U.S. Department of Health and Human Services

Food and Drug Administration

TO: Leon Rodriguez, JD
Director Office of Civil Rights, HHS

FROM: Jonca Bull, MD
Director, Office of Minority Health

DATE: January 17, 2014

SUBJECT: Food and Drug Administration's (FDA) Language Access Plan for FY 2013-2015

FDA is pleased to submit the attached Language Access Plan. In 2013, in accordance with Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, issued August 11, 2000, HHS created a Language Access Plan that outlined 10 elements its agencies should include in their individual plans to ensure that "departmental language access goals and strategies are fully implemented."

Consistent with this plan, FDA also identified limited English proficiency as a key area of focus for improving its communications in its response to section 1138 requirements of the Food and Drug Administration Safety and Innovation Act of 2012.

We hope that you will find this plan helpful and look forward to FDA's continued participation on the HHS Language Access Steering Committee in advancing this important initiative.

Attachment

cc: Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

The Food and Drug Administration

Language Access Plan

FY 2013 – 2015

Contact: Office of Minority Health (OMH)

U.S. Department of Health and Human Services

Food and Drug Administration

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Background[1]

In accordance with Executive Order 13166, *Improving Access to Services for Persons with Limited English Proficiency*, issued August 11, 2000, all agencies operating under the U.S. Department of Health and Human Services (HHS) must ensure[2] that their programs are accessible to individuals with limited English proficiency (LEP).[3]

In 2013, HHS created a Language Access Plan that outlined 10 elements its agencies should include in their individual plans to ensure that "[d]epartmental language access goals and strategies are fully implemented."[4] Consistent with this plan, the U.S. Food and Drug Administration (FDA) identified LEP as a key area of focus for improving its communications in its response to Section 1138 of the Food and Drug Administration Safety and Innovation Act of 2012.[5]

FDA is the HHS agency responsible for the regulation and oversight of foods, tobacco products, human prescription and non-prescription drugs, biological products,[6] cosmetics, medical devices, products that emit radiation, and veterinary products.[7] FDA's mission includes helping the public get the accurate, science-based information they need to maintain and improve their

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[1] This directive is intended only to improve the internal management of FDA's Language Access Program and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers or employees, or any person.

[2] U.S. Department of Justice, 2001, Executive Order 13166, 2001, Improving Access to Services for Persons with Limited English Proficiency. Available at: http://www.justice.gov/crt/about/cor/Pubs/eolep.php. Accessed on December 17, 2013.

[3] Individuals who do not speak English as their primary language and who have a limited ability to read, speak, write, or understand English can be limited English proficient or LEP. These individuals may be entitled to language assistance with respect to a particular type or service, benefit, or encounter. Limited English Proficiency (LEP) A Federal Interagency Website. Frequently Asked Questions. Available at: http://www.lep.gov/faqs/faqs.html#OneQ1. Accessed on December 17, 2013.

[4] The HHS Language Access Plan complied with the Plain Writing Act of 2010 and aligned its strategies with OCR guidelines and the National CLAS (Culturally and Linguistically Appropriate Services) Standards of 2013.

[5] FDA, 2013, Ensuring Access to Adequate Information on Medical Products for All with a Special Focus on Underrepresented Subpopulations and Racial Subgroups. Available at: http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM359890.pdf. Accessed on December 17, 2013.

[6] Biological products include vaccines and blood products.

[7] U.S. Food and Drug Administration. What does FDA regulate? Available at: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm. Accessed on Dec. 13, 2013.

health and by minimizing the risks associated with FDA-regulated products.[8] Executive Order 13166 supports FDA's mission by directing FDA to ensure that individuals with LEP have meaningful access to FDA's programs and services.[9]

In the past decade, the United States has seen a dramatic increase in the number and diversity of LEP stakeholders.[10] Although the total U.S. population has grown by about 25 percent during this period, the total number of LEP Americans has increased by nearly 50 percent. According to the U.S. Census Bureau, 20.8 percent of all people living in the United States in 2011 reported speaking a language other than English at home.[11]

