2015 Plain Writing Act Implementation Update Survey

Note: Please provide the information requested below by April 3, 2015. 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. You can see your current senior official that you provided last year in the chart at the bottom of the Department's plain writing webpage: http://www.hhs.gov/open/plain-writing/.

Name & Title: Ricardo H. Grijalva, Director of Training & Development
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Note: We will include the name and e-mail address of this person on the Department's plain writing webpage.

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

Plain Language Workgroup Members' names are available on our web page at FDA.gov.
http://www.fda.gov/AboutFDA/PlainLanguage/ucm346291.htm

2. What steps has your agency taken since March 2014 to 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.

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

For the last 2 years, FDAU has been able to complete all or part of 6 out of the 8 strategies. An owner was clearly established by the agency, agency outreach and awareness occurred through advertising, by publishing plain language tips and grammar gaffes in Employee/FDA News email, and by inviting special speakers. Through the ForeSee Survey, we have even managed to obtain some public feedback about the clarity of our FDA.gov web pages.

Implementation Plan Accomplishments & Ongoing Activities:

- Weekly tips written and posted in the FDA/Employee News
- Plain Language Introduction at FDA's New Employee Orientation
- The Center for Food, Safety, and Applied Nutrition's (CFSAN) quarterly plain language newsletter
- The Office of Regulatory Affairs' "ORA Communications Toolbox," which includes tips and guidance on plain writing
- Plain Language Workgroup Meetings
- Health Literacy Workgroup Meetings

- Continued employee plain language training (see section on "Training" for specifics)
- FDA.gov Plain Language public web page
- Inside.FDA.gov Plain Language Resource Center for FDA employees
- Plain language-specific questions on the ForeSee public survey

a. Since March 2014, 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.

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.

Although we don't have systems in place to track the type and number of documents written using plain language, we have trained 764 FDA employees in plain language principles and plain writing between February 2014 and December 2014. When surveyed following their plain language class, attendees responded that they plan to use most or all of the plain language principles they learned.

3. Measurement:

a. <u>How do you track the conversion of existing documents into plain writing?</u>

The FDA has established a work group to develop and manage initiatives related to Plain Language. One of these initiatives is to define and establish a methodology for tracking our numerous existing documents for conversion into plain writing. Our agency has between 9,000

and 10,000 employees. Since July 2013, when we developed our implementation plan, we focused on building employee awareness of and providing training on plain language. However, some centers and offices have specific divisions whose staff reviews documents to ensure they're written using plain language. Please see the 2 examples below.

- The Center for Devices and Radiological Health's, Office of Communication and Education, Division of Health Communication, clears safety communications, Class I Recall notices, and drafts of "One-Pagers" for recently approved devices. They ensure that these documents are written clearly and in plain writing for the public.

- The Center for Drug Evaluation and Research's (CDER) Office of Communication (OCOMM) staff reviews many documents written by CDER employees before public release. All OCOMM staff is taking the "Foundations of Plain Language" class.

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

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

- Enhancing their ability to test their content through specific training in Usability and Message Testing and by using the FDA's Message Testing Network.

  FDA's Message Testing Network: This Network helps FDA employees test their content and documents for clear communication. Approximately 800 FDA employees participate as reviewers in this network.

  Usability and Message Testing Workshop: We held a Usability and Message Testing workshop this year; instructors included an expert from GSA and FDA's Message Testing Network leader. Fifty FDA employees learned how to test their content for plain writing and clear communication.

- Mandating the use of plain writing by adding elements on plain writing and plain language into performance evaluations and position descriptions.

- Capturing public comments via the ForeSee Survey about content on our FDA.gov web site (see part C for specific information).

c. How do you measure (i) the effectiveness of your plain writing program; and (ii) the effectiveness of your plain writing documents (i.e., whether the public can easily understand and use them)?

i. The effectiveness of your plain writing program?
We regularly survey class attendees to obtain feedback on class content, the instructor's delivery and teaching methods, the handouts, and the plain language

principles they learned. Over 80% of them said they would use most or all of the plain language principles they learned to write future documents.

ii. The effectiveness of your plain writing documents (i.e., whether the public can easily understand and use them)?
We recently added 2 plain language questions to the ForeSee public survey. If the respondent scores the question as a 5 or lower (1-10 Likert scale), they're asked to give us comments. One goal for the Plain Language Workgroup is to review and analyze these comments and identify strategies for making our content more clear.

