FOOD AND DRUG ADMINISTRATION TRANSPARENCY INITIATIVE:

INCREASING PUBLIC ACCESS TO FDA'S COMPLIANCE AND ENFORCEMENT DATA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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EXECUTIVE SUMMARY

On October 3, 2011, the Food and Drug Administration (FDA) issued a report entitled, *Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency's Compliance and Enforcement Data*. The report advanced eight draft proposals for making FDA's publicly available compliance and enforcement data more accessible and user-friendly.[1] Following extensive public comment on the report and internal FDA deliberation, the FDA Commissioner adopted all eight draft proposals,[2] committing FDA to exploring numerous avenues for increasing the transparency and public accessibility of its compliance and enforcement data.[3]

To develop plans for addressing the eight initiatives, FDA established eight working groups with representatives from all of FDA's centers and several of its offices.[4] Each group was asked to draft a report on its initiative and to include recommendations for moving forward. This report is the culmination of all of their efforts. The eight initiatives and the recommendations from the relevant working groups for enhancing the transparency and public accessibility of its compliance and enforcement data are summarized here.

It is critical to note that the Agency's ability to analyze, design, implement, test and document these recommendations depends on the availability of resources.

Background

As part of its mission to protect public health, FDA is responsible for a broad range of compliance and enforcement activities, such as inspecting and follow-up with manufacturing facilities, to ensure compliance with relevant statutes and regulations. FDA is committed to increasing the transparency of these activities with the goal of enhancing the public's understanding of FDA's decisions, promoting the accountability of FDA, and fostering an understanding among regulated industry about the need for consistently safe and high-quality products.

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[1] The 2011 report is available at http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf. Accessed September 19, 2013.

[2] See the January 31, 2012, report, *Exploratory Program to Increase Access to the Agency's Compliance and Enforcement Data*.

[3] See http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm289638.htm. Accessed September 19, 2013.

[4] Represented offices include FDA's Office of Regulatory Affairs, Office of Information Management, Office of External Affairs, Office of Foods, and Office of Policy.

FDA's compliance and enforcement activities involve the collection of huge amounts of information about FDA-regulated manufacturing facilities and the products they manufacture. Manufacturers submit some of these data to fulfill their requirement to register their facilities and list their products with FDA; FDA generates much of these data during facility inspections. Data may relate to observations made during inspections and, when necessary, regulatory actions FDA takes, such as issuing Warning Letters. FDA makes substantial amounts of this information available to the public without disclosing ongoing investigations, trade secrets, confidential commercial information, the existence of marketing applications, or other non-public information.

It is critical that these compliance and enforcement data be of the highest quality. Not only do high-quality data enhance the efficiency of FDA's decision-making and the validity of FDA actions, but such data also assist the public and Agency stakeholders in making informed decisions about the products FDA regulates. Thus, the data FDA makes publicly available must also be presented in a fashion that enables efficient use.

FDA faces numerous challenges as it works to successfully receive, maintain, and make publicly available compliance and enforcement data. Key challenges include problems attributable to the multiple and disparate automated and manual systems that have developed over time to receive and maintain the data due to the Agency's transition from paper-based to electronic recordkeeping practices. Despite these challenges, however, FDA is working to improve the quality, consistency, and timeliness of its compliance and enforcement data and to make its compliance and enforcement activities more transparent.

This report explains the findings and recommendations of the FDA working groups tasked with exploring how best to implement the eight initiatives adopted by the FDA Commissioner. The eight initiatives and Working Group recommendations are summarized here.

***Initiative 1*:**

FDA will explore different ways to improve data quality and facilitate more timely data disclosure by expediting data entry, expediting inspection review and classification, and/or updating the data more frequently. Tools to improve data quality and speed data disclosure may include, for example, providing new technologies to investigators, introducing other process improvements, and/or implementing administrative incentives. To implement these types of tools effectively, FDA also will explore how frequently data should be updated in order for it to be useful to stakeholders.

To improve the quality, consistency, and timeliness of FDA's compliance and enforcement data, the Working Group for Initiative 1 advanced recommendations for improving Master Data Management (MDM) and enhancing FDA's IT capacity. FDA should implement MDM improvements by consolidating, coordinating, and synchronizing basic facility-identifying data in one place and by linking information about each FDA-regulated facility to a single identifier (UFI) as proposed in the September 2013 Draft Guidance for Industry, "Specification of the Unique Facility

Identifier (UFI) System for Drug Establishment Registration".[5] This UFI will create a single authoritative source for facility-identifying information and eliminate the current multiple and disparate versions of data identifying the same facility in FDA data systems. This effort would build on data harmonization efforts already under way in some FDA centers. However, implementing the compatibility to extract this information once the UFI is assigned remains a lengthy and resource-intensive project.

New electronic tools should be deployed—including portable high-speed scanners for onsite document scanning, voice recognition software, mobile computing devices, and an electronic questionnaire interface to collect inspection information—to increase the efficiency and effectiveness of its inspectional processes.

The Working Group recommends adoption of new transmission standards and procedures to enable manufacturing facilities to electronically submit compliance and enforcement information to FDA. New standards and procedures will also foster the inspectors' use of standardized electronic forms based on control questions to facilitate submission of inspectional data. Inspectors should also be able to electronically transmit identified potential violations. The Working Group recommendations follow:

1. *FDA should continue efforts to consolidate basic facility information in one place, establishing a single authoritative source for facility identifying information.*
2. *FDA should embrace Master Data Management as an implementation priority.*
3. *FDA should expand and standardize the electronic tools and procedures available to FDA staff.*
4. *FDA should continually assess the utility of its electronic tools to support enhanced investigator efficiency.*
5. *FDA should consider system changes that enable facilities to submit their compliance and enforcement information electronically.*
6. *FDA should consider using standardized investigator forms to help promote reporting consistency.*

[5] See http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm367199.pdf.

***Initiative 2*:**

Although FDA's inspections database Web page currently provides an e-mail address where stakeholders can submit questions about the database, FDA will explore whether (1) reporting buttons, or other tools specifically focused on error reporting, would allow stakeholders to more easily identify potential errors in compliance and enforcement data, and (2) the Agency can implement procedures for investigating potential errors and correcting data, when appropriate, that would enable the Agency to remedy the errors more expeditiously.

Error reporting buttons allow users to click a radio button on a Web page to automatically report data errors. Based on its review, the Working Group for Initiative 2 concluded that, although some aspects of error reporting buttons might prove beneficial in the future, (1) current error reporting capability that relies on FDA centers/offices to determine how to investigate and follow-up on submitted error reports is sufficient and gives the public several ways for easily reporting potential compliance and enforcement data errors to FDA; (2) FDA center and office processes for investigating potential errors are responsive and adequate; and (3) FDA's current processes enable quick updating of data errors. In addition, reports from FDA staff routinely communicating with the public about compliance and enforcement data reveal that the public does not apparently perceive current error reporting options as insufficient or difficult to use.

Nonetheless, if FDA decides to revisit this issue, the Working Group proposes that FDA consider instituting immediately effective automated data refreshes of the compliance and enforcement data FDA makes available on its public and internal Web sites. Refreshes would be error-correcting to the extent that they would cleanse those Web sites of outdated data.

Because Tools and Processes were considered adequate, Working Group 2 had no recommendations at this time.

***Initiative 3*:**

FDA will explore how to present its compliance and enforcement data graphically and better utilize mobile Web applications to draw more users to its compliance and enforcement Web pages and to encourage data analysis.

FDA discloses significant amounts of compliance and enforcement data from multiple sources in a variety of formats, including spreadsheets, Web pages, and searchable databases. FDA has also posted such data in graphic form. For example, graphs of annual enforcement statistics, including warning letters, recalls, injunctions, seizures, and civil money penalties, are available on the Web site. Additional graphs depicting FDA performance for inspections, warning letters, and recalls are available on FDA Track. FDA uses graphs, tables, and downloadable datasets to present information on the types of regulatory violations investigators observed on FDA Forms 483 as well as quality systems violations cited in Warning Letters. Despite all such efforts, however, there may be ways to enhance transparency via the use of more graphical representations of compliance and enforcement data.

Although the Center for Devices and Radiologic Health (CDRH) features a mobile app that shares device recall and adverse event information and CDRH is developing another app for reporting adverse event information, the Working Group initially concluded that FDA's Web sites generally were not formatted for use on mobile devices and thus did not qualify as mobile-friendly environments. However, FDA launched a mobile Web site in November 2013. Initially, content on this site is limited to information of key interest to the public, such as consumer updates, recalls, safety alerts, and news releases.

The Working Group believes that a stakeholder needs assessment should be undertaken to determine which compliance and enforcement data will benefit from graphical display or a mobile Web application, and feedback should be solicited from regulated industry and other stakeholders before moving forward with the development of mobile applications. Finally, FDA should investigate the use of quick response (QR) codes, *a type of two-dimensional/matrix barcode that typically allows a user to scan to receive additional information, usually by opening up a URL on the Web where dedicated content can be displayed.*

Working Group 3 recommends the following:

1. *A centralized entity should be responsible for the Knowledge Management required for transferring lessons learned from ongoing initiatives that graphically present compliance and enforcement data, develop mobile Web applications, or support data analysis.*
2. *Modifications and updates to ORA's Inspection Observation Database should be assessed and modifications made to encourage and assist users in data analysis. Currently, the site provides information on inspectional observations by fiscal year and in a downloadable data set.*
3. *FDA should consider additional usability efforts to enhance the navigation of its Web sites and make compliance and enforcement data more accessible.*
4. *A stakeholder needs assessment should be performed to determine which data would benefit from graphical display or a mobile Web application.*
5. *Additional feedback should be solicited from regulated industry and other stakeholders before moving forward with the development of mobile applications.*
6. *Now that it has developed a mobile Web site, FDA should evaluate the use of QR codes,.*
7. *The Working Group for Initiative 3 also adopts and incorporates by reference the following recommendations advanced by the Working Group for Initiative 4:*
    - *Consider implementing a dashboard tool to present compliance and enforcement data in a user-friendly manner*
    - *Establish an editorial board to manage and curate the page devoted to compliance and enforcement at www.fda.gov/iceci site to better integrate and limit duplicative postings of FDA's compliance and enforcement data.*

***Initiative 4*:**

FDA will explore whether it can better integrate its compliance and enforcement data, as well as its other publicly available data on regulated firms, to make the data more user-friendly and easier to analyze.