The Impact of Limited English Proficiency on Health Care

As the U.S. population of LEP stakeholders grows, so does the need to make vital health and medical information available (e.g., in translation or through interpreters) in a language that LEP consumers, patients, and care givers (LEP stakeholders) can comprehend, and then disseminate it widely to reach targeted, non-English speaking groups. However, studies show that about half of LEP stakeholders in need of such language services do not get them. Without access to language support, many LEP stakeholders will not fully comprehend vital health and medical information, leaving them vulnerable to medication errors.[12]

For example, there have been cases in which children overdosed on prescription medications because their non-English-speaking parents could not accurately interpret the English-language drug label.[13] Therefore, to prevent these types of errors related to drugs and other products,

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[8] FDA Mission Statement, available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM298331.pdf. Accessed on January 6, 2014.

[9] Department of Justice, 2001, Executive Order 13166*:* Improving Access to Services for People with Limited English Proficiency. Available at: http://www.justice.gov/crt/about/cor/Pubs/eolep.php. Accessed on December 13, 2013.

[10] As of 2007, 200 different languages were spoken in the United States. See Chen, A, Youdelman, M, and Brooks, J, 2007, The Legal Framework for Language Access in Healthcare Settings: Title VI and Beyond, Journal of General Internal Medicine. 22.2: 362-367. Available at: http://link.springer.com/article/10.1007/s11606-007-0366-2/fulltext.html. Accessed on December 13, 2013.

[11] U.S. Census Bureau. Language Use in the United States: 2011. Available at: http://www.census.gov/prod/2013pubs/acs-22.pdf?eml=gd. Accessed on December 13, 2013.

[12] U.S. Food and Drug Administration. Medication Errors. Available at: http://www.fda.gov/drugs/drugsafety/medicationerrors/default.htm. Accessed on December 13, 2013.

[13] U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. Language Barrier. Available at: http://www.webmm.ahrq.gov/case.aspx?caseID=123. Accessed on December 13, 2013.

FDA recognizes that it must minimize language barriers by more effectively communicating necessary and accurate information to LEP stakeholders.

FDA Communication Methods and the LEP Population

FDA primarily communicates with consumers, patients, and health care professionals, using product labeling, the Web site, press releases, media interviews, reports, journal articles, speeches, public presentations, and radio/television announcements to inform the public about the products it regulates.[14]

In recent years, Internet-driven technologies have transformed the way FDA engages patients, consumers, and health care professionals. Many FDA stakeholders, including LEP stakeholders, now use social media platforms, like Web casts, YouTube, Facebook, and Twitter to receive communication. Thus, FDA is already using social media to target an increasingly diverse audience, providing the public with greater opportunities to benefit from the Agency's information.

FDA is increasingly translating information and delivering it through written, electronic, and telephonic communication channels to guarantee that new safety alerts promptly reach targeted non-English speaking communities and their health care professionals. To strengthen and expand these efforts, FDA has developed a Language Access Plan (Access Plan), which includes, among other goals, translating critical communications into languages widely spoken in targeted communities. It is essential that FDA use all available resources to help safeguard against potential medication and other product errors caused by language barriers.

FDA Language Access Plan Overview

Using the 10 elements outlined by HHS in its Language Access Plan, FDA developed associated action steps and is now working to implement them and establish priorities that will best meet the needs of LEP stakeholders.

FDA has convened a Language Access Plan Steering Committee (Steering Committee) to oversee Agency strategies and processes for expanding language access and to manage

[14] U.S. Food and Drug Administration, 2013, FDA Report Ensuring Access to Adequate Information on Medical Products for All. Available at: http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM359890.pdf. Accessed on December 13, 2013.

implementation of the Access Plan. Communications experts from FDA product centers and offices serve on the Steering Committee, which is led by FDA's Office of Minority Health (OMH).

The Steering Committee was tasked with 1) conducting an inventory of existing activities, 2) identifying gaps in critical services, 3) consulting with stakeholders, and 4) developing a plan to ensure a consistent approach across FDA for communicating with LEP stakeholders. FDA's Access Plan is organized around the following 10 HHS cross-cutting elements.

