Department of Health and Human Services
2020 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 is developing our 2020 compliance report to demonstrate our 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. Please provide information from your division by responding to the questions below, on pages 2-4, and return the completed document through SPS to the Executive Secretariat (Exec Sec) by 6PM Friday, March 6, 2020.

Moving forward, the standardized schedule in coming years will be as follows:

- 1st week of February: Exec Sec sends the annual Plain Writing Request for Information to divisions.
- 1st week of March: Divisions submit responses.
- 1st week of April: Exec Sec posts the HHS Plain Writing Act Compliance Report at http://www.hhs.gov/open/plain-writing/

If you have any questions, please contact Dr. Ekaterini (Kat) Malliou at Ekaterini.Malliou@hhs.gov.

<div align="center">**[FDA]**</div>

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 2019 through March 2020, please describe:

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

1. **Coronavirus Disease 2019 (COVID-19):**
   https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19

2. **The Center for Tobacco Products (CTP) Youth e Cigarette Prevention Infographic 2019**:
   Campaign posters and other educational materials, developed in collaboration with Scholastic, to increase awareness of youth e-cigarette prevention.

   📄 YoutheCigarettePrev
   entionInfographic20

   In a continuing collaboration with Scholastic to increase awareness of youth e-cigarette prevention, FDA has mailed new "*The Real Cost*" campaign posters to all U.S. high schools, in plain language that resonates with the youth audience. The posters for display in high school bathrooms, where teens are often faced with the decision to use e-cigarettes, deliver messages such as:
   1. "*You might as well flush your lungs while you're at it. Vaping can deliver toxic metal particles, like nickel, lead and chromium directly into your lungs.*"
   2. "*When you find out what's in a vape, you won't be relieved. Vaping can expose you to some of the same cancer-causing chemicals as those found in cigarette smoke.*"

3. **The Center for Biologics Evaluation and Research (CBER)**
   Is It a Cold or the Flu? Prevention, Symptoms Treatments:
   https://www.fda.gov/consumers/consumer-updates/it-cold-or-flu-prevention-symptoms-treatments

Additional Center Submissions:
CBER
   - FDA Warns About Stem Cell Therapies:
     https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies
   - Vaccination Is the Best Protection Against Measles:
     https://www.fda.gov/consumers/consumer-updates/vaccination-best-protection-against-measles
   - Please also see "Research Summaries" under Innovation and Regulatory Science for examples of converting complex science into a more understandable form:
     https://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm

The Center for Devices and Radiological Health (CDRH)
- Certain Medtronic MiniMed Insulin Pumps Have Potential Cybersecurity Risks: FDA Safety Communication (36,000 pageviews)
- UPDATE: The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication (29,000 pageviews)
- Unique Device Identification System pages (327,000 pageviews)

The Center for Veterinary Medicine (CVM)
- *FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy*
- *FDA Investigates Contaminated Pig Ear Pet Treats Connected to Human Salmonella Infections*
- *Statement by FDA Commissioner Scott Gottlieb, M.D., on efforts to reduce animal testing through a study aimed at eliminating the use of dogs in certain trials* – FDA's Office of Media Affairs drafted this statement with input from CVM

CTP
1.Campaign posters and other educational materials, developed in collaboration with Scholastic, to increase awareness of youth e-cigarette prevention.

FDA and Scholastic have also developed free plain language posters and other resources that were distributed to 1.3 million educators, as well as doctors, youth groups, churches, public health agencies, and others who may find them helpful in educating youth on the dangers of e-cigarette use.

Many of these materials are available to order or download for free through the CTP Exchange Lab. The Exchange Lab provides CTP tobacco education resources in plain language to support public outreach efforts. In the March 2019–March 2020 time frame, about 7.5 million print materials were disseminated through the Exchange Lab and through conferences and events. Materials include tobacco education and prevention resources for health providers, educators, state and local entities, and public health professionals.

2. *Office of Small Business Assistance Feature* (as part of a webpage update), which exemplifies the many additional plain-language features available on CTP's website

CTP continually works on updating its website, always mindful of making the content as clear and easy to understand as possible. As part of that—and with many small businesses such as vape shops being affected by FDA's tobacco regulatory requirements—the Small Business Assistance for Tobacco Product Industry webpage was revamped. The page introduces CTP's Office of Small Business Assistance (OSBA) and contains thoughtfully organized information, including videos setting forth requirements that apply to small businesses.