The Working Group for Initiative 4 concluded that FDA's compliance and enforcement data systems/databases can be better integrated to enable easier data extraction. Accomplishing this is important, not only to FDA's internal and external stakeholders, but also to its effective and efficient use of the information to achieve its public health and regulatory missions.

FDA's many compliance and enforcement databases and systems are located at the Agency level (i.e., owned and operated by FDA's Office of Regulatory Affairs or ORA) and at center-specific and local (i.e., intra-center) levels. Greater integration of compliance and enforcement data residing in multiple systems could yield significant benefits, including elimination of duplication and redundancy; diminished need for inefficient, costly, labor-intensive, and time-consuming manual data entries and manipulations; reduced potential for conflicting and erroneous data; and enhanced ability to make important linkages that can currently require advanced skills with the various FDA reporting tools and knowledge of the databases. Developing customized views and reports would assist in FDA's efforts to improve data quality and timeliness, resulting in more efficient and expeditious data analyses, which, in turn, would substantially contribute to better-informed and more efficient compliance and enforcement decision-making.

The Working Group for Initiative 4 concluded that better integration and consistency of compliance and enforcement data are also needed on FDA's Web sites. FDA's Web page development, posting, and communications processes remain largely decentralized, with each center deciding what compliance and enforcement data it will post on its Web site. It is currently difficult to locate FDA's numerous Web site postings of compliance and enforcement data because they are not organized in an integrated fashion, and navigation throughout the Web site for such data is neither intuitive nor user-friendly.

Recommendations from the Working Group for Initiative 4 include the following:

1. *FDA should implement a dashboard tool to enable presentation of compliance and enforcement data in a user-friendly manner.*
2. *FDA should provide additional funding for the Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS) (a data mart) to enhance integration of the compliance and enforcement data available in its siloed data universes.*
3. *FDA should empanel a board to study and advance recommendations to enhance navigation of the Web sites that make compliance and enforcement data available.*
4. *FDA should establish and support an editorial board for the agency-wide compliance and enforcement Web page (i.e., www.fda.gov/iceci) to improve access to all of FDA's posted compliance and enforcement data.*

***Initiative 5*:**

FDA will explore whether additional, or more specific search criteria (*e.g.*, criteria that would enable individual product-specific or violation-specific searches), or more sophisticated search capability (e.g., predictive name searches) would make the inspections database more user-friendly and the data easier to analyze.

FDA's compliance and enforcement databases often present users with limited descriptions of searchable fields to assist them in effectively finding information of interest. Additionally, text required to initiate searches must be spelled correctly to avoid returning no or erroneous results, with only minimal allowance of variable or incorrect spellings.

Providing inspection information in a searchable format could greatly assist the regulated industry and the public at large in researching and monitoring the results of inspections of firms manufacturing and distributing FDA-regulated products. Inspectional results are a key indicator of a firm's compliance with laws and regulations FDA enforces to ensure the safety of those products. Results that cannot be searched may obscure or lead to misinterpretation of a regulated firm's compliance status. For example, a search for one or more inspections using a misspelled firm or facility name that yielded no results could suggest that no relevant inspections had been performed when, in fact, one or more had.

The Working Group for Initiative 5 believes that current methods for searching inspections can be improved. For example, dashboards, application programming interfaces (API), and predictive search and predictive text can contribute substantially to external users' search capabilities.

Despite formidable challenges to implementation, the Working Group makes the following recommendations:

1. *FDA should implement the use of dashboards to enhance search capability.*
2. *FDA should expand the use of application programming interfaces.*
3. *FDA should make predictive search/predictive text capability available.*

***Initiative 6*:**

FDA will explore whether posting additional data compilations or analysis, such as the Agency's most common inspections observations or the warning letter compilations, both of which it already posts, would increase transparency or better inform the Agency's own compliance efforts.

A significant amount of Agency-wide and center- and office-specific compliance and enforcement data is currently available on FDA's Web site, and some of these data are posted as compilations or analyses. The Working Group for Initiative 6 concluded that posting compilations or analyses of compliance and enforcement data is important because not all users

have the capability or resources to independently analyze raw data. Although existing compilation or analysis data appeared to provide a suitable overview of FDA compliance and enforcement activities, the Working Group noted some gaps, especially related to inspections.

Working Group 6 makes the following recommendations:

1. *Data should be updated regularly.*
2. *FDA should expand the amount of compliance and enforcement data it makes available in the form of compilations and analyses.*

***Initiative 7*:**

FDA will explore ways to make better use of social media, such as Facebook and Twitter, as well as Agency-sponsored webinars and automatic e-mail notifications to better communicate with the public about its compliance and enforcement efforts.

FDA has increasingly recognized the potential of *social media* to offer the public important health-related information, and various FDA components maintain social media. FDA's offices and centers currently share compliance and enforcement information with the public via a variety of social media outlets, including Facebook, Twitter, FlickR, and YouTube. FDA reaches consumers, patients, health care associations, nonprofit organizations advocating or exchanging information about specific health issues, health care professionals, and others. FDA also communicates with the public through a blog (FDAVoice); e-mail (automatic email notifications are available through subscriptions); and Webinars (which provide a variety of information of interest to stakeholders and sometimes opportunities to hear and pose questions to FDA officials).

Recently, in response to new social media strategies, FDA has experienced steady and dramatic increases in social media engagement and response (e.g., from April 2012 to April 2013 Twitter followers increased 261%; YouTube uploads increased more than 78%). However, use of social media to communicate about compliance and enforcement matters has been limited. FDA should develop a strategy for increasing the dissemination of compliance and enforcement data through social media. This could enlarge the audience for such information to approximately 600,000 people while advancing the President's Executive Orders on Transparency and Digital Government. Finally, FDA should make more use of its subject matter experts when posting responses to questions posed by social media recipients of FDA's compliance and enforcement data. In light of these findings, Working Group 7 recommends the following:

1. *FDA should establish and implement a strategy to increase the dissemination of and audience for FDA compliance and enforcement data through social media.*
2. *FDA should enlist the assistance of its subject matter experts when responding to questions using social media.*

***Initiative 8*:**

FDA will provide appropriate context for the compliance and enforcement data that it discloses to help ensure that the data are not misinterpreted or misused. Depending on the circumstances, appropriate contextual information may include, without limitation:

- Information regarding how frequently the data are updated,
- Information regarding the reliability of the data,
- Information regarding the average lapse of time between the inspection and the posting of inspection classification information,
- Definitions of inspection classification types (i.e., official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI)), and
- A statement explaining that the Web site's lack of information regarding a particular facility does not imply compliance or non-compliance (i.e., users should not infer that facilities that have not been inspected recently, or at all, are (or are not) in compliance with FDA laws and regulations).

The Working Group for Initiative 8 found that contextual information pertaining to some of FDA's inspectional databases was sometimes difficult to locate, and compliance and enforcement data generally could be made more prominent on its Web site. The current location of key information—accessible from the Transparency Initiative Web site— is neither intuitive nor user-friendly. Given the importance of and public interest in posted compliance and enforcement data, this information should be accessible from FDA's homepage .

Because compliance and inspection information is posted in many different forms on many different Web pages (i.e., Agency-wide, center- and office-managed Web sites), an editorial board should be created to maintain and curate the page devoted to compliance and enforcement found at www.fda.gov/iceci. This page should be prominently linked from the main FDA Web site as well as on each Center's product-specific tab of the main FDA Web site. This page should be all-inclusive and provide links to all enforcement data posted on FDA's various sites, regardless of the data's source, and FDA centers that operate and maintain compliance and enforcement Web pages should link to the main Agency-wide page. To foster transparency and encourage a greater understanding of how FDA's regulatory and enforcement activities advance its mission to protect public health, compliance and enforcement data should be easy to find, appropriately contextualized, and fully accessible. Working Group 8 makes the following recommendations:

1. *FDA should create a frequently asked questions (FAQ) guidance document to provide appropriate definitions and context for compliance and enforcement data.*
2. *FDA should make the compliance and enforcement data it discloses more prominent on its Web site.*
3. *FDA should improve the organization and consistency of its posted compliance and enforcement data and develop an editorial board dedicated to the main compliance and inspection data Web site (www.fda.gov/iceci). This Web page should be clearly accessible from the primary FDA Web site and contain links to all such available data FDA discloses.*

INCREASING PUBLIC ACCESS TO FDA'S COMPLIANCE AND ENFORCEMENT DATA

BACKGROUND

As part of its mission to protect public health, FDA is responsible for a broad range of compliance and enforcement activities, such as inspecting manufacturing facilities to ensure compliance with relevant statutes and regulations. FDA is committed to increasing the transparency of these activities with the goal of enhancing the public's understanding of FDA's decisions, promoting the accountability of FDA, and fostering an understanding among regulated industry about the need for consistently safe and high-quality products.

FDA's compliance and enforcement activities involve the collection of huge amounts of information about FDA-regulated manufacturing facilities and the products they manufacture. Manufacturers submit some of these data to fulfill their requirement to register their facilities and list their products with FDA; FDA generates much of these data during facility inspections. The data may involve documentation of observations made during inspections and, when necessary, of regulatory actions taken, such as issuing Warning Letters. FDA makes substantial amounts of this information available to the public.

Having access to high-quality compliance and enforcement data is critical to FDA staff as they make regulatory decisions, and these data can also be very useful to the public as they make decisions about which medical products to purchase and use. However, to maximize its usefulness, the data must be accurate, up-to-date, understandable, and easily accessible. FDA is working to improve the quality, consistency, and timely availability of its compliance and enforcement data and to make its many compliance and enforcement activities transparent.