- **Element 1**: Assessment: Needs and Capacity
- **Element 2**: Oral Language Assistance Services
- **Element 3**: Written Translations
- **Element 4**: Policies and Procedures
- **Element 5**: Notification of the Availability of Language Assistance at No Cost
- **Element 6**: Staff Training
- **Element 7**: Assessment: Access and Quality
- **Element 8**: Stakeholder Consultation
- **Element 9**: Digital Information
- **Element 10**: Grant Assurance and Compliance

FDA Language Access Plan

The Agency designated FDA's OMH, in collaboration with its Office of External Affairs (OEA) and Office of Equal Employment Opportunity (OEEO), to set up a cross-Agency Steering Committee.

FDA's Access Plan is organized around the 10 HHS elements. Within each element, FDA has identified specific needs, gaps, and goals relating to FDA's commitment to protect public health, including access for LEP stakeholders to vital health information.

The following sections describe specific action steps FDA intends to take to strengthen LEP stakeholder access to important health information.

Element 1: Assessment: Needs and Capacity

The Steering Committee was tasked with a number of actions, including developing and implementing a survey tool (see Appendix A) for assessing current language assistance activities and identifying gaps where language assistance could be improved.

In general, FDA product centers use U.S. Census data as the primary basis for prioritizing language access needs. The centers also consider on a case-by-case basis, specific circumstances in which language access may need to be modified or expanded, based on the issue and its significance to LEP communities. FDA intends to take the following action steps.

Action Steps

1. By the end of Q1 2014, the Steering Committee will develop a charter that will outline its duties and identify responsible parties.

2. OMH, collaborating with other FDA Steering Committee representatives, will conduct an annual assessment to include the following:

    - Inventory current language services for LEP stakeholders (e.g., using face-to-face, telephone, consumer- and patient-directed FDA written communications, and Web sites).

    - Identify where language services are inadequate.

    - Engage internal subject-matter experts as well as patient and consumer advocacy organizations to review FDA language services and applicable research and identify best practices for engaging LEP stakeholders.

    - Consistent with available resources, identify next steps to enhance FDA language assistance services.

3. The Steering Committee will develop a database of qualified FDA bilingual and multilingual staff, who may serve as interpreters and translators. OMH will be the resource for contract interpreter and translation services.

4. FDA will share identified language capacities and needs across the Agency, including the names of staff with expertise in delivering culturally and linguistically appropriate language services to LEP stakeholders.

5. Under the leadership of the Steering Committee, FDA will use data from its Office of Regulatory Affairs field staff, the U.S. Census, as well as the Centers for Disease Control and

Prevention (CDC) and other public health surveillance agency data to identify specific languages or dialects at national and regional levels in greatest need of language services.

6. FDA will seek feedback from patient and consumer stakeholders about how FDA can best deliver language services (based on the 10 elements in this Access Plan).

7. FDA will modify its Access Plan as is needed, based on this feedback.

8. FDA will research and develop new strategies for strengthening language assistance to LEP stakeholders, consistent with available resources.

Element 2: Oral Language Assistance Services

FDA recognizes that LEP stakeholders need to receive vital health information and be able to report serious adverse events or problems with FDA-regulated products. FDA will identify language service needs for its main phone number, each product centers' consumer communication offices, and other relevant FDA regional offices, including district headquarters and consumer complaint offices.

Each FDA center and regional office, depending on its key audience(s), will establish an FDA point of contact for LEP stakeholders (e.g., an office, official, or phone number). OMH will maintain this list of contacts as a resource for the Steering Committee.

Action Steps

The Steering Committee will:

1. Review existing procedures for procuring oral language services, including through HHS Program Support Center procurement programs and working with the HHS Office of Civil Rights.

2. Identify and review existing language service agreement(s) within HHS and set up a central master contract for all language services if this is determined to be more efficient.

3. Monitor requests for telephone language assistance for interpreter services at headquarters and in the regional offices, and clarify FDA protocol for ensuring immediate access to a contract interpreter via telephone. A system will be developed for collecting data on requests for and use of oral language services by FDA LEP stakeholders, as well as use of FDA staff and expended resources (by region and nationwide).