A new CTP's Office of Small Business Assistance feature article explains requirements for small businesses and how to seek help from the center's small business office. The story appears with many other plain language articles on a new *Feature Stories* webpage presenting these pieces under the categories *About Tobacco Products, Addition, and Quitting; Tobacco's Health Effects in*

Youth and Others; Regulation, Compliance, and Enforcement; and *Science and Research.* CTP features stories, as well as other materials, use illustrations as appropriate to support readers' comprehension of the points being communicated.

3. CTP Connect Newsletter

The *CTP Connect* email newsletter, such as the [January 2020 issue](#), uses clear terminology to summarize recent CTP actions to protect public health. The email 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 details 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* and/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.

> a. *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 employees across nine centers and offices 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 2019 to March 2020 includes:

CDRH
- New documents: Estimated 13 safety communications, 4 letters to health care providers, 49 recall notices, 36 new device approvals, 2 consumer updates, 5 web pages
- Revised documents: 5 updated safety communications, 3 updated letters to health care providers, 6 consumer updates, 15 web pages

CTP effectively reaches various, and vast, target audiences with its plain-language resources, through its public education efforts and other informational resources about tobacco products and the dangers they present. These efforts progressed greatly in the March 2019–March 2020 time frame, and below are some examples of new documents along with associated numbers.

In a collaboration with Scholastic, FDA recently developed clearly, simply written [new resources](#) designed to help educate 12- to 18-year-olds through youth e-cigarette prevention efforts. This effort alone reached out to 1.3 million educators with resources. Among them: five lesson plans, two infographics, five videos, and two take-home sheets for families. In collaboration with Scholastic, as well, e-cigarette prevention posters were mailed to all U.S. high schools in August 2019. More FDA and Scholastic resources are in development and expected to be available in

spring 2020.

To help illustrate the range of types of plain language information that CTP creates and disseminates, a *My Vaping Mistake* series of videos was released in early 2020 as part of the center's *The Real Cost* Youth E-Cigarette Prevention Campaign. The four-episode series features teens' true stories of the physical and emotional effects of e-cigarette addiction.

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. In March 2019– March 2020, about 7.5 million print materials were disseminated through the Exchange Lab and through conferences and events.

Some recently added resources include:
Print Materials
- *Chemicals in Vaping* posters. These five posters—focused on chromium, lead, nickel, formaldehyde, and nicotine—help educate youth about the potential dangers of e-cigarette use.
- Digital age verification calendar. This tool helps retailers determine if a customer is old enough to legally purchase tobacco products.
- Loosies decal and fact sheet. A 5"x7" double-sided window sticker informs retailers and their customers about the federal rules prohibiting the sale of single cigarettes known as "loosies." A Spanish version is available.
- *Every Try Counts* posters, coasters, and car air fresheners. These new resources from CTP are part of the "*Every Try Counts*" campaign designed to encourage adult cigarette smokers to quit through messages of support underscoring the health benefits of quitting.

Social Media Content
- 11 short vaping videos, designed to educate youth that vapes can contain chemicals that could be harmful to the body, are available for download to share on Instagram and Facebook.

Feature stories are another format for communicating information in clear, concise language. These are examples from among a wide range of feature stories explaining regulatory, compliance, and science actions taken by CTP toward reducing death and disease from tobacco products. (A newly created "*Feature Stories*" webpage provides a more comprehensive view of all recent articles.)

- How are Non-Combusted Cigarettes, Sometimes Called Heat-Not-Burn Products, Different from E-Cigarettes and Cigarettes?
- Questions and Answers on the National Youth Tobacco Survey: How We Collect and Analyze Data to Understand Youth Tobacco Use
- Chemicals in Tobacco Products and Your Health
- Question and Answer with Matt Holman, Ph.D., Director of CTP's Office of Science

The National Center for Toxicological Research (NCTR's) primary audience is the scientific community, therefore, its top accomplishments are its research publications.