On October 3, 2011, the Food and Drug Administration (FDA) issued a report entitled, *Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency's Compliance and Enforcement Data*, which advanced eight draft proposals to make FDA's publicly available compliance and enforcement data more accessible and user-friendly.[6] In announcing the availability of this report, FDA sought public comment on these proposals by December 2, 2011.[7]

Following a review of public comments submitted in response to the 2011 report and recommendations from the Transparency Task Force, on January 31, 2012, FDA issued a follow-up report (*Exploratory Program to Increase Access to the Agency's Compliance and Enforcement Data)*, in which FDA's Commissioner adopted all eight draft proposals, thereby committing FDA to exploring numerous avenues for increasing the transparency and public

[6] See http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf. Accessed September 19, 2013.

[7] See 76 *Federal Register* 61367 (October 4, 2011).

accessibility of its compliance and enforcement data.[8] The eight initiatives the Commissioner directed be explored are as follows:

Initiative 1: FDA will explore different ways to improve data quality and facilitate more timely data disclosure by expediting data entry, expediting inspection review and classification, and/or updating the data more frequently. Tools to improve data quality and speed data disclosure may include, for example, providing new technologies to investigators, introducing other process improvements, and/or implementing administrative incentives. To implement these types of tools effectively, FDA also will explore how frequently data should be updated in order for it to be useful to stakeholders.

Initiative 2: Although FDA's inspections database Web page currently provides an e-mail address where stakeholders can submit questions about the database, FDA will explore whether: (1) reporting buttons, or other tools specifically focused on error reporting, would allow stakeholders to more easily identify potential errors in compliance and enforcement data, and (2) the Agency can implement procedures for investigating potential errors and correcting data, when appropriate, that would enable the Agency to remedy the errors more expeditiously.

Initiative 3: FDA will explore how to present its compliance and enforcement data graphically and better utilize mobile Web applications to draw more users to its compliance and enforcement Web pages, and to encourage data analysis.

Initiative 4: FDA will explore whether it can better integrate its compliance and enforcement data, as well as its other publicly available data on regulated firms, to make the data more user-friendly and easier to analyze.

Initiative 5: FDA will explore whether additional, or more specific search criteria (*e.g.*, criteria that would enable individual product-specific or violation-specific searches), or more sophisticated search capability (*e.g.*, predictive name searches) would make the inspections database more user-friendly and the data easier to analyze.

Initiative 6: FDA will explore whether posting additional data compilations or analysis, such as the Agency's most common inspections observations or the warning letter compilations, both of which it already posts, would increase transparency or better inform the Agency's own compliance efforts.

Initiative 7: FDA will explore ways to better utilize social media, such as Facebook and Twitter, as well as Agency-sponsored webinars and automatic e-mail notifications, to better communicate with the public regarding its compliance and enforcement efforts.

Initiative 8: FDA will provide appropriate context for the compliance and enforcement data that it discloses, to help ensure that the data is not misinterpreted or

[8] See http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm289638.htm. Accessed September 19, 2013.

misused. Depending upon the circumstances, appropriate contextual information may include, for example:

- Information regarding how frequently the data is updated
- Information regarding the reliability of the data
- Information regarding the average lapse of time between the inspection and the posting of inspection classification information
- Definitions of inspection classification types (i.e., official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI))
- A statement explaining that the Web site's lack of information regarding a particular facility does not imply compliance or non-compliance (i.e., users should not infer that facilities that have not been inspected recently, or at all, are (or are not) in compliance with FDA's laws and regulations).

To develop plans for addressing the eight initiatives, FDA established eight working groups with representatives from all of FDA's centers and several of its offices.[9] Each group was asked to draft a report on its initiative and to include recommendations for moving forward. This report is the culmination of all of their efforts. In the eight sections that follow, each working group responds to its initiative with pertinent observations, conclusions, and recommendations to enhance the transparency and public accessibility of its compliance and enforcement data.

It is important to note that successful implementation of the recommendations developed for this report is subject to the availability of resources. All of the recommendations advanced in this report are being referred to the Transparency Task Force, which, after assessing their relative priority in the context of one another as well as other Agency priorities, will consult with senior FDA leadership about the feasibility of implementing them to the extent available resources permit.

[9] Represented offices include FDA's Office of Regulatory Affairs, Office of Information Management, Office of External Affairs, Office of Foods, and Office of Policy.

Initiative 1

FDA will explore different ways to improve data quality and facilitate more timely data disclosure by expediting data entry, expediting inspection review and classification, and/or updating the data more frequently. Tools to improve data quality and speed data disclosure may include, for example, providing new technologies to investigators, introducing other process improvements, and/or implementing administrative incentives. To implement these types of tools effectively, FDA also will explore how frequently data should be updated in order for it to be useful to stakeholders.

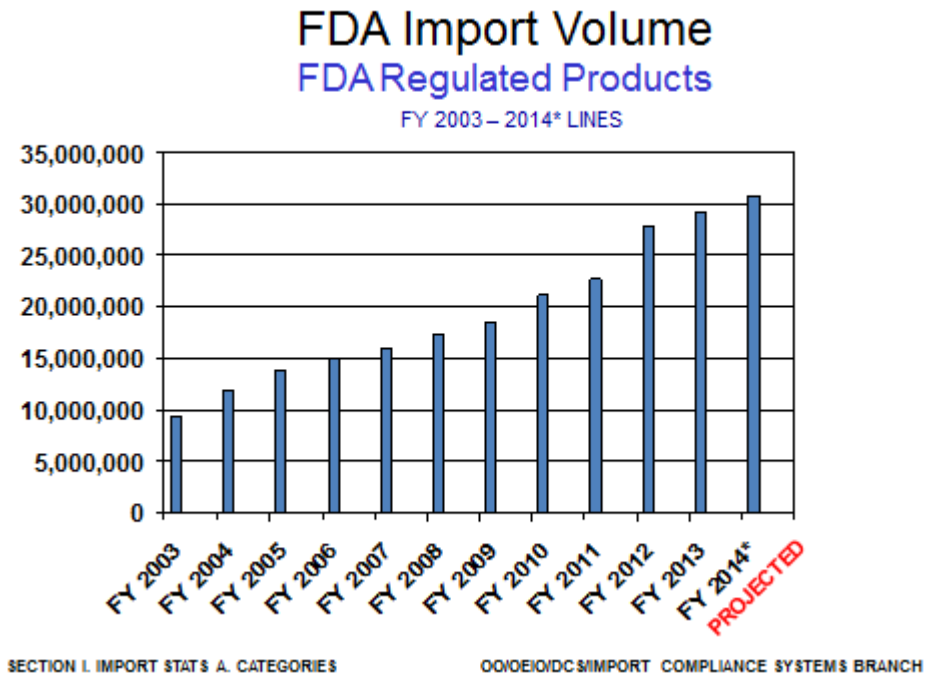
Background and Overview

FDA staff, consumers, patients, their caregivers, health care professionals, and other stakeholders need up-to-date, understandable, and easily accessible science-based information about the safety and quality of medical products. Improving the quality, availability, and timely availability of FDA's compliance and enforcement data will assist FDA staff as they make regulatory decisions. It will also be useful to the public and relevant stakeholders to make informed decisions about the safety and quality of the medical products they use. Compliance and enforcement data may even be useful in fostering innovation and improved quality in the manufacture of medical products.

Recent legislation, including the Food Safety Modernization Act (FSMA)[10] and the Food and Drug Administration Safety and Innovation Act (FDASIA),[11] have emphasized the importance of developing and sustaining an FDA data environment capable of meeting the regulatory and public health challenges posed by an ever growing and increasingly globalized marketplace. It is now quite common for FDA compliance and enforcement activities to involve drugs, devices, and foods that contain components or elements manufactured in different states, regions, and countries, as reflected in the following graph. Increasing importation of an array of products from different countries, some of which have varying public health standards, poses increasing challenges for FDA personnel and systems.

[10] Public Law 111-353 (January 4, 2011).

[11] Public Law 112–144 (July 9, 2012).



A. Challenges to Quality/Timeliness of Compliance and Enforcement Data

It is critically important to FDA's mission to be able to properly identify the manufacturers and processors of the products that FDA regulates. FDA uses a variety of data on the firms within the medical product supply chain to evaluate the potential for safety risks related to the medical products they manufacture. However, FDA faces substantial challenges as it collects and maintains information about these facilities. One challenge results from the fact that, increasingly, facility and product registration information is difficult to present to the public in the U.S., because it is submitted to FDA from countries where the primary spoken language is not English, and the submitter's information or descriptions are not always suitable. Further, the audience for the information is not limited to U.S. residents or native English speakers, and it is a challenge to present the information in languages for all audiences. Another key challenge relates to problems due to the Agency's transition from paper-based to electronic recordkeeping practices and the multiple and disparate systems that have developed over time to receive and maintain the data. Currently, each FDA program area manages its own facility data systems. As a result, often multiple records are generated on the same facility, using different data standards, elements, and identifiers**.**

The Agency is working to harmonize identification and tracking of FDA-regulated products across the Agency to seamlessly associate them with related facilities. For example, FDA's Center for Food Safety and Nutrition (CFSAN) and its Center for Devices and Radiological Health (CDRH) use the FDA Unified Registration and Listing System (FURLS), created in 2003 to centralize facility registration. In 2008, the Harmonized Inventory Project implemented a common registration system, known as eLIST, for use in the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for

Veterinary Medicine (CVM).[12] A key FDA goal remains to facilitate legacy data cleanup efforts and eliminate duplication.

For another example, FDA has published a draft Guidance for Industry in September 2013 on "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration" where, for drug establishment registration, FDA specified a UFI System. At this time, FDA's preferred UFI for a drug establishment is the Data Universal Numbering System D-U-N-S (DUNS) number, assigned and managed by Dun and Bradstreet. The FDA has been using the DUNS number as a registration number for drug establishments since the implementation of electronic drug registration and listing for information on the electronic submission of registration and listing data.[13]

FDA's Office of Regulatory Affairs' (ORA's) Regulatory Business Information Services (RBIS) investment supports the integration and cleanup of FDA data on regulated manufacturing facilities through its pioneering data quality system, the Firms Master List Services (FMLS). This system pulls together data from multiple sources, including FURLS, Food Firm Registration Module (FFRM) as well as other FDA data systems.[14] FMLS also helps to integrate data on establishments with Dun & Bradstreet (D&B) information that uses D&B matching to associate its Firm Master List records with D&B records (identified by Data Universal Numbering System or DUNS numbers[15]). Thus, ORA's FMLS system is helping reduce redundancy in FDA's data on establishments.