4. Ensure that individuals providing oral language assistance have the necessary training and experience to communicate terminology relevant to FDA subject areas.

5. Identify qualified bilingual staff for use as interpreters during emergencies (see Element 1). The contact information for all bilingual employees should be available to front-line staff who manage consumer inquiries.

6. Oversee the development of procedures for ensuring that all interpreters, including those who are FDA staff, have adequate linguistic skills to communicate effectively in English and the language of the LEP stakeholder.

Costs

Existing FDA staff and budget resources from each center will support this project.

Monitoring

The Steering Committee will:

- Regularly analyze data collected by FDA staff and contractors providing oral language assistance in each regional office and headquarters.
- Stay up to date on available language services under existing contracts.
- Routinely assess effectiveness of existing contracts and the quality of language services.
- Develop and document processes to determine changing needs and make annual resource projections.

Element 3: Written Translations

FDA must ensure that vital written communications are translated consistent with the requirements outlined in Element 1 (Assessment: Needs and Capacity).

FDA will continue to translate press releases, consumer updates, vital medical product safety communications, fact sheets, and other documents to ensure that LEP stakeholders have meaningful access to the Agency's critical information, programs, and services. Examples of written materials include paper and electronic documents (e.g., recalls, consumer alerts, product safety announcements, publications, notices, correspondence, Web pages, signs, and fact-sheets).

Moreover, based on the most recent U.S. Census report on spoken language in the United States, FDA has determined that, along with English and Spanish, it will translate *vital documents* and *critical consumer information* (terms defined in Appendix B) into the six other main languages spoken in the United States: Mandarin Chinese, Tagalog, Vietnamese, French, German, and Korean, as appropriate.

FDA will seriously consider adding other languages or translating additional documents if a particular issue is relevant to a particular population not listed in the paragraph above. When translations are not available or oral communication is more effective, FDA will provide oral language services consistent with the respective provisions of this plan and available resources.

Action Steps

The Steering Committee will take the following steps:

1. Review existing language service contract(s) that deal with translation services with the goal of creating a master contract for all language services (See Element 2).

2. Examine opportunities to use translation resources available through other government entities, such as the National Virtual Translation Center.

3. Determine which FDA documents or Web pages meet the definition of *vital documents* and *critical consumer information* (see Appendix B); examine newly created documents or Web pages to decide whether they are *vital* or *critical* or contain *vital* or *critical* information; translate appropriate documents, in whole or part, as necessary.

4. Develop criteria to determine when a particular document or Web page should be translated and into what languages.

5. Include clearly visible links to key FDA Web pages that direct LEP stakeholders to translations of vital written materials (See Element 9).

6. Use prominently displayed taglines in appropriate languages on FDA's Web site and on other written communications where translations are not available. Taglines let LEP stakeholders know that oral language assistance is available and how to access it (See Element 9).

7. Develop a written policy to ensure timely and accurate translation of written correspondence and materials (See Element 4).

8. Develop procedures for ensuring that LEP stakeholders receive vital written correspondence in the stakeholder's preferred language. Examples of written correspondence are 1) letters or notices regarding a complaint or inquiry; and 2) denial or closure of a complaint; and letters or notices that require an LEP individual's response.

Costs

FDA will use existing Agency staff, contracts, and resources to support this project.

Monitoring

The Steering Committee will:

- Conduct evaluations, as needed, to identify additional languages, if any, into which additional documents or portions should be translated (See Element 1).

- Seek feedback from advocacy- and community-based organizations about the quality of translated FDA documents and translated pages on FDA's Web site (See Element 8).

Element 4: Policies and Procedures

FDA will document all policies and procedures necessary for implementing an effective language assistance program and distribute them to Agency employees.

FDA will implement specific written policies and procedures for each of the Access Plan elements. FDA policies and procedures for language access will help ensure that LEP stakeholders have meaningful access to vital health information on FDA-regulated products.

