares tips on plain writing and upcoming plain language classes.
- CVM [In Plain English, Please](#) article on its website discusses importance of plain writing 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 agency-wide in-person *FDAU Plain Language* classes to Adobe Connect webinars. FDA emphasized more on-demand training options and publicized *Digital.gov* webinar events on the Plain Language Resource Center intranet and *FDA Announcements*.
- FDAU offered new *FDAU Technical Writing* course offerings

Center-specific improvements included:

CBER focused more on participant walkaways and interactivity within its plain language training events. CBER increased its hands-on exercises, check point evaluations and



quizzes to reinforce learning objectives to ensure the successful transfer of knowledge.

CDER is developing a Strategic Communications plan that will incorporate using plain language as a best practice.

In March 2020, CDRH began providing their Master Technical Writing participants with a laminated “wallet-size” card including tips on plain writing, technical writing and proofreading. The tips are provided in the training slides and workbook as a reference for participants. Additionally, participants may contact the instructor directly to engage in individualized sessions to practice and improve their writing skills.

### **New Initiative for 2021**

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.

*For 2021, please describe:*

- a. How your agency plans to use plain writing to promote equity in your agency’s policies, programs, and activities.*

CBER works with FDA’s Office of Minority Health and Health Equity to develop materials promoting equity and access to CBER-regulated products. During the pandemic, CBER translated COVID-19 Vaccine Patient Fact Sheets into about 30 languages and posted them on FDA.gov.

CDER Office of Communication translated outreach materials on various topics, such as hand sanitizers, into multiple languages during the COVID-19 pandemic.

CDRH uses plain language, inclusive language, and incorporates 508-compliance standards in all internal and external communication. Whenever possible, the center

collaborates with third-party disseminators, such as patient advocacy groups, physicians' societies, and FDA field staff to ensure their messages reach underserved populations and patient communities throughout the U.S.

CTP 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 ages 13-17 in the U.S., and more than half of them are at-risk for tobacco use. The campaign is scheduled to launch in the latter half of 2021.

CTP is updating 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 is also improving its language about ethnicity and race in this year's editorial guide. CTP is updating its style guide in both English and Spanish.

CVM has a long-standing commitment to diversity, equity, and inclusion to harness the power of diversity of thought, background, and experience essential for an 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 identifying what diversity is, and how to leverage diversity to create a more dynamic and inclusive workplace. Additionally, all staff complete unconscious bias training to help identify potential blind spots as well as preventing harassment training to raise awareness. In these trainings, participants discuss the importance of incorporating inclusive language in documents in accordance with Federal Plain Language Guidelines.

CVM expanded its outreach program to Spanish speakers with limited English proficiency by translating selected website content for pet owners, animal producers, veterinarians, and other groups in the animal health industry into Spanish. In 2020, CVM posted over 30 articles, one graphic, several images, and one *Guidance for Industry* in Spanish: [Publicaciones en español del Centro de Medicina Veterinaria \(CVM\)](#).

## **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.*