NCTR produces approximately 30 new non-scientific documents a year, though.
For its non-scientific audience, the most impactful and significant plain language documents and web content include:

1) NCTR Research Highlights, scientific research accomplishments posted to the Internet;
2) NCTR division one-pagers describing research and accomplishments for seven research divisions/office;
3) annual budget narratives;
4) congressional documents, such as issue papers, responses to various data calls, Senate and House report language, hearing prep write-ups, and initiative write-ups; and
5) NCTR principal investigator/researcher bios posted on FDA.gov that undergo significant edits and rewrites in plain language.

CVM examples include:
- CVM Guidance for Industry (GFI) #256 – Compounding Animal Drugs from Bulk Drug Substances
- CVM Updates – CVM uses this page to communicate relevant and timely information about FDA and animal health to the public.
- Outbreaks and Advisories – CVM uses this page to communicate important safety and health information regarding animal feed and pet food to the public.
- Questions & Answers: FDA Center for Veterinary Medicine's Investigation into a Possible Connection Between Diet and Canine Heart Disease
- An Explanation of the Freedom of Information Act (FOIA) for the Rest of Us- Articles to explain various topics to an internal CVM audience.

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

CDRH
- Revised templates for safety communications, *Letters to Health Care Providers*, recalls, and email and webinar slides.
- Redesigned key web pages, including navigation pages, for Medical Devices and Radiological Health content using plain writing and UX principles:
  - Do Cell Phones Pose a Health Hazard?
  - Unique Device Identifier: UDI Basics
  - Certain Medtronic MiniMed Insulin Pumps Have Potential Cybersecurity Risks: FDA Safety Communication

CVM
Webpages:
- *Development & Approval Process (Animal Drugs and Animal Food Additives)*
- *Freedom of Information (FOI) Summaries for Approved New Animal Drugs*

Consumer YouTube videos:
- *Pet Emergency Preparedness Kit: Don't Fail to Plan*
- *Xylitol and Dogs, A Deadly Combination*

Office of Operations (OO) Office of Talent Solutions updated the Job Opportunity Announcement (JOA) Template in plain language, encouraging FDA Hiring Officials to use the new template that uses pronouns, and is free of federal jargon, acronyms, and agency-specific terms for easier understanding for job seekers.

CDER Office Of Translational Sciences Communication Efforts for Guidance Awareness and Training Guidance Snapshot- Formal internal communication plans to announce guidance publications with announcements in center-wide emails and intranet banners. Guidance snapshots are brief one/two-page internal documents that use visuals and plain language to describe how a guidance will affect CDER staff.

CBER continues to follow plain language principles in all forms of communication in order to provide clear, timely and reliable educational resources about important health and safety information (including health fraud enforcement) to a broad and diverse audience that includes, consumers, regulated industry, academia, researchers, and other government agencies.

CBER makes every effort to develop new content and update existing resources in plain language. However, updating regulatory statutes and related scientific content into this format can present some challenges.

CTP remains mindful of the various target audiences it is working to inform, which include youth and adults; smokers and nonsmokers; retailers that include small businesses such as vape shops; and people with various levels of literacy, as described in more detail in the section above. The continual expansion and analysis of the center's smoking and e-cigarette use prevention campaigns such as *The Real Cost* and *Every Try Counts* is an example of the center's vigilance in this respect.

CTP has had a longstanding commitment to plain writing, which is reflected across a continually updated website. Its [Tobacco Products](#) homepage, for example, has been updated over recent months to help ensure the layout is self-explanatory and easy to follow. The center's programmatic areas are highlighted at the top of the webpage in simple terms and headline stories are presented right below, with images and clear descriptions. Subheads further down the page help website visitors find basic and more in-depth information, under sections titled *Market a Tobacco Product, Information by Tobacco Product Type, Small Business Assistance,* and *About the Center.*

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

FDA.gov
Plain Writing: It's the Law! Additions:
- *2019 Annual Plain Writing Act Compliance Report*
- 2019 Plain Language Award Recipients
- Updated examples in *Plain Writing at Work* section