Action Steps

1. FDA will develop, distribute, and train staff and management on FDA's written policy to help ensure that timely and accurate oral and written language assistance is provided in FDA's field offices and headquarters. The policy will be compiled into a language access manual to assist all FDA employees routinely in contact with the public and as a readily accessible reference for all other Agency employees. The manual will contain guidelines on:

    - Types of available oral and written language assistance

    - Procedures on how to provide language services effectively, such as in responding to calls from LEP stakeholders and during in-person encounters

    - Managing situations in which the LEP stakeholder brings an interpreter, including when the interpreter is a minor or family member

    - Circumstances under which an FDA bilingual staff person and/or contracted interpreter will be used

    - Methods for assessing the bilingual capabilities of staff

    - The process for documenting oral and written language assistance provided to LEP stakeholders, and

    - The process for ensuring that an LEP stakeholder's language assistance needs/requests, both oral and written are documented so that all future contact with FDA will be in the appropriate language for that person.

2. FDA will develop and distribute a written policy to ensure timely and accurate translation of written materials, which will include:

    - Circumstances under which bilingual staff and/or contracted services will be used
    - Procedures for responding to correspondence from LEP stakeholders
    - Methods for assessing and ensuring proficiency and competency of bilingual FDA staff or contract translators
    - Criteria for assessing, on an ongoing basis, those documents or Web pages that should be translated into said languages, and
    - The process for documenting translation services provided for LEP stakeholders

3. FDA will continue developing a list of best practices in the delivery of language services in the areas of food, drugs, biological products, and devices, veterinary products, cosmetics, and tobacco products to be used as a resource for FDA employees, and other HHS agencies and recipients.

4. FDA will designate staff who will be responsible for implementing and coordinating FDA language access activities.

Costs

Existing Agency employee and budget resources will be used to support this project.

Monitoring

- FDA will update its policies and best practices list periodically, and as necessary.

Element 5: Notification of the Availability of Language Assistance at No Cost

FDA will inform stakeholders orally and in writing of the availability of language assistance services at no cost.

Action Steps

Under the leadership of the Steering Committee:

1. Provide information on the availability of language services as part of the initial recorded options on FDA's telephone line (1-888-463-6332).

2. Work with the HHS Office of Civil Rights to compile and address complaints about the effectiveness of FDA's language assistance services.

3. Review the FDA Web site regularly to ensure that it provides meaningful access to LEP stakeholders.

Costs

Existing HHS/FDA employee and budget resources will be used to support this project.

Monitoring

- Working with the Office of Civil Rights, FDA will review its notification practices periodically, and as is necessary based on stakeholder input.

Element 6: Staff Training

FDA will commit resources, as available, to ensure that FDA management and staff understand and implement the policies and procedures in this Access Plan in their center or office. Agency training, including Plain Language training, will help ensure that FDA employees understand the importance of effective communication with LEP stakeholders in FDA programs and outreach activities.

FDA will develop a language services curriculum for FDA employees that outlines procedures for ensuring that LEP stakeholders have meaningful access to services and programs. The curriculum will include training on providing language services through a variety of communication methods, including telephone, telecommunication relay services, in-person encounters, outreach activities, and written correspondence. The curriculum will also incorporate additional in-service training for those FDA employees whose routine duties include interactions with the public.

Action Steps

FDA will develop a training curriculum that includes:

1. Information on language services as part of Plain Language training

2. Language services awareness in new employee orientation, emphasizing the need for translations on a case-by-case basis for safety issues of particular relevance to LEP

stakeholders. Baseline training for FDA employees on LEP needs and FDA procedures for providing language services as part of New Employee Orientation

3. The FDA Steering Committee will create a one-stop LEP information center for Agency staff on FDA's intranet to include:

   - How FDA staff or LEP stakeholders can access these services
   - How to respond to calls from LEP stakeholders
   - How to provide oral language assistance to LEP stakeholders during in-person encounters and
   - How to document the needs of LEP stakeholders
   - Language assistance requirements and relevant case law
   - FDA's LEP guidance materials and related guidance
   - List of effective best practices related to language services, and
   - Tools to ensure that information on LEP needs in the field offices is up to date; monitor effectiveness of the field's LEP program to determine whether additional language services are needed; secure language assistance services, as needed.

