<u>2017 Plain Writing Act Implementation Update Survey</u>

Note: Please provide the information requested below by Monday, March 13, 2017. Your responses will be included in our annual compliance report. Thank you for your assistance.

1. Points of Contact:

    a. Please confirm the senior official in your OpDiv or StaffDiv responsible for plain writing. Your current senior official is listed in the chart at the bottom of the Department's plain writing webpage: http://www.hhs.gov/open/plain-writing/.
        i.   Name & Title: LaKeisha M. McClendon, Chief Learning Officer
        ii. Email: LaKeisha.McClendon@fda.hhs.gov
        iii. Phone: 240-402-0105

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

    b. Please identify any other personnel working on plain writing in your agency whom we may contact to follow up to your responses to this survey.
        Julie Frandsen, Management Analyst
        Julie.frandsen@fda.hhs.gov
        301-796-4738

2. What steps has your agency taken since March 2016 to begin or continue implementation of the Plain Writing Act? Please describe, including:

    Since writing the plain language implementation plan, "A Roadmap to Clarity, Investing in Plain Language (PL) at FDA," FDA University's (FDAU) goal has been to focus on 8 strategies outlined in the plan. These strategies essentially match the goals outlined in the "Plain Writing Act of 2010" and the Office of Management and Budgets Plain Language Guidance.

        The strategies are:
        1. Ownership
        2. Agency Outreach & Awareness
        3. Training & Education
        4. Plain Language Web Pages
        5. Reporting
        6. Compliance
        7. Incentives & Awards
        8. Public & Stakeholder Participation

For the last 4 years, FDAU continues to implement of all or part of 6 out of the 8 strategies: ownership, agency outreach and awareness, plain language training through U.S. Department of Health and Human Services online Plain Language training and in-person FDA University and Center-specific training, updating FDA.gov and Inside.FDA Plain Language Web sites, annual reporting, and overseeing the annual Plain Language award.

a. Since March 2016, what types of documents and how many (estimate is acceptable, please specify) of each has your agency written in plain writing? Please also specify how many of each were new and how many were substantially revised.

   i. We post many documents, letters, and write large amounts of content on the FDA.gov Web site. The documents our FDA employees write include, but are not limited to: guidance, regulations, consumer safety notices and updates, recall notices, warning letters, information and untitled letters, and policies and procedures.

   ii. Office of Information Management and Technology (OIMT) Privacy Office applies a plain writing approach when preparing and reviewing public materials. Since March 2016, the Privacy Office has reorganized the Privacy Program page on FDA.gov for clarity, transparency and ease of use by members of the public; assisted in the development of and approved roughly 5 (3 new, 2 revised) Privacy Act Notice Statements published on Web pages and forms administered by FDA programs; and reviewed and approved 50 Privacy Impact Assessments (PIAs) for publication on HHS.gov.

   iii. Center for Food Safety and Applied Nutrition (CFSAN's) Office of Cosmetics and Colors (OCAC) has published 4 new Web pages in plain language and substantially revised 6 others. They responded to 18 letters and about 50 email requests. Topics include, for example, questions from consumers on cosmetic safety and adverse event reporting, and questions from industry on topics such as labeling requirements and whether a product is regulated as a cosmetic or a drug.

   iv. Office of Regulatory Affairs (ORA): Approximately 91 pages of ORA's Web site were newly created and revised to comply with plain language principles. They did not track revisions vs. created, as much of the information needed to be completely overhauled and rewritten from individual interviews.

3. Measurement:

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

   i. We don't currently have systems in place for tracking. One of the plain language initiatives is to define and establish a methodology for tracking our numerous existing documents for conversion into plain writing. We are planning to develop metrics working with the Risk Communication

and Health Literacy Workgroup, which contains members from the former Plain Language Workgroup.

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

We have no metrics currently in place to directly measure whether our covered documents use plain writing. However, our implementation plan identifies strategies encouraging employee compliance through:

   i.   FDA's Internal Message Testing Network, led by the Risk Communication Staff. Since 2010, 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.

   ii. Usability and Message Testing- training is available through GSA's DigitalGov University.

c. How do you measure (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)?

   i.   We regularly survey FDAU Plain Language class attendees to obtain feedback on class content, the instructor's delivery and teaching methods, and the instructional exercises.
      1. Comments from 2016 evaluations include: "Good examples," "practical tips," "useful for job," "helpful exercises," and "very interactive."
      2. Suggestions include: providing more handouts of resources and tips, targeting exercises to FDA communications, and longer and more advanced classes.
   ii. We request feedback on our FDA.gov Plain Language Web page to FDAUniversity@fda.hhs.gov about FDA letters, reports, or information on our web pages, 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?

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

We are limited in fully complying with the Plain Writing Act because of the following challenges:

   i.   Lack of a budget allocated to plain language and health literacy;

ii. Lack of an FTE assigned to implement plain language, plain writing, and health literacy;
iii. The need for HHS-level support on issues such as compliance related to position descriptions, performance evaluations, and budget allocation;
iv. The volume and variety of content written by FDA employees;
v. The size of the agency; the distribution of employees in United States and other countries.