ORA has also recently embarked on creating a golden copy (a master record of data on a facility) by adopting modern technologies such as Master Data Management (MDM). MDM is a comprehensive method enabling linkages of critical data to one file, called a master file, which provides a common point of reference. Again, the objective is to reduce the use of multiple and potentially inconsistent versions of the same master data in different parts of FDA's data systems. ORA has developed an MDM strategy and roadmap within the last few months and is currently beginning work to implement an MDM pilot. Once a golden copy of a record is created, it can be made available for use in all concerned systems across FDA.

B. Timeliness/Efficiency of Regulatory Decision-Making with Paper-Based Recording Processes.

Compliance and enforcement processes were generally established using mainly paper processing, and much of the information tracked by the applications and databases FDA has used over the past 20 years remains in hard copy form. Historically, many types of compliance and enforcement communications FDA issues to facilities have been and continue to be by paper. For example, at the conclusion of a facility inspection, the FDA investigators provide written observations in paper form to the facility on a FDA Form 483. Likewise, an establishment's

[12] Data standards councils are another area of emphasis beginning to quantify real gains in improving data quality and in turn accessibility. In this context, FDA's Data Standards Council serves as FDA's coordinator for health and regulatory information standardization.

[13] See http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm367199.pdf.

[14] These include OASIS/MARCS Imports and FACTS/MARCS, data systems that are described in the discussion of Initiative 4 below.

[15] DUNS numbers are unique nine-digit sequences D&B provides to identify facility sites.

routine response to FDA observations (including Warning Letters), as well as documents FDA requests from facilities concerning their voluntary recall of products they have distributed, are usually provided on paper.

This paper-based approach has required FDA to expend valuable resources entering data and confirming data accuracy, completeness, and overall quality. Multiple FDA personnel often access and review paper submissions. Upon receipt by FDA, paper submissions must be processed, copied, and distributed, or the submissions may be converted into an electronic format or scanned for further distribution. The time and resources required for these activities are an inefficient use of FDA's workforce.

Decisions about whether compliance and enforcement data related to a submission can be disclosed can also be affected by the time it takes FDA to complete its review. Therefore, any time that can be conserved in the handling of the submissions can speed public access to FDA's compliance and enforcement data.

Recommendations

Building on the foundation of productive efforts already underway in FDA, the Working Group for Initiative 1 arrived at recommendations in the following areas to advance data quality and timeliness and increase efficiency:

- Master Data Management
- IT enhancements (i.e., electronic tools and transmission standards and procedures)

For each area of emphasis, the Working Group identified a number of opportunities to leverage existing projects and initiatives and fill gaps that exist in current data-related processes.

Master Data Management

1. *FDA should continue efforts to consolidate basic facility information in one place, establishing a single authoritative source for facility identifying information*

As discussed previously, FDA has retained the services of Dun & Bradstreet to assist with the effort to address the issues of data quality and timeliness of data disclosure to implement Master Data Management (MDM) for facility identification and verification. This work should continue with the goal of establishing a single authoritative source for facility-identifying information and providing opportunities for linking information about each facility to the same unique identifier so that all information can be easily brought forward for quality control and regulatory decision-making.[16] Implementation of section 701 of the recently passed Food and Drug Administration Safety Innovation Act (FDASIA), which requires a unique facility identifier (UFI) for drug establishment and drug importer registration and for drug importers, should greatly advance this effort. In September of 2013, the Agency issued a draft guidance specifying the UFI.[17]

[16] One challenge that may affect the consolidation of basic facility information is the lack of registration and listing requirements in some program areas. For example, currently, retail establishments that sell regulated tobacco products are not required to register; therefore, obtaining this information is resource-intensive.

[17] See http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm367199.pdf. FDA has chosen the Data Universal Numbering System (DUNS) as the basis for the UFI.

2. *FDA should embrace Master Data Management (MDM) as an implementation priority.*

The Working Group recommends that FDA embrace MDM as an implementation priority, incorporating key master data attributes, including name, address, contact information, geocodes, and possibly product-line(s) involved or type of activities undertaken at the facility. Adoption of this recommendation would improve FDA's current systems and practices by consolidating basic facility identification information in one place and eliminating the use of multiple and potentially inconsistent versions of the same facility-identifying master data in FDA data systems.

IT Enhancements

3. *FDA should expand and standardize the electronic tools and procedures available to FDA staff.*

The transition from paper and manual processes to completely electronic ones to track compliance and enforcement information and perform work and make decisions based on this information would increase that information's quality and timeliness. Enlarging and standardizing the types and range of electronic tools and procedures available to FDA personnel could considerably advance achievement of these objectives.

Investigators need a tool set that will allow them to effectively and efficiently conduct inspections and create, store, and transmit inspectional information in a timely manner. CDRH's Mammography Program Reporting and Information (MPRIS) database, which supports the statutorily mandated responsibility for certification and inspection of all mammography facilities in the United States under the Mammography Quality Standards Act (MQSA), is exemplary. MPRIS allows for the creation, storage, and transmittal of inspectional information in an efficient and effective manner from the inspection site in real-time. The availability of portable high-speed scanners for onsite document scanning would reduce or eliminate the need to physically transport paper documents, improve the security of the information, and eliminate the need for physical document storage. Voice recognition software offers another option for the transition of inspectional information into institutional electronic environments.

The Working Group also recommends that increased electronic tool capability be augmented by an electronic decision tree, "roadmap style" rational questionnaire interface to help streamline collection of inspection information. The collection tools identified above could help generate work products with minimal investigator time (e.g., Establishment Inspection Reports). The Center for Tobacco's (CTP's) Tobacco Inspection Management System (TIMS) inspection tool set is a good example of a streamlined inspection system using smartphones to electronically capture discrete information and images. The system has the added ability to transmit the data wirelessly from the field to FDA data centers.[18]

4. *FDA should continually assess the utility of its electronic tools to support enhanced investigator efficiency.*

To increase investigator efficiency and productivity, expedite the development and transmission of regulatory documents for faster review times, and foster greater consistency in the inspection process, FDA should continuously assess the utility of its electronic tools by identifying

[18] ORA recently piloted the use of electronic tablets for use on poultry inspections using a custom data collection tool.

potentially useful new tools as they become available and periodically updating them as needed and improving electronic tools already being utilized.

5. *FDA should consider system changes to enable facilities to submit their compliance and enforcement information electronically*

The Working Group recommends that FDA consider system changes that enable manufacturing facilities to submit their compliance and enforcement information electronically. Permitting routine electronic submission of compliance and enforcement data by facilities (e.g., responses to inspections and warning letters, or recall notifications and supporting documentation) would reduce the need for manual entry and enable multiple stakeholders immediate access to such information. This would additionally give FDA staff charged with its review rapid access to the information and increase the timeliness of FDA's public disclosure of compliance and enforcement data to the extent it is publicly releasable.

FDA's electronic receipt of information from facilities would not be precedent-setting. To the contrary, FDA currently receives several industry submissions in electronic form, including medical product marketing applications and reports of product-associated adverse events and some manufacturing deviations. FDA maintains an Electronic Submissions Gateway for some electronic submissions. The Working Group believes that the Gateway could also be used for the electronic submissions of facilities' compliance and enforcement information that are currently submitted on paper.[19] Additional resources would be needed to design and maintain the electronic repository required to accept and store the submissions and to perform outreach to establishments on the new submission procedures.

6. FDA should consider using standardized investigator forms to help promote reporting consistency.

The inspection forms could vary according to inspection type or focused areas of concern (e.g., identification of NAIs,[20] VAI,[21] or OAIs[22]) and be structured based on responses to control questions that alert investigators and reviewers to potential violations. (The Working Group acknowledges that standardized forms will not be appropriate for all inspection types, particularly complex inspections requiring a great deal of individualized attention.)

Electronic formatting of standardized forms could enable investigators to immediately forward inspection results to their division offices for review. The structure of the electronic forms could

[19] For more on the Gateway, see http://www.fda.gov/forIndustry/ElectronicSubmissionsGateway/default.htm. Accessed September 19, 2013.

[20] A *no action indicated* (NAI) inspection classification occurs when no objectionable conditions or practices were found during the inspection, or the significance of the documented objectionable conditions found does not justify further actions.

[21] A *voluntary action indicated* (VAI) inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance. Inspections classified with VAI violations are typically more technical violations of the Food, Drug, and Cosmetic Act.

[22] An *other action indicated* (OAI) inspection classification occurs when significant objectionable conditions or practices were found and regulatory action is warranted to address the establishment's lack of compliance with statutory or regulatory requirements.

be user-friendly and would require minimal training to implement. Forms could also be designed to pose follow-up questions depending on answers to prior questions. The Working Group recognizes, however, that implementing this recommendation would require a great deal of development, design, and equipment.

INITIATIVE 2

Although FDA's inspections database Web page currently provides an e-mail address where stakeholders can submit questions about the database, FDA will explore whether (1) reporting buttons, or other tools specifically focused on error reporting, would allow stakeholders to more easily identify potential errors in compliance and enforcement data, and (2) the Agency can implement procedures for investigating potential errors and correcting data, when appropriate, that would enable the Agency to remedy the errors more expeditiously.

Background and Overview

A. Adequacy of Current Tools for Correcting Database Errors

Other U.S. government agencies, including the Environmental Protection Agency (EPA),[23] have used error reporting *buttons* that make it possible for users of their compliance and enforcement databases to report data errors. Error reporting buttons enable users to click a radio button on a Web page to automatically report data errors. EPA's error reporting buttons associate error reports with specific entries in an enforcement and compliance database. These reports are then routed to the office managing the database for review and follow-up.

The Working Group for Initiative 2 has carefully analyzed the pros, cons, and feasibility of installing error button capability. The Group has concluded that, although some aspects of error buttons might prove beneficial in the future, (1) FDA's current error reporting capabilities offer the public several ways to easily report potential errors to FDA; (2) FDA center and office processes for investigating potential errors are responsive and sufficient; and (3) FDA's current processes allow data errors to be quickly updated both internally and on its public Web site.