4. Training FDA staff and management on procedures to provide oral language assistance effectively. Procedures for providing oral language assistance will also be posted on accessible points of contact for ready reference. These materials will cover the following (See Element 4):

   - Baseline training for FDA employees, as part of New Employee Orientation, on LEP needs, FDA procedures for providing language services, and the type of oral language services available, including language resources available in the field offices and headquarters (e.g., language service technology, intranet resources, and bilingual staff).
   - Regular in-service trainings for FDA employees whose routine duties include interactions with the public. Trainings will provide up-to-date information on how to access language services. Update other employees through electronic correspondence, as necessary.

Costs

Funding for training, a training manual, and any other training aides (tangible and electronic), as resources permit.

Monitoring

- The Steering Committee will update FDA employees annually, as needed, on the scope and nature of available or planned language assistance services and the specific procedures through which such services can be accessed at the employee's work location.
- The Steering Committee will identify and implement best practices for FDA employees on providing language services.
- The Steering Committee will develop mechanisms to monitor the existing and emerging needs of LEP stakeholders and incorporate those needs into specific trainings for FDA employees.
- The Steering Committee will ensure that FDA employees are using specific language assistance procedures covered by the trainings (an FDA Access Plan training team will conduct the assessment).
- The Steering Committee will conduct periodic reviews to evaluate the effectiveness of the LEP training materials and update the materials, as necessary.

Element 7: Assessment: Access and Quality

FDA will regularly assess the accessibility and quality of LEP language services.

FDA plans to conduct periodic reviews to assess the accessibility and quality of language services and related activities. This assessment will include determining whether new documents, Web content, programs, services and activities need to be made accessible to LEP stakeholders. Any new findings will be accompanied by a notice of changes in services to the public as well as supplemental training for FDA personnel on FDA's Web site, as needed.

Action Steps

The Steering Committee will:

1. Serve as a resource for existing language assistance services and monitor changes in stakeholder needs.

2. Oversee FDA capacity to address language access and resource needs.

3. Develop uniform intake and data collection procedures for contact with LEP stakeholders, including standard forms for recording data, and training staff on the procedures.

4. Establish schedules for field reports on data collection results that will be reviewed and analyzed regularly by headquarters (at least twice a year).

5. Assign Language Access Coordinators in each FDA product center, field office, and headquarters. Among other responsibilities, these individuals will:

    - Serve on FDA's Language Access Implementation Team

    - Oversee data collection

    - Coordinate language services for LEP stakeholders

    - Address stakeholder concerns or complaints about the availability and quality of language assistance services

    - Ensure FDA personnel adhere to the procedures outlined in FDA's Language Access Policy and Implementation Plan, including distributing materials to inform staff of language access policies and procedures and

    - Create an annual summary report of FDA progress and compliance with Executive Order 13166.

6. Track and evaluate feedback, including complaints on an annual basis, and integrate concerns into specific program updates to improve services.

7. Identify FDA Web site content development priorities related to LEP stakeholders.

8. Develop a process to evaluate the quality of translated documents.

9. Collaborate with community-based organizations to assist with monitoring the quality of translations of vital documents and non-English Web pages (Element 7).

10. The HHS Office of Civil Rights will assess quality and access regarding complaints received for FDA language services.

Costs

Existing FDA employees and resources will be used.

Monitoring

- The Steering Committee will develop an annual summary report providing evaluation and analysis of current FDA LEP stakeholder language requirements and assess adequacy of existing language services provided by FDA.

Element 8: Stakeholder Consultation

FDA will consult stakeholders in the disease and consumer advocacy communities, in accordance with this and other Federal policies to identify language access needs of LEP stakeholders. FDA's engagement with stakeholders will inform improvements in assessing stakeholder needs and Agency capacity.

Action Steps

1. The Steering Committee, in consultation with the Agency's Office of Health and Constituent Affairs/Office of External Affairs will develop a plan for stakeholder consultation in implementing FDA's Access Plan.

2. A plan for periodic stakeholder consultation will be developed and implemented to assess the adequacy of meaningful access to FDA information by LEP stakeholders.