4. Examples:

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

      i. ORA Import Web Page Plain Language Before and After on Personal Importation, Import Detentions, and Food Importation (see attachment). These Before and After examples demonstrate the massive updates needed to transform dense regulatory language to a user-friendly Q&A Web site collection available at www.fda.gov/imports.

      ii. CFSAN's Office of Cosmetics and Colors (OCAC)
          1. Limiting Lead in Lipstick and Other Cosmetics https://www.fda.gov/cosmetics/productsingredients/products/ucm137224.htm
          2. How to Report a Cosmetic-related Problem

             https://www.fda.gov/downloads/Cosmetics/ComplianceEnforcement/AdverseEventReporting/UCM458128.pdf
          3. Nail Products

             https://www.fda.gov/cosmetics/productsingredients/products/ucm127068.htm
          4. Cosmetics Q&A: Why are cosmetics not FDA-approved? https://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm135709.htm
          5. Color Additives/Science & Research https://www.fda.gov/ForIndustry/ColorAdditives/ScienceandResearch/default.htm

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

      i. CFSAN's Office of Cosmetics and Colors (OCAC)
         Shelf Life/Expiration Dating
         https://www.fda.gov/cosmetics/labeling/expirationdating/ucm2005204.htm

ii. Strategic Plan for Risk Communication and Health Literacy
https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/riskcommunicationadvisorycommittee/ucm526451.pdf

iii. FDA Office of Criminal Investigations
https://www.fda.gov/ICECI/CriminalInvestigations/

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

i. Food Safety for Moms-To-Be
https://www.fda.gov/Food/FoodborneIllnessContaminants/PeopleAtRisk/ucm081785.htm

ii. CBER plain writing examples used to explain childhood vaccines to parents/caregivers, explain the blood donor deferral guidance, and explain the blood donation process to the public:

- https://www.fda.gov/biologicsbloodvaccines/resourcesforyou/consumers/ucm345587.htm
- https://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm
- https://www.fda.gov/forconsumers/consumerupdates/ucm048368.htm

iii. Office of Counterterrorism and Emerging Threats (OCET)

- Zika Virus Diagnostic Development
https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm494615.htm
- Zika Virus Response Updates from FDA: Fast Facts
https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm
- Zika reference materials infographic:
https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm

iv. ORA Import Web Page Plain Language Before and After on Personal Importation, Import Detentions, and Food Importation (see attachment).

ORA's Import Web pages revision may have enhanced the safety of a percentage of the 35 million products imported into the U.S. each year. A major rewrite project focused on increasing the FDA import community's knowledge of FDA import requirements into the U.S. for food, drugs, medical devices, biologics, animal food, and tobacco. Now, importers do not have to refer to dense and complex regulations; they can reference step-by-step instructions in plain language. Products imported correctly without hundreds

of calls made to each import office for clarification significantly improved FDA staff efficiency by allowing employees to focus on their review of entries. Additionally, clearly defined expectations for importers and brokers better protects public health by making it easier to follow regulations designed to protect consumers. Less problematic entries result in fewer problematic products in the U.S.

ORA's Office of Partnerships revised a significant portion of their Web pages. This site touches the 50 states' contract inspections, regulatory standards for a variety of products such as milk and mammography machines, and millions of restaurants subject to the Retail Food Regulatory Program Standards. Under the new Food Safety Modernization Act (FSMA) local regulators will work more closely with FDA and will need to reference FDA pages, contact information, and programs. These new pages help achieve better compliance with new food safety regulations and collaboration between regulatory partners: https://www.fda.gov/forfederalstateandlocalofficials/default.htm

5. Training

   a. Has your agency been using the LMS Plain Writing training? https://lms.learning.hhs.gov/Saba/Web/Main/goto/GuestOfferingDetails?offeringId=dowbt000000000025313
      a) Yes, since its creation.
   a. How do you determine who should take it?
      a. This training is available to all FDA federal employees. A link to the training is featured on Inside.FDA's Intranet Plain Language Resource Center at: http://inside.fda.gov:9003/ProgramsInitiatives/Communications/PlainLanguage/default.htm.
   b. What percentage of employees completed the training?
      a. Less than 1% of FDA's 16,000 employees have completed the training, but we hope to start advertising it more aggressively, and as an alternative to in-person training that fills up quickly.
   c. What specific feedback have you received from those who already completed the training?
      a. We have received feedback that it is very helpful and useful information.
   d. How do you expect to use this training this year?
      a. We hope to advertise the HHS training in conjunction with the celebration of the anniversary of the Plain Writing Act in October in a message from the Commissioner.
   e. If you do not use the LMS Plain Writing training, please describe, in detail, any plain writing training/programs you did use.

FDA University (FDAU) has trained over 2,100 FDA employees (580 in 2013, 764 in 2014, 315 in 2015, and 442 in 2016) in plain language.

Since March 2016, FDAU has offered 34 two-hour, Instructor-led Foundations of Plain Language classes for 442 employees with 14 more classes scheduled for the remainder of 2017. In October, 2016, five classes were also held at the National Center for Toxicological Research (NCTR) in Jefferson, AR.