FDA enforcement and compliance databases displaying information on its public Web site include an email address and/or a phone number where users may submit questions or report possible data errors. Each FDA center or office determines how investigations and follow-up are conducted for possible errors in its area. For example, in March 2012, FDA's ORA published the *ORA Quality Manual*, designating ORA managers responsible for ensuring that employees follow established procedures to identify, investigate, and correct any reported data quality

[23] U.S. Environmental Protection Agency's Enforcement and Compliance History Online (ECHO) is a publicly accessible Web tool maintained by EPA to provide compliance and enforcement information for approximately 800,000 regulated U.S. facilities. The tool reads into EPA's Integrated Data for Enforcement Analysis (IDEA) system, which copies many EPA and non-EPA databases monthly and organizes the information to facilitate cross-database analysis. The data accessed by ECHO from IDEA are only as current as the most recent IDEA refresh date and scheduled refreshes occur monthly. *Real-time* data are not presented on the site (http://www.epa-echo.gov/echo/). Accessed September 19, 2013.

issues. Such procedures include clearly documenting reported inaccuracies and implementing appropriate actions to correct and prevent future recurrence of data quality issues.[24]

The Working Group recognizes the need for flexibility in how each center or office manages error report tracking, investigation, and follow-up processes, and that the current center and office practice of developing tailored policies and protocols meets this requirement. For example, enforcement or compliance data submitted to FDA on a voluntary basis may require different processes to investigate possible errors, as these data are often not reported in a standard format.

Finally, discussions with database managers and FDA communication offices revealed that FDA rarely receives error reports from the public using available email or phone options. Additionally, upon identifying errors, the public can contact the office responsible for the data and work directly with FDA experts to resolve outstanding issues. FDA staff who routinely communicate with the public about enforcement and compliance data report that the public does not appear to perceive current error reporting options as insufficient and/or difficult to use. The Working Group concludes that center and office processes for investigating and correcting possible errors are sufficient to enable FDA to resolve reported issues expeditiously. As a result, the Working Group did not identify a need for new error reporting capabilities at this time.

B. Automated Data Refreshes

The Working Group also considered whether FDA should institute systems and procedures for automatically refreshing FDA's public Web site to reflect changes made to its compliance and enforcement databases. When updates are made to those databases, the updated information is retained behind the FDA firewall until a scheduled refresh occurs or the center or office managing the database requests that FDA's Office of Information Management (OIM) refresh the data. This delay may allow outdated information to be publicly available since internal databases are continuously updated with new and corrected information. Current mechanisms minimize this possibility by allowing OIM to immediately refresh data on both internal and external Web sites when notified of a change. Recognizing, however, that the task of routinely responding to refresh requests could become onerous for OIM, the Working Group believes that, should this eventually prove too burdensome, FDA could explore immediate automated refreshes of FDA enforcement and compliance databases. Automated refreshes would refresh FDA public Web sites in real-time whenever an update or change occurs in an internal compliance and enforcement database. To enable automatic refreshes, FDA would have to review current center and office quality control procedures to ensure they are sufficient to support live data updates.

FDA deals with data that may be confidential and/or must be redacted before being made publicly available. FDA takes significant measures to protect such information. To enable automated refreshes, center and office processes for making appropriate redactions of data before they are entered into an FDA compliance and enforcement database that will be made public may need to be adjusted. Additionally, during an investigation, FDA centers and offices may need to develop a way for removing or hiding from public view possibly erroneous data. Such features would require significant development and production time by OIM and additional training of FDA center or office staff entering data into compliance and enforcement databases.

[24] ORA Quality Manual, ORA-QMS-POL.002, March 2012. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/UCM136320.pdf. Accessed September 19, 2013.

A final consideration when exploring the feasibility of automated refreshes is that certain FDA compliance and enforcement databases include manual data compilations from several FDA datasets. Because FDA manually creates these compilations, automated refreshes are not possible. FDA must ensure that it continues to clearly display refresh dates on all publicly available FDA compliance and enforcement databases so the public is aware of the currency of the data presented.

The Working Group recognizes that the resource burden required to overhaul current FDA compliance and enforcement database systems and business processes governing data maintenance pose a considerable challenge to implementation.

In summary, because providing accurate enforcement and compliance data is important to realizing its regulatory and public health missions, FDA has instituted many quality control measures to achieve this goal. After careful consideration of the benefits, costs, and feasibility of implementing new error reporting, investigation, and correction procedures and following careful examination of the benefits of refresh buttons, the Working Group has concluded that current procedures are sufficient. The Working Group for Initiative 2 makes no recommendations at this time.

INITIATIVE 3

FDA will explore how to present its compliance and enforcement data graphically and better utilize mobile Web applications to draw more users to its compliance and enforcement Web pages and to encourage data analysis.

Background and Overview

FDA currently discloses significant amounts of enforcement data to the public. As Appendix 1 reveals, an environmental scan the Working Group for Initiative 3 performed before formulating its recommendations inventoried the following for each of FDA's centers:

- How centers are presenting their compliance and enforcement data
- Whether compliance and enforcement data files were available for downloading
- Whether compliance and enforcement data were already graphically presented
- The extent to which data and search engines are provided for stakeholders to access the data
- The extent to which mobile devices, such as phones and tablets, can readily view compliance and enforcement data

Disclosure of the compliance status of facilities manufacturing, processing, packing, and holding currently marketed, FDA-regulated products can help the public make more informed marketplace choices while encouraging industry compliance. FDA makes much compliance data available on its Web site. A primary way to access FDA's compliance and enforcement information is through ORA's Inspection Database. This dataset specifically reveals the final classification of inspections conducted of clinical trial investigators; institutional review boards (IRB); and facilities involved with the manufacture and marketing of FDA-regulated products. To ensure that disclosures do not interfere with planned enforcement actions, some information may not be posted until such actions have been taken. The information is presented in both searchable database and Excel spreadsheet formats and includes information on classification, project area, firm name, inspection end date, country area, district, city, state, and zip code. Users can sort the data. The database is updated twice a year.

FDA's weekly *Enforcement Report* furnishes compliance and enforcement data on recalled products for all FDA commodities. Its format was revised in June 2012 to provide a simpler, clearer, and more user-friendly report offering downloadable data for analyses. The report format continues to be reviewed and modified to improve usability. [25]

[25] Product recall data will also be accessible soon through OpenFDA, an initiative that will make FDA public data freely available for use outside of FDA without requiring private parties to copy, merge or reconfigure the data. Both an interface and meta data will be provided to allow an application, for example, to query the data in openFDA from the openFDA web site. FDA's Office of Informatics and Technology Innovation (OITI) is currently preparing product recall and two other data sets for openFDA that cut across FDA organizational lines. All product recalls FDA issues, along with Meta data, will be available via openFDA in summer 2014.

FDA also posts on its Web site press releases firms issue on recalls, market withdrawals, and safety alerts for FDA-regulated products.

FDA's Web site also contains annual graphs of enforcement statistics, including warning letters, recalls, injunctions, seizures, and civil money penalties.[26] Additional graphs depicting FDA's performance for inspections, warning letters, and recalls are presented on the FDA Track Web page.[27]

Center-specific information and databases are available to the public as well. For example,

- CDRH hosts a center-specific site that allows downloads of recall information, offers inspection outcome data linking to Warning Letters, and provides a total product life cycle view integrating recall information with other CDRH databases. CDRH also has a mobile app that shares recall and adverse event information; CDRH is developing another app for reporting adverse event information. CDRH posts annual information on the types of regulatory violations observed by investigators and on FDA Forms 483 in addition to quality systems violations cited in Warning Letters. This information is presented in graphs and tables.[28]
- CTP provides information on inspections of tobacco retailers and even links to the Warning Letters found in the posted Warning Letters site.
- CDER furnishes enforcement data on clinical investigators that includes a search tool and postmarket requirements and commitments that users can search and download.
- CBER proactively posts public information on its Web site concerning regulatory actions (untitled letters) and administrative actions (notices of intent to revoke, orders to cease manufacturing, etc.).

Based on review of information it obtained on the center presentations of their compliance and enforcement data, the Working Group observed the following:

- Processes to present data are currently under revision based on feedback from stakeholders in an effort to ensure maximum transparency and enhance data quality and consistency.
- Data across the centers are available in a variety of formats, including spreadsheets, Web pages, and searchable databases.
- Many centers feature multiple sources of compliance and enforcement data, rather than using a one stop shopping approach.
- The centers' use of graphics to represent data has been inconsistent.

[26] This Web site is available at the following location: http://www.fda.gov/ICECI/EnforcementActions/ucm247813.htm. Accessed September 19, 2013.

[27] For information on this and other FDA Track postings, see the following Web site. http://www.fda.gov/AboutFDA/Transparency/track/default.htm. Accessed September 20, 2013.

[28] This CDRH information is available at the following location: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199911.htm. Accessed September 20, 2013.

- Formatting of center data for use on mobile devices had been limited in the past.[29]
- All centers use the GovDelivery email subscription service to make data update notifications available.
- Some centers use video mechanisms such as YouTube to present compliance and enforcement information.

Recommendations

The following general principles guided the Working Group's development of recommendations: (1) The scope should be limited to traditional types of compliance and enforcement data (e.g., results of inspections, recalls, warning letters) and (2) recommendations should be realistically achievable within a time frame of one to two years. The Working Group's recommendations for Initiative 3 follow:

1. *A centralized entity should be responsible for the Knowledge Management required for transferring lessons learned from ongoing initiatives that graphically present compliance and enforcement data, develop mobile Web applications, or support data analysis.*

2. *Modifications and updates to ORA's Inspection Observation Database should be assessed and modifications made to encourage and assist users in data analysis. Currently, the site provides information on inspectional observations by fiscal year and in a downloadable data set.*[30]

3. *FDA should consider additional usability efforts to enhance the navigation of its Web sites and make compliance and enforcement data more accessible.*

4. *A stakeholder needs assessment should be performed to determine which data would benefit from graphical display or a mobile Web application.*

5. *Additional feedback should be solicited from regulated industry and other stakeholders before moving forward with the development of mobile applications.*

6. *Now that it has developed a mobile Web site, FDA should evaluate the use of quick response (QR) codes, a type of two-dimensional/matrix barcode that typically enables a user to scan to receive additional information, usually by opening up a URL on the Web where dedicated content can be displayed.*

7. *The Working Group for Initiative 3 also adopts and incorporates by reference the following recommendations advanced by the Working Group for Initiative 4:*

    - *Consider implementing a dashboard tool to present compliance and enforcement data in a user-friendly manner*

[29] In November 2013, FDA launched a *mobile-friendly Web site*, the initial content of which is limited to high-visibility areas, such as consumer updates, recalls, safety alerts, and news releases.