3. The Steering Committee will seek feedback from advocacy- and community-based organizations about the quality and comprehensiveness of translated FDA documents and translated pages on FDA's Web site.

Costs

Existing FDA employees and resources will be used

Monitoring

Stakeholder feedback will be reviewed to inform ongoing improvements and to assess the adequacy of existing language services provided by FDA.

Element 9: Digital Information

FDA will establish and maintain an infrastructure that effectively distributes information online in a manner to ensure meaningful access by LEP individuals and those in underserved communities.

FDA will develop and maintain a Web site that effectively distributes information to ensure meaningful access by LEP stakeholders.

Action Steps

1. FDA will designate a Language Access Coordinator in each center, field office, and headquarters to serve on the Steering Committee. This person will be responsible for implementing strategies to ensure that FDA's publicly available digital information is accessible to LEP stakeholders and underserved communities. This person will also oversee the placement of links on the FDA Web site to documents that are available for viewing or downloading in languages other than English.

2. The Steering Committee will use and promote the resources on www.lep.gov by providing links to the lep.gov site on FDA's Web site.

3. The Steering Committee will include clearly visible links to key pages of FDA's Web site to direct LEP stakeholders to translated versions of written materials.

4. The Steering Committee will use prominently displayed *taglines* in appropriate languages on FDA's Web site and on other written communications where translations are not available; taglines will inform LEP stakeholders of the availability of oral language assistance and how to access this service.

5. The Steering Committee will explore opportunities to leverage social media to increase awareness of FDA's services and benefits.

Costs

Existing resources from all centers will be used for this project.

Monitoring

- FDA will identify content development priorities and implement them as resources allow.

- FDA will respond to feedback from community-based organizations and LEP stakeholders concerning Web site content.

Element 10: Grant Assurance and Compliance

FDA's Office of Acquisitions and Grants Services and the Steering Committee will work together to review the inclusion of compliance language for grant announcements.

Action Step

The Office of Acquisitions and Grants Services and the Steering Committee will work together to determine the appropriate compliance language for grant announcements relative to LEP stakeholders.

Appendix A: FDA Centers and Office Assessment Survey Template[15]

Limited English Proficient (LEP) population served by FDA

1. **Demography** – An assessment of the number of proportions of Limited English Proficient (LEP) individuals from a particular group served or encountered in the eligible service population may help determine whether language assistance should be provided. The greater the number of proportion of LEP individuals served or encountered, the more likely language services are needed.

   a) Has your Center developed a demographic profile of the population served or likely to be served (by primary language spoken)? YES/NO

   - If YES, list the language groups and the languages you provided.
   - If NO, describe the actions that your Center will implement to improve assessment in this area.

   b) What language services to LEP consumers/patients is your Center providing in other languages?

[15] Edited for future use December 2013.

Service	**Language** Please specify (Spanish, Chinese, etc.)
Articles	
Blogs	
Electronic newsletter	
Guidance(s)	
Infographics	
Podcasts	
Public Service Announcements (PSA)	
Radio	
Television	
Regulations	
Social Media (Facebook, Twitter, You Tube, etc.)	
Telephone Access	
Web casts	
Web content	
Other	

c) Does your Center have a contract with a translation or interpreting company?

- If YES, what is the name of the company and what is the cost (approximately) that your Center is spending yearly on these services?

d) Do you have designated Bilingual Communications Specialists in your Center to ensure regulatory accuracy of translations? YES/NO

- If YES, is the Bilingual Specialist certified by a recognized professional translator organization?

e) List the community-based organizations that your Center partners with to reach out to LEP individuals

2. **Frequency of Contact** – The more frequent the contact with a particular language group, the more likely that enhanced language services in that language are needed. Additionally, agencies may consider whether appropriate outreach to LEP individuals could increase the frequency of contact with LEP language groups.

a) Does your Center have a process for surveying, collecting and/or recording primary language data for individuals that contact your Center? YES/NO

- If YES, describe the categories used in the collection of data, where the data resides, and who can access the data.

- If NO, describe actions that your Center will implement to improve assessment in this area.