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

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

- Lack of a budget allocated to plain language and health literacy
- Lack of additional FTEs assigned to implement plain language, plain writing, and health literacy
- The need for HHS-level support on issues such as compliance related to position descriptions and performance evaluations and budget allocation
- The volume and variety of content written by FDA employees
- 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.

Import Basics

Declaring Goods: All goods proposed for entry into the U.S., including goods for personal use must be declared to U.S. Customs and Border Protection (CBP). CBP's regulations and forms are located on their website.

FDA Jurisdiction: CBP automatically alerts the FDA to all imports that fall under its jurisdiction, and FDA reviews the admissibility of those entries. Products subject to FDA review include:

- Animal foods and human foods, except most meat and poultry
- Drugs for humans or animals
- Biologics, including human cells and tissues
- Cosmetics

- Medical devices and electronic products that emit radiation, including computers
- Tobacco products

Admissibility: Imported products must meet the same standards as those set for domestic products. Imported products must not be distributed into U.S. commerce until FDA has determined their admissibility.

FDA-regulated products are refused entry if they appear to be adulterated, meaning the products are contaminated, are not safe, do not otherwise meet `applicable standards, or are misbranded, meaning the labels contain false or misleading information. If such problems cannot be corrected, the products must be destroyed or removed from the U.S.

Getting Help: Importers and others who are not familiar with U.S. import regulations often hire licensed representatives' as their agents when offering goods for entry.

FDA's authority over certain imported products is granted by Congress.

b. Please submit three documents that you intend to revise or rewrite.

Centralized Entry Review Pilot

Each day, ORA entry reviewers make initial decisions about whether to admit imports arriving at ports of entry in their districts. Could it be more efficient, and could the work be more evenly distributed, if investigators shared the workload by reviewing imports outside their own districts? A 49-day pilot program to explore that option, called centralized entry review (CER), returned a wealth of information, some of which can improve current operating procedures. During the pilot, certain ORA employees performed import entry review of products arriving at any one of 14 ports in six districts. Only the entry review portion of the screening process was changed, and local district personnel continued to handle any necessary next steps, including compliance actions, product examinations, or sampling.

"While the pilot was fraught with many challenges, it has shown us how to improve the process as it is currently practiced," said ORA ACRA Melinda K. Plaisier. "In that respect, it exceeded the goal of giving us in-depth data to inform future decisions concerning the use of a centralized entry review process."

Among the many findings, the pilot quantified problems that slow down entry review, costing both importers and ORA time and money. Findings suggested opportunities for improvement and led to recommendations for a renewed emphasis on more frequent training for both industry and ORA entry reviewers, standardization of entry decisions, and improved communications. Specific changes to data systems also appear warranted. FDA will consider each recommendation before further pursuing centralized entry review.

How the Pilot Worked

The need for optimal efficiency is critical, given that the volume of imports has steadily increased by 10 percent annually over the past decade and types of imports are increasingly more diverse. Yet the number of fulltime FDA employees dedicated to imports has remained constant. Moreover, most ports experience unpredictable peaks and troughs in their workload. In an effort to determine the functionality of CER, a pilot launched August 12, 2013 and operated seven days a week, rather than the usual five days a week, including Monday – Friday from 7 a.m. to 4 a.m., 7 a.m. to 10:30 p.m. on Saturdays and 6 a.m. to noon on Sundays. The pilot involved four major express couriers whose deliveries arrived at 14 ports in Florida, Alaska, Tennessee, New Jersey and California.

A comprehensive set of performance metrics was collected throughout the pilot that ended September 30, 2013 — six weeks earlier than planned due to the federal government shutdown. Those metrics helped guide analysis of the CER pilot and resulted in more than 30 recommendations made by the work group to ORA senior management.

Lessons Learned

Initially, import reviews handled by the pilot group took over twice as long as reviews in non-pilot ports. However, dramatic improvement occurred within weeks. By September 15, those decisions were taking comparable times in pilot and non-pilot ports. From that date forward, pilot ports were generally reaching admissibility decisions faster than non-pilot ports. There were vast differences in average review time for different commodities. CDER and CVM products took the longest time, while CBER commodities took the least—10 hours on average for CBER products compared to 30 hours for CDER and CVM products.