FDA intranet:
- *Plain Language Resource Center* Additions*:*
  - *Plain Language Summit 2019*
  - *Principles of Speaking Plainly DigitalGov* webinar
  - New *FDA Plain Language: an Introduction* online class in LMS
  - New *FDAU Plain Language* in-person class offerings
  - Nominate 2020 ClearMark Plain Language Awards link
  - Clarity 2020 International Conference link

- *NCTR Plain Language Tips* at (http://inside.fda.gov:9003/NCTR/ucm525124.htm)
  - NCTR intranet homepage rotating web banner featured plain language tips, as well as on local TV monitors

   d. *Other relevant accomplishments.*

[Enter your descriptions in paragraph format, here]

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 2019 through March 2020, 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 (CCI), and constructing communications for the needs of the target audience. The expected outcomes include increased use of plain language and documents written so that they are understood by audiences with limited proficiency in English or limited health literacy.

CDRH
- Communication directors encourage and help enforce plain language best practices in review of draft communications and discussions with employees.
- Center director works with communication leadership to monitor external impact and encourages and supports use of plain language to help assure internal and external audiences receive clear and actionable messages.

CVM senior officials review outgoing documents to ensure they meet plain writing standards for understanding outside of the center. Senior officials support and reinforce plain writing through center employee representation on the government-wide Plain Language Action and Information Network (PLAIN). The center's representative 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) when reviewing existing documents as part of their conversion process into plain writing. The CCI Tool is available for FDA-wide use on the 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 re-writes due to new content. However, ensuring that new – and existing – content adheres to the requirements within the Plain Writing Act of 2010 is a priority for the center.

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.

   OO's Office of Policy, Planning, Legislation, and Analysis (OPPLA) Clear Communication Index Training Team developed and implemented the *FDA Basic Plain Language Skills and Clear Communication Index Training* to teach FDA employees how to use the CCI and encourage its use to check communications for plain language throughout the agency.

   Some centers have adapted the tool specifically for their own employees' use. For example:

   The Center for Food Safety and Applied Nutrition (CFSAN) Office of Analytics and Outreach uses the CCI when developing all their external communications. They adapted the *FDA CFSAN Clear Information Tool* from the CCI Score Sheet.

   The Office of Regulatory Affairs (ORA) style guide promotes using plain language and contains the *Clear Communication Tool*, a modified CCI, specific to ORA requirements. ORA is training senior leaders, communication staff, and regular staff on clear communication and good writing based on the style guide.

> **The Office of the Commissioner (OC) Office of Women's Health (OWH)** uses the CCI research-based tool to develop and assess whether their covered documents use plain writing.

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.

For example, **CDRH** conducted internal message testing on a new cybersecurity safety communication, which identified plain language issues and lead to improvements.

3. *DigitalGov* Usability and Message Testing
4. **Editing software tools,** such as *StyleWriter, Microsoft Word,* etc., that check plain writing principles
5. **Center document clearance processes**

For example, **CDRH** assesses plain language inclusion during its document clearance process.

> 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.)*

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

1. *Could you understand what you read?*

2. *Could you quickly find what you needed within the information you read?*

3. *Did you know what action to take or how to use the information after reading it?*

CDRH
- Informally assesses documents as messaging and work products are developed. Identifies the need to revise messages based on identified user needs.
- Monitors the reception and follow-up conversation on communications to ensure they reach and are understood by their audience. This is primarily accomplished through monitoring of inquiries received to the center after communication is issued as well as through traditional and social media monitoring. CDRH employees update or reach out to stakeholders as needed to provide clarification on messaging or to respond to questions.
- CDRH participated in the 2019 Patient Engagement Advisory Committee meetings to obtain feedback on and recommendations about patient communication needs and how successful the center is in meeting them.
- Uses web analytics, particularly heat maps and scroll maps of new and revised pages, to learn how users interact with and react to plain language content on the pages.
- Uses keyword research to incorporate plain language terms in web content to improve readability as well as search engine performance.

Other centers, such as CVM, typically use web metrics as well (such as the number of page visits, and average time on page), to measure the effectiveness of documents.

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.

CDRH obstacles include low direct feedback from audiences and limited access to FDA's new customer feedback survey on FDA.gov that collects user data on FDA's web pages and the customer experience.

CVM cites challenges, such as a lack of resources for tracking and creating metrics, as well as the need for increased buy-in across the center about the importance of plain writing and implementing a formal plain writing program.