3. **Importance** – The more important the activity, information, service or program, or the greater the possible consequences of the contact to the LEP individuals, the more likely language services are needed. You should then determine whether denial or delay of access to services or information could have serious implications for the LEP individual.

a) How does your Center prioritize information for language access that could have potential serious consequences, either positive or negative, for a patient/consumer?

b) Have you determined the impact on actual and potential beneficiaries of delays in the provision of services/information or participation in your programs and/or activities? YES/NO

- If YES, what are they?

- If NO, what actions will your Center implement to improve assessment in this area?

4. **Resources** – Assessment will identify the resources (the institution of reasonable business dollars and personnel) available to ensure the provision of language assistance to LEP individuals participating in your programs and/or activities. The level of resources and the costs may have an impact on the nature of the language assistance provided. Reduction of costs for language services can be accomplished by such options as the use of technology (such as sharing through the internet, telephonic language lines, etc.); the sharing of language assistance material and services among and between recipients, advocacy groups, and Federal grant agencies; and reasonable business practices.

1. Have you identified the resources needed to provide meaningful access for LEP individuals? YES/NO

a. Are those resources currently in place? YES/NO

b. If NO, what actions will your Center implement to improve assessment in the area?

2. Have you identified the points of contact where a LEP individual interacts with your Center? YES/ NO

a. If NO, what action will your Center implement to improve assessment in this area?

3. With whom does your Center contract for language services?

a. In-house (certified language person)

b. Contract

Appendix B: Glossary of Terms

For the purpose of this Access Plan, the terms listed below have the following meanings:

Bilingual/Multilingual Staff

A bilingual/multilingual staff member is one who has demonstrated proficiency in English and at least one other language. The staff member can also interpret accurately, impartially, and effectively to and from such language(s) and English, using any specialized terminology necessary for effective communication, but his or her main job responsibilities are those other than interpretation. An FDA staff member who only has a rudimentary familiarity with a language other than English is not considered *Bilingual/Multilingual Staff* under this Access Plan.

Critical Consumer Information

Critical consumer information is written or oral information that communicates the benefits and risks of FDA-regulated products to health care professionals and patients, especially to LEP and underrepresented populations, including racial subgroups.

Interpreter

An interpreter is a person who has demonstrated proficiency in both spoken English and at least one other language, and who can interpret accurately, impartially, and effectively to and from such language(s) and English using any specialized terminology necessary for effective communication, and who understands interpreter ethics and client confidentiality needs. A person who has rudimentary familiarity with a language other than English would not be considered an interpreter under this Access Plan.

Interpretation

Interpretation involves the immediate oral communication of meaning from one language (the source language) into another (the target language) by an interpreter.

Language Assistance/Language Services

Language assistance/language services is considered all oral and written language services needed to assist LEP stakeholders in communicating effectively with FDA staff to provide LEP stakeholders with meaningful access and an equal opportunity to participate fully in the services FDA administers.

Language Access Coordinator

This individual is responsible for ensuring that his or her respective FDA component adheres to its Access Plan, policy directives, and procedures to provide meaningful access to LEP persons. Coordinators will serve on the HHS OCR Language Access Implementation Team.

Limited English Proficiency

Limited English proficient individual means an individual who does not speak English as his or her primary language and who has a limited ability to read, write, speak, or understand English in a manner that permits him or her to communicate effectively with FDA and have meaningful access to and participate fully in the programs and services FDA administers.

Language Line

A language line is a telephonic interpretation service. Through this mode of interpretation, a language line services interpreter listens to the limited English speaking stakeholder, analyzes the message, and conveys its original meaning to the FDA staff member.

Taglines

Taglines are brief messages in non-English languages that may be included in or attached to a document that is written in English that describe how LEP persons can obtain translations of the document or an interpreter to read or explain the document.

Translation

Translation conveys meaning from written text in one language to written text in another.

Vital Documents

Vital documents include, but are not limited to, FDA fact sheets, consumer critical information, complaint forms, consent/release forms, notices to complainants, and other documents that convey the benefits and risks of drugs and medical products to health care professionals and patients.