ORA's Import Trade Auxiliary Communications System (ITACS) is extremely valuable, but ITACS use amongst couriers in the pilot project was very low—less than one percent. The experience in the pilot suggests strategies and incentives be developed to increase ITACS use, but that should occur only after ITACS is tested to ensure it is capable of managing high volumes. Currently planned upgrades to ITACS will improve communications between FDA and filers/brokers.

Between 10 and 20 percent of all lines required additional documentation for FDA reviewers to make an admissibility decision. Commodity types most frequently cited for poor data quality were medical devices, pharmaceuticals and antibiotics, in that order. Findings identified opportunities for improvement and led to recommendations for a renewed emphasis on frequent training of both the import industry and ORA entry reviewers, the standardization of entry decisions, and improved communication. The experience also suggested specific changes to data systems.

Online Reporting Analysis and Decision Support

Several fixes were recommended for the Online Reporting Analysis and Decision Support System (ORADSS). A shared communication platform for all ports was identified as crucial to preventing multiple reviewers from accessing emails simultaneously, thereby creating confusion or duplication of efforts.

Entry reviewers who chose to work from home reported being very satisfied, although managing remote workers over four time zones requires additional consideration. “A lot of hard work and effort went into this pilot, and we will continue to evaluate and apply the lessons learned.” said Plaisier.

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

Entry Submission Process for Imports

All FDA-regulated products must be in compliance with the Food, Drug, and Cosmetic Act at the time of entry into the U.S. FDA electronically reviews all entries submitted to us by Customs and Border Protection.

You can help expedite a decision on the admissibility of your imports by providing accurate and complete information at the time of entry and by responding quickly to requests for additional documents.

If you submit inaccurate or incomplete information, FDA can flag your entry for manual review or automatic detention without physical examination.

Submitting the Entry to CBP and FDA; and,

CBP and FDA Review Entry

Below is a step-by-step diagram describing the entry submission and FDA review process.

FDA Regulated Products:
Entry Submission and FDA Review Process

Phase 1 | Before You Import

Step 1 | Determine if your product is FDA-regulated (link to 1.3.x Is my product regulated or 4.2 HTS)

Step 2 | If so, determine if product is on FDA import alert (link to 3.2 import alerts)

Step 3 | Gather FDA required information for product (link to 2.2.1 transmission of information)

Step 4 | Gather product-specific FDA information to demonstrate compliance with U.S. law. Ensure product meets FDA regulations prior to importation into the U.S. (Link to section in 1.3.x)

Food | Medical Devices | Electronic Products | Drugs | Biologics

Animal Food | Cosmetics | Tobacco | Animal Drugs

Step 5 | Submit Prior Notice notification for all food entries, if applicable (link to 2.1.3 Prior Notice)

Phase 2 | Submitting The Entry to CBP and FDA

Step 6 | Obtain a bond three times the amount of product value (link to CBP Bond Info or 1.1 commercial entries)

Step 7 | Enter information required by U.S. Customs and Border Protection [external link]

Step 8 | Enter basic information required by FDA (link to 2.2.1 transmission of information)

Step 9 | Determine and enter FDA product code (2.1.x Link to specific requirements pages or a new page devoted to product coding)

Step 10 | Enter affirmation of compliance codes to expedite admissibility decision (link to 2.1.2 a of C)

Food | Medical Devices | Electronic Products | Human Drugs | Biologics

Animal Food | Cosmetics | Tobacco | Animal Drugs

Step 11 | Upload any additional documents you'd like to include in your entry packet to the FDA ITACS (2.1.x Link to ITACS)

Step 12 | Submit entry to FDA and CBP via automated broker interface

Phase 3 | CBP and FDA Review Entry

Step 13 | CBP makes a conditional release and automatically forwards to FDA

Step 14 | FDA electronically screens of all entries; may auto-release low-risk products and flag high-risk products for manual review

Step 15 | FDA evaluates food entries for prior notice requirements (if applicable)

Step 16 | FDA local office manually reviews entry packet (if applicable)

Step 17 | FDA releases entry or detains entry (link to 3.0 steps)

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

b. **How do you determine who should take it?**

Plain Language classes are available to all FDA employees. They are encouraged to improve their writing skills and register for our Plain Language classes.

c. **What percentage of employees completed the training?**

In the past 2 years FDAU has focused on training and education of FDA employees. These Plain Language classes are 3-1/2 hour classes, "The Foundations of Plain Language". FDAU has trained over 1300 FDA employees (580 in 2013, 764 in 2014).