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 contractors.

NCTR management, in coordination with the Communications Branch has encouraged its researchers to have their PowerPoint presentations reviewed and edited by members in the Communications Branch before presenting. Additionally, the NCTR Communications Branch has made a concerted effort to make edits and improvements to all written communications.

CDRH incorporated informal trainings, discussions, and checklists on writing effective messaging into clear communication best practices.

[Enter your descriptions in paragraph format, here]

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 2019 through March 2020, please describe:

   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 2019* and *DigitalGov* webinar *Principles of Speaking Plainly,* and the Center for Plain Language *ClearMark Awards.*

CVM promotes plain writing by publishing monthly tips on effective communication in *CVM News*, a weekly newsletter sent out to all center employees. Their article on plain writing: In Plain English, Please is posted on *FDA.gov*. Throughout the year, they often use web banners at the top of this webpage to promote plain writing-related news and activities.

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

The Office of the Commissioner (OC) Honor Awards FDA Plain Language Award formally recognizes FDA writers who succeed in making our documents easier to read by communicating clearly using the tools and techniques of plain language.

2019 Recipients include:
Office of Policy, Planning, Legislation, and Analysis (OPPLA) Clear Communication Index Training Team-
for exceptional efforts promoting clear communication cross-agency through developing and implementing the new Clear Communication Index training

Office of Foods and Veterinary Medicine (OFVM) Produce Safety Guidance Fact Sheets and Webpage-
for excellence in addressing the information needs of the farming community and helping them to comply with new food safety regulations

Office of Regulatory Affairs (ORA) Honor Awards 2019 Plain Language Award:
Division of Project Management Project Portfolio Report Improvement Group-
for continuously acting to ensure the Project Status Reports provided to ORA Executive Advisory Committee are high-quality, informative, timely, and use plain language

CVM 2019 Plain Language Award:
Medicated Feed Combination Approval Package Revision Team-
for implementing improvements to office documents that more clearly and effectively communicate CVM's approval of medicated feed combinations

CDRH provides kudos and informal recognition as a first tier of awards, followed by more formal cash and time-off incentive awards, and nominates excellent examples 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.*

FDA Position description (PD) language for written communication varies based on the position and duties to be performed. While the term *plain writing ability* may not be mentioned specifically, certain components of plain writing are included in PD's:

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

Center-specific responses:
CDRH
The expectation for clear communication and plain language use is identified in the performance plans and position descriptions (PD) of employees who develop and clear communications for CDRH. For example, in the health communication specialist PD, the following major duty/responsibility is noted:
- *serving as CDRH plain language focal point.*

In the PMAP for the same position, the following is a measure of successful outreach:
- *Work products are usable, understandable, and appropriate for intended audiences (e.g. consumers, industry, health care providers, and government health authorities).*

In the same performance plan,
- *technical knowledge in developing clear and effective written communication* is also included.

Many **CBER** employees have plain language included in their PMAPs:
- *Work products are written at the level of the intended audience (plain language, readability, education level).*

Plain writing and editing were included in the job descriptions of the three CBER Communication Branch employees and were included in the job announcements for a Communications detail. As part of the interview process for any positions in Budget Formulation (which requires a lot of writing) or the Communications Branch, a writing assignment is given after the interview that requires the applicant to take highly scientific content and convert it into plain language – as plain as science data can be.

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

We share the *Center for Plain Language's ClearMark Awards* call for nominations with FDA centers and offices through FDA's intranet *Plain Language Resource Center*, *FDA Notices* announcements, and the *Risk Communication and Health Literacy Working Group*, so centers and offices may self-nominate. Due to the nomination fee required for each *ClearMark Awards* submission, many centers do not participate.

[Enter your descriptions in paragraph format, here]

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 2019 through March 2020, please describe:

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

- *U.S. Department of Health and Human Services Plain Language Training*-10; 132 Total since its release.
- *FDAU Plain Language* (in-person and webinars)-266
    FDA University (FDAU) has trained over 2,855 FDA employees (580 in 2013; 764 in 2014; 315 in 2015; 442 in 2016; 235 in 2017; 253 in 2018; 266 in 2019)

- *FDA Basic Plain Language Skills and Clear Communication Index Training*-10; 32 Total since its release

Center-specific training:
CBER hosted a total of 253 personnel that completed plain writing training from March 2019 through March 2020.