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

i. Center for Food Safety and Applied Nutrition (CFSAN) Staff College offers courses in plain language, and OCAC has encouraged staff to take this training.

ii. Center for Veterinary Medicine (CVM) Plain Language Training

iii. Center for Biologics Evaluation and Research (CBER) has a robust writing program. The following courses are available to CBER employees:

- How to Write Effective Comments to Sponsors: A Plain Writing Workshop
- Clear and Concise E-mail Writing (How to Write & Manage Effective Emails that Get Results)
- Individual Writing Coaching
- Practical Grammar and Proofreading Skills
- Technical Writing for Reviewers

6. Agency Support, Incentives, and Recognition

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

i. Yes. As previous senior officials have done, we plan to request that the FDA Commissioner and Center Directors write a message communicating the Plain Writing Act's requirements to write documents in plain writing and highlighting HHS and FDA Plain Language training available to FDA employees.

ii. FDA's Chief Learning Officer also plans to write a message of support highlighting plain language training available to FDA employees.

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

- Public FDA.gov Web Page (https://www.fda.gov/AboutFDA/PlainLanguage/default.htm):

      a.   Added Before and After Plain Writing Examples

      b.   Updated contact information

- Inside.FDA's Plain Language Resource Center Web Page (http://inside.fda.gov:9003/ProgramsInitiatives/Communications/PlainLanguage/default.htm):
  a. Added Registration link for FDAU Plain Language Classes
  b. Added link to 2017 Center for Plain Language ClearMark Awards
  c. Added link to NCTR Plain Language Tips
  d. Added link to Office of Regulatory Affairs' "ORA's Interactive Communications Toolbox," which includes tips and guidance on plain writing
  e. Added link to CDC Clear Communication Index
  f. Updated contact information

- SharePoint Plain Language Site: The development of this site is complete and we plan to create folders to capture information to respond to next year's 2018 Plain Writing Act Survey.
- Center-Specific Example: The Center for Biologics Evaluation and Research (CBER) ensures that their Web page content is developed using the principles of plain language and clear communication.

c. Please describe incentives or rewards you provide to employees to encourage the use of plain writing.
      i.   The Plain Language Award is presented at the Office of the Commissioner (OC) Honor Awards Ceremony to formally recognize FDA writers who succeed in making our documents easier to read, i.e. communicating clearly by using the tools and techniques of Plain Language.

         2016 Plain Language Award Recipient:
         Office of Minority Health (OMH) Outreach and Communications Team, for advancing FDA communications outreach efforts and Plain Language targeting underserved communities through Web site improvements and social media.

      ii.   Center for Biologics Evaluation and Research (CBER) approved and awarded one plain language award for its 2016 CBER Honor Awards.

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

      i.   Office of Information Management and Technology (OIMT) Privacy staff performance plans include a requirement that staff follow plain language guidelines when drafting communications.

ii. A number of Center for Biologics Evaluation and Research (CBER) employees have plain language included in their PMAPs
   1. "……correspondence is logical, clear, follows plain language guidelines……"
   2. "Work products are written at the level of the intended audience (plain language, readability, education level)."
iii. Office of Regulatory Affairs (ORA) senior leader PMAPS now contain an element of Communication.

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

   i. We currently do not have a plain language budget that supports paying the nomination fee. However, we can share the Center for Plain Language's award announcement with other FDA Centers and offices through FDA Employee News announcements and the Risk Communication and Health Literacy Working Group so that they can self-nominate. We also post the information on Inside.FDA's Plain Language Resource Center.

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

   - Identify a senior leadership champion;
   - Identify a plain language advisor;
   - Develop an implementation plan;
   - Build awareness by posting plain language events in employee-wide emails, Web features, and digital display;
   - Develop a budget to support plain language initiatives and training;
   - Develop a plain language/health literacy workgroup including members from across the agency;
   - Develop an email inbox for plain language feedback; and
   - Start a training program.

      Center-specific responses:
      i. OIMT Response: Peer review/edits to provide a fresh set of eyes, ensuring acronyms and jargon are explained, reducing number of words with greater than 2 syllables. The Privacy Office provides written guidance advising all programs submitting draft documents to the Office for review/approval to avoid jargon, and clearly define technical terms and references.
      ii. CFSAN/OCAC has implemented procedures for developing public information collaboratively, with scientists, regulatory experts, and the writer-editor working together to ensure that they provide information people can access, understand, and use. The majority of its Web content has been written in plain language for several years.

       iii. ORA intends to publish a first-ever style guide which includes a modified CDC Clear Communication index, specific to ORA requirements in 2017. ORA intends to train senior leaders, communication staff, and regular staff on clear communication and good writing based on the style guide in 2017/2018.

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

- Hold regular meetings with other agencies' plain language representatives to share best practices.
- Initiate regular correspondence with agency leaders reminding them of the importance of a plain language program and their support. Include information about HHS' Plain Language Training.
- Encourage all agencies to include plain language initiatives and training in budgets.
- Initiate and add plain language statements to position descriptions and performance evaluations at the HHS-level and encourage it at the agency level.
- Work with PLAIN to develop a pool of HHS-wide and agency-wide Plain Language Trainers who are federal employees.

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