[30] ORA is currently reviewing the information to improve the data's graphical display and usability for the public.

- *Establish an editorial board to manage and curate the page devoted to compliance and enforcement at www.fda.gov/iceci site to better integrate and limit duplicative postings of FDA's compliance and enforcement data.*

INITIATIVE 4

FDA will explore whether it can better integrate its compliance and enforcement data, as well as its other publicly available data on regulated firms, to make the data more user-friendly and easier to analyze.

Background and Overview

The Working Group for Initiative 4 has concluded that FDA can do more to integrate its publicly available compliance and enforcement data and other publicly available data on regulated firms, to make the data more user-friendly and easier to analyze.

FDA collects, processes, and generates a burgeoning volume of compliance and enforcement data, much of which is publicly accessible on FDA's Web site. These data are housed in and extracted from multiple databases, and, to the extent they are Internet-accessible, they are made available through links interspersed throughout FDA's Web site that can be difficult to locate.

FDA is committed to enhancing the predictability, consistency, and transparency of its regulatory decision-making in the context of a rapidly changing scientific landscape through improved integration of the large compliance and enforcement data sets it has amassed. To the extent that such integration will enable and facilitate complex analyses illuminating the identification of key compliance and enforcement trends and risk factors as well as the compliance status of FDA-regulated firms and products, the Working Group believes that it will also serve many of the objectives underlying, informing, and animating the FDA's Transparency Initiative.

A. Multiple Compliance and Enforcement Data Systems/Databases

FDA established, maintains and hosts numerous compliance and enforcement data systems and databases at FDA-wide, center-wide, and local (i.e., intra-center) levels. The following section provides a brief overview of the various FDA- and center-wide systems and databases. For a detailed list of these systems and reports, including definitions and other relevant information, see Appendix 2.

1. Agency-Wide Databases

FDA's Office of Regulatory Affairs (ORA) is the lead office for all FDA field activities, including inspections and enforcement. ORA operates all FDA-wide compliance and enforcement data systems, including the following:

- Operational and Administrative System for Import Support (OASIS)
- Field Accomplishments and Compliance Tracking System (FACTS)
- Compliance Management System (CMS)
- Recall Enterprise System (RES)

- Turbo Establishment Inspection Report[31] (Turbo EIR)
- Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

ORA generates a number of compliance and enforcement reports from these systems, some of which are available to and used by other FDA components and the public. Reports include the following:

- Inspections Classification Database and Search
- Inspections Observations
- Warning Letters
- Enforcement Report
- Recall, Market Withdrawals, and Safety Alerts
- FDA Debarment List
- Enforcement Statistics
- Clinical Investigators—Disqualifications Proceedings
- Import Alerts
- Import Refusals

FDA's Centers depend heavily on ORA's FDA-wide compliance and enforcement data systems. For example, for internal purposes, CFSAN relies on CMS, FACTS, RES, and OASIS for its compliance and enforcement data and, except for untitled letters[32] and actions related to specific initiatives,[33] CFSAN posts no real-time compliance or enforcement information on FDA's Web site independently of ORA's databases. All FDA centers, including those housing and publishing information from their own center-specific compliance and enforcement databases and systems similarly rely on ORA databases and data systems.

For example, CBER uses inspection classification data from FACTS; recall data from RES (including publicly accessible enforcement reports); regulatory action (advisory, administrative, and judicial) information from CMS (including publicly accessible warning letters); import action (alerts, detentions) information from OASIS and CMS; inspection observations data and establishment inspection report information from Turbo EIR. CBER also uses firm profile information from FACTS and COMSTAT (a database developed to summarize key quality assurance information about facilities that manipulate drugs, devices, and certain biologics that addresses a facility's ability to operate according to FDA regulatory requirements).

Similarly, CDER's Office of Compliance relies on numerous ORA data systems and databases, including, for example, CMS for the data entry of enforcement and other actions such as warning letters, import alerts, injunctions, and debarments. See Appendix 2 for more details.

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[31] An establishment inspection report (EIR) is issued to a firm or facility following an inspection by an FDA or contract inspector. If concerns are identified, the firm may receive a Form 483, to which it must respond. For more, see http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm. Accessed October 22, 2013.

[32] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm283010.htm. Accessed September 20, 2013

[33] See, for example, Warning Letters related to caffeinated alcoholic beverages (http://www.fda.gov/Food/FoodIngredientsPackaging/ucm190366.htm) and Warning Letters to marketers of dietary supplements containing dimethylamylamine (http://www.fda.gov/Food/DietarySupplements/default.htm). Accessed September 20, 2013

2. Center-Specific Data Systems/Databases

To varying degrees, some of FDA's centers have created and use their own independent systems to acquire, generate and/or track compliance and enforcement data tailored to their needs. For example, CBER has created and maintains two center-specific data systems: Direct Recall Classification (DRC) and Biologic Product Deviation Reports (BPDRs). BPDR data are housed in CBER's Biologics Compliance Information System (BCIS), which, in turn, has been interfaced with CBER's DRC system, thereby transferring BPDR data to CBER's DRC Program.

CDER has a number of center-specific compliance and enforcement data systems, including the Establishment Evaluation System (EES), Drug Quality Reporting System (DQRS), Substance Registration System (SRS), Electronic Drug Registration and Listing System (eDRLS), and Document Archiving, Reporting & Regulatory Tracking System (DARRTS). In some instances, CDER relies on interfaces it has created involving some of its center-specific systems that enable data and information to be shared.

CDRH has established and maintains and operates the CDRH Ad-Hoc Reporting System (CARS), a data warehouse permitting ad hoc queries and generation of user-customized analytical reports as well as canned reports. Updated daily, CARS allows data from several transactional systems to be analyzed together. Within CARS, CDRH has integrated data from across the Total Product Life Cycle (TPLC) database, which brings together large volumes of compliance and enforcement and other data from several sources. CDRH also maintains center-specific compliance and enforcement data sets. CARS pulls and integrates substantial volumes of data from ORA-operated and owned systems. CDRH augments this information with additional data not available in ORA's systems for retrieval and analysis by its personnel. Its recall data set, for example, includes more data than are entered into RES.

Appendix 2 provides more information on these various center-specific systems.

3. Local (i.e., Intra-Center) Data Systems/Databases

Some centers additionally house compliance and enforcement data systems/databases at local (i.e., intra-center as opposed to center-wide) levels. For example, sub-offices in CDER's Office of Compliance capture enforcement and compliance data in various electronic formats. Most of the data are entered and stored in databases while some are displayed electronically in each office's internal and external Web sites.[34]

CDRH's Extranet-based Mammography Program Reporting and Information System (MPRIS), which supports the center's statutorily mandated responsibility for certification and inspection of

[34] CDER's local compliance and enforcement databases include: Office of Scientific Investigations (OSI) Access Database, Office of Drug Security, Integrity and Recalls (ODSIR) Access Database, Incidents and Informants databases, Field Alert and Biological Product Deviation tracking database. For instance, the Office of Scientific Investigations (OSI) publishes warning letters, inspection data analysis, and other enforcement reports in its external Web site that are more detailed than ones published by ORA's office of enforcement. OSI's report of inspection outcomes contains detailed statistical analysis and trends revealed by compliance and enforcement data.

all mammography facilities in the United States under the Mammography Quality Standards Act (MQSA), is another example of a local compliance and enforcement data system.[35]

B. Lack of Data System/Database Integration

The ever mounting volumes of compliance and enforcement data dispersed throughout multiple systems and databases pose real challenges. FDA's compliance and enforcement data systems and databases are, with few exceptions, not linked, making it difficult for users to find information or produce reports combining data elements from these systems and databases.[36] Moreover, in some cases, systems designate a firm by different names or variants of names or with different addresses or facility sites, making it even more difficult to obtain a comprehensive view of a firm's compliance history.

It is critical that the data and terminologies identifying firms and facilities throughout these systems be harmonized through the use of data standards. Without standardization, linking relevant data systems will not ensure capture and retrieval of all material information.

The lack of database harmonization and integration also means that data extracted from these systems in response to inquiries or for posting to the Internet can require extensive and resource-draining manual intervention, verification, and manipulation, especially given that multiple systems may lead to inconsistent data reporting. As a result of these many challenges, it can be very time- and resource-consuming to perform complex analyses that enable the identification of key trends and potential risk factors and a comprehensive understanding of the compliance histories of specific firms and their products.

FDA has already taken a number of steps to provide public access to substantial volumes of its compliance and enforcement data, as evidenced by the Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS).[37] This reporting database, or *data mart*, is making it possible for users to access multiple systems and pull data from disparate transactional systems. But more must be done to foster data integration to ensure that users can obtain a *complete picture* of the compliance status of FDA-regulated firms. Data integration between and among these systems is proving to be complex and resource-intensive.

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[35] Maintained by CDRH's Division of Mammography Quality Standards, this standalone, integrated database management system, which functions as a centralized data repository, permits the electronic tracking and monitoring of a mammography facility's accreditation, certification, inspection, and compliance history and produces reports based on predefined business rules. FDA and State MQSA inspectors use laptop computers to record inspection results, which they send to a centralized database, which, in turn, are used by FDA-approved accreditation bodies, certification states, and District Offices.

[36] For example, ORA field personnel reviewing import entry lines for admissibility of products often have to move from one system—e.g., PREDICT, FACTS, and OASIS—to another to verify information. Enhanced integration of these systems would improve the food safety import review process while helping to move compliant cargo more efficiently through the entry review process to market.

[37] ORADSS is a centralized data warehouse that provides integrated decision support for regulatory compliance and allows users access to integrated views across several FDA data systems. Many of ORA's compliance and enforcement data systems—among them CMS, FACTS, RES, and OASIS—can use ORADSS for reporting.