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

We conduct course evaluations at the conclusion of each Plain Language class. We have received glowing and positive remarks regarding this workshop.

e. <u>How do you expect to use this training this year?</u>

FDAU will develop and give up to 10 presentations for FDA Plain Language Program. FDAU will give up to 10 to 12 presentations entitled "Foundations of Plain Language".

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

FDAU coordinated 2 special events (Usability & Message Testing and the Speakers' Bureau). Our FDAU Plain Language Coordinator attended 31 meetings (including the HHS Health Literacy workgroup, FDA's Language Access Plan workgroup, FDA's Health Literacy workgroup, the Clear Communication Index workgroup (CFSAN), and other miscellaneous meetings as invited to provide Plain Language expert input). FDAU coordinated 5 plain language working group meetings (which includes representatives from almost every FDA center and some offices). We also worked with a contractor to develop the PL web-based training modules (to date we have had 26 meetings and have a beta version ready to test)

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?

FDA's leadership has supported the plain writing requirements in the following ways:

- *Selection of a Senior Advisor on Plain Language:* hired July 2012.
  FDA Commissioner's email (October 2012): Dr. Margaret Hamburg issued an email to FDA employees recognizing the Plain Writing Act and the importance of using plain language and clear communication in all our public information.
- *Center for Drug Evaluation and Research email* (June 27, 2013): the Deputy Center Director for Regulatory Programs issued an email reminding staff to use plain language principles in all official documents.
- *Plain Language Training:*

a. Several Centers have each scheduled 2 plain language training classes in 2014; a total of 9 classes are scheduled for 2014 and we've received requests for 2 more.

b. Several Division Directors have scheduled plain language training for their staff and attended the training themselves.

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

- *Public FDA.gov Web Page:* In March 2013, we user-tested our FDA.gov Plain Language web page. We received valuable feedback that we used to revise our web page.
- *Plain Language Resource Center Web Page*: In February 2014, we user-tested our plain language web page for FDA employees. We received valuable feedback that we used to revise our web page.
- *SharePoint Plain Language Space:* We are currently developing and designing our Plain Language SharePoint spaces including pages for FDA employees, Plain Language Workgroup members, and the Plain Language Planning Team.
- *Center-Specific Example:* The Center for Biologics Evaluation and Research (CBER) ensures that web page content is developed using the principles of plain language and clear communication.

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

FDA offers an annual plain language award. We are currently reviewing the criteria and developing a nomination process.

The CBER Center Director Honor Awards include the Plain Language Award as part of the FDA Awards, but for CBER employees.

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

One of our compliance strategies in our implementation plan is to add a general statement on plain writing ability to position descriptions across FDA. However, this is an area where we need the support of the Department of Health and Human Services.

That said, 2 offices within the agency initiated their own compliance strategies:

- CDRH's Office of Communication and Education's, Division of Health Communication added an item to their performance evaluation about using plain language when writing their content.
- CBER's Office of Communication, Outreach, and Development job descriptions include the following statement: "Work products are written at the level of the

intended audience (plain language, readability, education level)."

- The Office of Regulatory Affairs emphasizes plain language in the job descriptions of those who write documents for both internal and external audiences.

e. <u>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?</u>

No, we currently do not have a plain language budget that supports paying the nomination fee. However, we share the Center for Plain Language's award announcement with other FDA offices and centers so that they can self-nominate.

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

- Identify a senior leadership champion
- Identify a plain language advisor
- Develop an implementation plan
- Build awareness by posting plain language tips in employee-wide emails and on web pages
- Develop a budget to support plain language initiatives and training
- Develop a plain language workgroup including members from across the agency
- Develop an email inbox for plain language
- Start a training program

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

- Hold regular meetings with other agencies' plain language representatives so they can share best practices
- Initiate regular correspondence with agency leaders reminding them of the importance of a plain language program and their support
- Encourage that all agencies develop budgets for plain language initiatives and training
- Initiate and add plain language statements to position descriptions and performance evaluations at the HHS-level and encourage it at the agency level

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