CDRH offers *Master Technical Writing: A Plain Writing Workshop,* as well as courses that emphasize certain elements of plain language below:

Master Technical Writing: A Plain Writing Workshop-36
Practical and Proofreading Grammar Review-10
Technical Writing Skills-13
Master Four-Part Harmony -44
MDUFA IV Deficiency Provisions: New Insight and Resources for Four-Part Harmony-794

CVM-A total of 138 staff members from various offices across the center participated in the communication-related trainings provided in 2019.

NCTR - 60 staff researchers took plain language courses taught by Dr. Karen Kuralt, Associate Professor and Graduate Coordinator for the Dept. of Rhetoric and Writing at the University of Arkansas (Little Rock).

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

FDA University 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 2019, most participants responded that they were "extremely satisfied" with the overall effectiveness of the course and the instructor.

Comments from 2019 evaluations include:
- *My communication and writing skills will be better, for internal and external documents and emails.*
- *Editing for coherence. Writing in active voice is very helpful.*
- *The content was clearly and plainly presented and covered areas that I can use right away in my work.*
- *I appreciate the instructor's effort to engage remote learners; it's too easy to just trudge through the material when the meeting is virtual.*

Suggestions for improvement include:
- *This subject is too broad to be covered by a 2-hour course.*
- *Exercises were very simple. It could have been more complex.*
- *The group exercises, even virtually they were helpful If the exercises were available as a download or a filled out (at the end) so we know what words to replace.*

<u>Center-specific feedback:</u>

CBER surveyed class attendees on how the trainings contribute to the work they do to support the center's mission. Responses ranged from moderately satisfied to completely satisfied with the majority falling between considerably satisfied and completely satisfied.

CVM evaluates its courses to ensure that they offer 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.

CDRH-Examples of Level 1 Evaluation summaries for courses referenced above are attached.

Basics of Four-Part Harmony.pdf   Master Technical Writing.pdf   Practical Grammar.pdf   RCP Basics of Writing.pdf   Technical Writing.pdf

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

<u>FDA-wide training:</u>
- *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
  - 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 (see examples below)

<u>Center-specific training:</u>
CBER continues to have a robust writing program for its employees. In addition to the *U.S. Department of Health and Human Services Plain Language Training*, CBER offers:

- 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

CVM offers several communication-related trainings, such as *Technical Writing* and *Practical Grammar*. In these trainings, participants review the *Plain Writing Act of 2010* and discuss how to write using the Federal Plain Language Guidelines. Participants also practice plain writing in sample documents.

NCTR provided several plain language training sessions to 60 of its researchers. Dr. Karen Kuralt, Associate Professor and Graduate Coordinator for the Dept. of Rhetoric and Writing at the University of Arkansas (Little Rock), provided the training with the goal of improving employees' written communication.

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

CVM's article In Plain English, Please, on *FDA.gov* educates its stakeholders and the general public on plain writing.

In addition to **CBER's** vendor-led trainings referenced in the section above, CBER developed a course on plain language specifically targeted to staff responsible for internal and external communications.

CDRH-The Master Technical Writing and Four-Part Harmony courses (see attached announcements) offered as a part of the Reviewer Certification Program (RCP) include exercises asking participants to prepare sample review documentation. The participants review each other's sample documentation for format, inclusion of appropriate content, and use of plain language.

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Tech Writing 26 Mar 2

The 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.

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

Focused outreach to field staff through:
- Expansion of *FDAU Plain Language* virtual training to field staff with seven new webinars since March 2019, and eight more scheduled for the remainder of 2020.
- Released new *FDA Plain Language an Introduction* online training in HHS Learning Portal (LMS) in March 2019, accessible to field staff. This 2-hour course teaches the learner the

tools to clearly communicate their message using the seven principles of plain language through examples and job aids.

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.

Name: Nicole McCray-Dixon
Title: Director, FDA University, Office of Human Capital Management
Email: Nicole.Mccray-Dixon@fda.hhs.gov
Phone: (202) 774-6489

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