C. Improving Compliance and Enforcement Data Web Sites

In the meantime, FDA could do more to make its compliance and enforcement data available on its various Web sites in a more user-friendly manner. FDA's Web page development, posting, and communications processes remain largely decentralized, with each center deciding what compliance and enforcement data it will post. In addition, the numerous Web pages containing compliance and enforcement data are difficult to locate because they are not organized in an integrated fashion. A search for data beginning on FDA's homepage (www.fda.gov) reveals no link to any kind of high concentration of publicly accessible enforcement and compliance information.

Much, but not all, data can be accessed through links appearing on one of FDA's Transparency Initiative pages (i.e., Information about FDA Compliance and Enforcement Actions).[38] However, having to navigate to the Transparency section for compliance and enforcement data is neither intuitive nor user-friendly.[39]

The Working Group also noted that the presentation of compliance and enforcement information is inconsistent from center to center. Thus, finding all of the compliance and enforcement data to which FDA Web sites have afforded stakeholders access can be very difficult.

D. Potential Benefits of Data Integration

The Working Group believes that increased integration of compliance and enforcement data residing in multiple systems would confer numerous benefits, including the following:

- Eliminate data duplication and redundancy
- Diminish the need for manual data entries and manipulations
- Reduce potential for conflicting and erroneous data
- Enhance ability to make important linkages that can currently require reconciling information extracted from multiple data systems and databases.

All of these benefits, in turn, could bring the following additional gains:

- Improved data quality
- More efficient and expeditious compliance and enforcement data analyses
- Process and resource savings

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[38] See http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm254426.htm. Accessed September 20, 2013.

[39] To get there from FDA's home page, first select "Transparency" under "FDA Initiatives." Once there, the compliance and enforcement information page can be accessed by selecting the link Information about FDA Enforcement and Compliance Actions under Tools and Resources, on that page's lower right side. Alternatively but more onerous, one could reach this Web page by going to FDA's main FDA Transparency Initiative page at http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/default.htm and selecting the link FDA Basics under Resources for You and then selecting the link FDA Basics for Industry, again under Resources for You. Once there, the link Compliance and Enforcement transports one to a Compliance and Enforcement page at http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm273036.htm, where the link FDA Compliance and Enforcement Actions finally takes one to the page Information about FDA Compliance and Enforcement Actions.

- Better-informed and more efficient compliance and enforcement decision-making

The timelier availability and dissemination of more accurate, less conflicting, and more readily accessible and analyzable compliance and enforcement data would advance FDA's pursuit of its risk-based approach to assessing and ultimately ensuring industry compliance. More important, perhaps, increased transparency could spur improvement in industry's quality systems. CDRH's Office of Compliance has pioneered the concept that providing as much high-quality compliance and enforcement data as possible will increase industry's use of those data to ensure better quality medical products. Greater database integration can allow for a more comprehensive picture on devices and enables industry to better understand what might improve their own quality systems.

Finally, enhanced integration of compliance and enforcement data on FDA's Web site would advance the Transparency Initiative goal of making it easier for its external stakeholders to locate, review, and analyze FDA's Internet-accessible compliance and enforcement data and gain a better understanding of the compliance histories and statuses of FDA-regulated firms and of industry-wide compliance and enforcement risks and trends.

Recommendations

The Working Group makes the following recommendations:

1. *FDA should implement a dashboard tool to enable the presentation of compliance and enforcement data in a user-friendly manner.*

The Working Group recommends that FDA consider acquiring software licenses to deploy dashboards—highly user-interactive and relatively low-cost systems[40] for extracting, uploading, and then integrating compliance and enforcement data from multiple databases for display and availability to stakeholders.[41] Dashboards accessible from FDA's public-facing Web sites could provide interfaces that enable users to concurrently access, review, and analyze compliance and enforcement data residing in multiple systems. Such interfaces could prove invaluable in affording user-friendly access to analyzable data,[42] much of which could be used to generate customized reports tailored to users' interests, needs, and concerns or selectively downloaded by users into spreadsheets.[43] Dashboards would support transparency by permitting visualization of

[40] Dashboard licenses would require no significant up-front investment, and dashboards could become operable relatively soon after procurement.

[41] Dashboards were used to integrate the databases for the EPA ECHO and DOL Enforcement Data 2.0 extolled by the January 16, 2011, Presidential Memorandum on Regulatory Compliance and featured in the October 3, 2011, report, *Food and Drug Administration, Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency's Compliance and Enforcement Data*. See http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf. Also, see www.epa-echo.gov and http://ogesdw.dol.gov. Accessed September 20, 2013.

[42] Exploratory Initiative 4 required the Working Group to examine whether FDA "can better integrate its compliance and enforcement data, as well as its other publicly available data on regulated firms, to make the data more ***user-friendly*** and easier to analyze." (emphasis added) The Working Group notes that, in the absence of an adequate interface allowing the user to retrieve, access, and analyze the data, merely integrating data systems/databases does not guarantee user-friendliness or analyzability.

[43] The availability of such data for customized external stakeholder analyses, in turn, could lessen the public's dependence on the Agency's posting of data analyses and summaries it considers of greatest interest to the public.

multiple types of data and building visual relationships between disparate data sets, thereby enabling users to more easily identify key trends and potential public health risks and to access more comprehensive and relational data on specific firms and products.

2. *FDA should provide additional funding for the Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS) to enhance integration of the compliance and enforcement data available in its siloed data universes.*

3. *FDA should empanel a board to study and advance recommendations to enhance navigation of the Web sites that make compliance and enforcement data available.*

4. *FDA should establish and support an editorial board for the Agency-wide compliance and enforcement Web page (i.e., www.fda.gov/iceci) to improve access to all of FDA's posted compliance and enforcement data.*

FDA's homepage should reference and hyperlink to the www.fda.gov/iceci launch page, which should then list and hyperlink to all ORA, center-specific, and local compliance and enforcement data appearing or made available on FDA's various Web sites. Additionally, ORA's and each center's homepage should reference and hyperlink to one similarly formatted launch page listing and hyperlinking to all posted compliance and enforcement data. Although each center homepage may contain unique information reflecting the underlying center information, the compliance and enforcement data references and hyperlinks should always be posted on FDA's Agency-wide compliance and enforcement data launch page.

INITIATIVE 5

FDA will explore whether additional, or more specific search criteria (e.g., criteria that would enable individual product-specific or violation-specific searches), or more sophisticated search capability (e.g., predictive name searches) would make the inspections database more user-friendly and the data easier to analyze.

Background and Overview

The Working Group for Initiative 5 was assigned the task of making recommendations on how to improve the capacity to search FDA's public inspections databases. The Working Group focused on FDA's inspection-related databases, which, among other things, capture data reflecting observations made during inspections and form the bases for regulatory determinations (e.g., as reflected in Warning Letters) and firm responses to inspection observations.[44]

FDA currently provides inspection data to the public in several ways. A primary method for accessing and analyzing inspection information is ORA's Inspection Database[45] (e.g., identify an inspected firm and see the inspectional result, or *inspection classification*). This information can be searched using a select set of fields or downloaded into spreadsheet format. The data provided are typically updated twice a year with the search requiring the exact spelling of the firm name.

Observations from these inspections are included in ORA's Inspection Observations[46] database in summary form, showing the aggregate numbers of observations by type and center, none of which is tied to any specific firm inspection. Facility-specific inspectional observations and firm responses to those observations are not provided in database or tabular form, although documents themselves citing such observations can be obtained from the FOIA Electronic Reading Room.[47] Although not all inspections have documents available in the Reading Room, Warning Letters, including many recounting violations FDA observed during inspections, are posted online.[48] Warning Letters are posted in document form only, and any linkage to the original inspection and observations can be obtained only manually.

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[44] Outside the scope of these recommendations are CTP's compliance check inspections of tobacco product retailers and CDRH's Mammography Program Reporting and Information (MPRIS), which supports the statutorily mandated responsibility for certification and inspection of all mammography facilities in the United States under the Mammography Quality Standards Act (MQSA). These inspection programs differ in important respects from other FDA inspections.

[45] See http://www.fda.gov/ICECI/EnforcementActions/ucm222557.htm. Accessed October 22, 2013.

[46] See http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm. Accessed October 22, 2013.

[47] See http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.htm. Accessed October 22, 2013

[48] See http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm. Accessed October 22, 2013.

FDA centers also provide inspection information on other sites. For example, CDRH posts CDRH-specific inspectional information that have been integrated with information from ORA databases. CTP provides inspectional information of tobacco retailers and links to the CTP-related Warning Letters available from the Warning Letter site referenced above.[49]

Providing inspectional information in a searchable and complete format is pivotal to the capacity of regulated industries and the public at large to obtain and thereby monitor the results of inspections of firms distributing FDA-regulated products within and to the United States and its territories. Inspectional results are a key indicator of a firm's compliance with the laws and regulations FDA enforces to ensure the safety of those products.

Results that cannot be searched may obscure or lead to a misinterpretation of a firm's compliance status. For example, if a search for a specific inspection event using a misspelled firm name yields no results, one might conclude erroneously that no relevant inspection has been performed. Limitations in search capacity could also lead someone to a posted FDA Form 483[50] listing observations that the firm later satisfactorily addressed in its response to FDA.

The ability to search FDA's inspectional databases is inextricably tied to ensuring a complete and accurate picture of inspectional findings as well as understanding and appropriately interpreting firm- and/or product-specific compliance and enforcement data.

Recommendations

To enhance the user-friendliness and ease of searching and analyzing FDA's inspections data, the Working Group for Initiative 5 makes the following recommendations:

1. *FDA should implement the use of dashboards to enhance search capability.*

FDA should implement a dashboard tool that dynamically displays tables, graphs, and maps based on a user's inputs and enables use of specific search criteria capable of refinement through enhancing or reducing the level of detail employed in an initial search. This tool is discussed in detail in Recommendation 1 under Initiative 4 above. The refinement capability dashboards afford would enable users to drill down and generate more focused results from data returned from initial searches. Dashboards would also permit use of multiple criteria throughout the search.

2. *FDA should expand the use of application programming interfaces.*

The Working Group recommends that FDA expand the availability of application programming interfaces (API) to its public-facing databases. An API describes the way one piece of software asks another program to perform a service. APIs that can access inspections database(s), in conjunction with other tools, such as text indexing tools, would enable faster, automated searching from applications outside FDA, thereby affording external users and organizations (e.g., watchdog groups, other government regulators, and manufacturers) direct access to

[49] As already noted, tobacco retailer inspections are not included in this Working Group's recommendations.

[50] FDA uses a Form 483 to notify a firm's management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. For more details, see http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm. Accessed October 22, 2013

inspectional information. Systems can be designed to search data in a structured output format, independent of FDA-chosen methods for displaying and searching the information. Providing APIs to public-facing databases[51] would benefit those wishing to search the information in unanticipated ways.[52]

3. FDA should make predictive search/predictive text capability available.

The Working Group recommends that FDA make predictive search/predictive text capability available for searching its compliance and enforcement databases. Whatever mechanism is employed for providing search results, the results themselves should exactly or very closely match the searched-for terms where text fields are allowed in the search (e.g., approximate string matching or *fuzzy* searching). Predictive searching producing various possible search terms based on the letters the user initially types can correct for spelling errors that would otherwise result in a failed or incorrect search.[53]

In summary, the current methods for searching inspectional information can be improved with the addition of dashboards, APIs, and predictive search and predictive text. Enhanced searching will return better results and help to avoid missing or erroneous results derived from the entry of incorrect or misspelled search criteria.

[51] The process to provide a public-facing system and ensuring that system has the proper security and patches in place would necessitate IT assistance from FDA's Office of Information Management (OIM).

[52] It would also advance implementation of the President's Digital Government Strategy (http://www.whitehouse.gov/sites/default/files/omb/egov/digital-government/digital-government.html) through the HHS digital strategy (http://www.hhs.gov/digitalstrategy) Accessed September 22, 2013.

[53] Depending on the vendor used, the dashboard concept may also allow predictive search or predictive text.

INITIATIVE 6

FDA will explore whether posting additional data compilations or analyses, such as the Agency's most common inspections observations or the warning letter compilations, both of which it already posts, would increase transparency or better inform the Agency's own compliance efforts.

Background and Overview

FDA's public Web site is maintained by an FDA Web group located in the Office of the Commissioner and by Web teams located in the centers. The practice of posting enforcement and compliance data on the Web involves multiple layers of organizations collecting the data, producing the data for public access, and posting the data. For this reason, FDA's Web architecture is very complex. Various references and links to existing information are scattered throughout FDA's Web site, and relocating portions of the Web site to enhance efficiency would require a significant amount of work and time. Consequently, compliance and enforcement information—often from a multitude of standalone systems—is continuously added to different locations of the Web site. Available compliance and enforcement data can be difficult to find. This issue is discussed in detail in Initiative 4.

Based on its identification and review of current Agency, center, and office compliance and enforcement data postings, the Working Group for Initiative 6 concluded that significant amounts of compliance and enforcement data are currently available on FDA's Web site, some of which are in the form of compilations or analyses.[54]

The posting of compilations or analyses of compliance and enforcement data has important informational value. Although the Working Group generally agrees with public comments urging FDA to give priority to providing meaningful raw data on its public-facing Web site, the Working Group believes that posting compilation and analysis data serves an important role in informing about FDA's compliance efforts. This is because not all users have the capability or resources to independently analyze raw data. FDA's posting of compilation or analysis data can benefit users seeking basic, easily comprehended information concerning its compliance and enforcement activities.

Although existing compilation and analysis data appeared to provide a suitable overview of FDA compliance and enforcement activities, the Working Group observed a gap in the scope of posted compilation or analysis information on inspection activities. For example, although summary data are available concerning common inspectional observations, compilation or analysis information is lacking that could provide context or background (e.g., on the numbers of

[54] See for example, the Summary of Inspection Observations at http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm) and Enforcement Statistics, available at (http://www.fda.gov/ICECI/EnforcementActions/ucm247813.htm). Accessed September 24, 2013.

establishments subject to inspection, inspections performed, or resulting inspection classifications).

Recommendations

The Working Group for Initiative 6 makes the following recommendations:

1. *Data should be updated regularly.*

FDA should continue to post currently available data compilations or analyses for compliance and enforcement activities and update the data on a regular basis. Relevant information includes the Summary of Inspection Observations and Enforcement Statistics data posted on the main FDA Web site as well as the data posted on center- and office-specific sections of the Web site.

This recommendation does not contemplate posting additional data compilations or analyses for compliance and enforcement activities. However, the Working Group believes that promoting the regular, timely update of data would improve the current system.

The Working Group supports previous recommendations (e.g., Initiative 4) to create an oversight group to lead cross-Agency coordination of the compliance and inspectional Web pages with the goal of achieving regular and timely disclosure and updates.

2. *Current compliance and enforcement data compilation and analysis postings should be supplemented.*

FDA should supplement its currently available compliance and enforcement data with postings of additional compilation or analysis data concerning inspections, including, for example, compilations and/or analyses of data relating to the number of inspections performed each year, delineated by inspection classification (i.e., no action indicated, voluntary action indicated, and other action indicated) and country of inspection and placed in the context of the numbers of facilities subject to inspection.

INITIATIVE 7

FDA will explore ways to make better use of social media, such as Facebook and Twitter, as well as Agency-sponsored webinars and automatic e-mail notifications to better communicate with the public about its compliance and enforcement efforts.

Background and Overview

The public is using a variety of new methods to obtain information from Federal agencies, including use of social media. Social media is a powerful tool to help government agencies like FDA meet program goals. The primary functions of social media are to:

- *Share*: Inform citizens of public services through social content
- *Listen*: Observe, analyze, and understand what citizens are sharing to improve public services
- *Engage*: Respond, collaborate and create with citizens to improve public services (sharing and listening)

FDA, whose Web and Digital Media Staff in its Office of External Affairs oversees its social media program, has increasingly recognized the importance the public attaches to obtaining information via social media. Various offices and centers within FDA also maintain social media assets whose administration is managed by one of their designated Web team members.[55]

A. FDA's Social Media Assets and Reach

To varying degrees, FDA's offices and centers are currently sharing compliance and enforcement data via diverse social media avenues. Current use of Facebook, Twitter, Flickr, and YouTube reveal that FDA's social media audiences include consumers, patients, health care associations and nonprofit organizations advocating or sharing information about specific health issues, and health care professionals.

As of May 2013, data on FDA's social media assets and reach reveal the following:

- **Facebook**. 54,400 "Likes" recorded. Messages are updated two to three times daily, typically with consumer-focused stories, helpful hints about health, and stories about some of FDA's activities and purposes.

[55] In social media parlance, FDA personnel who administer social media sites are referred to as social media *owners*. They are to be distinguished from the creators of social media content—those at FDA who generate the data.

- **Twitter Accounts**.[56] The following 11 FDA Twitter Accounts[57] have a reach of approximately 550,000 followers:

  @US_FDA
  @FDAenEspanol
  @FDATobacco
  @FDACBER
  @FDAMedWatch
  @FDADeviceInfo
  @FDAanimalhealth
  @FDARecalls
  @FDA_Drug_Info
  @FDACDRHIndustry
  @FDAWomen

- **YouTube**. 550 videos, 5,993 subscribers and 2,258,525 video views

- **Flickr**. 4,837 items/1,433,647 views. Flickr is updated on a regular basis with a mix of personnel photos, historical archives, infographics, and, most regularly, a compendium of recalled items (foods or drugs) for which FDA received labels or photos from the recalling firms. FDA also frequently shares images from its Flickr account, such as the #FDAFridayPhoto that goes out every Friday to show people a bit of FDA history from the Agency's archival photoset.

- **Blogs**. FDA currently has one blog: FDAVoice (https://blogs.fda.gov/). FDAVoice is typically updated two to three times a week and is the official blog from FDA's senior leadership. It shares news, background, announcements, and other information about the work FDA does on behalf of the American public. Much of the information provided is for industry audiences, with some crossover to consumers.

  Automatic Email Notifications. FDA's Office of External Affairs manages GovDelivery to send out automatic email notifications, and center programs are also able to make use of this method to announce important events. FDA's free email alert service enables consumers and other audiences to receive important FDA news and information as it becomes available. To sign up, people select the topics that interest them and subscribe using a valid email address.[58]

- **Webinars**. FDA provides numerous opportunities to learn about a variety of topics, primarily through the FDA Basics Webinar Series. Each month, FDA offices and centers host online webinars. Senior FDA officials speak on specific topics and address

[56] All FDA Twitter accounts have been officially verified by Twitter as legitimate government resources. This allows the public to know that the information they receive originates from a legitimate source and not from an imposter site as occasionally occurs on Twitter.

[57] Three new Twitter accounts are being developed. These will be vetted for strategic viability and then verified once they are ready to go public.

[58] See for example, drug information, which can be accessed by clicking on the red envelope at: http://www.fda.gov/Drugs/ucm136245.htm. Accessed September 24, 2013.

listeners' questions.[59] Examples include the Guidance Webinar Series,[60] which aims to foster collaboration and transparency in the development of guidance documents through direct outreach to affected stakeholders and the OCTGT Learn Webinar Series,[61] which discusses the regulation of cellular, tissue, and gene therapy products.

FDA also disseminates educational webinar materials, including, for example, resource materials about device safety for health care professionals and patients.[62] FDA's collection of education webinar materials is an excellent resource for audiences looking for information on topics of interest or to increase their knowledge about work-related topics should they work in related or affected health fields.

- **Widgets**. A widget is a portable application that displays featured content directly on a Web page. Webmasters can embed a widget into their site to increase overall awareness about an important topic (members of the public can check with their Web hosting providers to see whether they would allow third party widgets from FDA to be installed). No technical maintenance is required once an FDA widget has been added, and FDA will automatically provide updates to content displayed on the widget.[63] An example of a useful FDA widget is CTP's widget putting out *news you can use*, which often includes news addressing compliance and enforcement matters. CTP also has a Tobacco Retailer Quiz Widget that includes compliance information.[64]

B. Social Media Accomplishments

Over the past year, FDA's social media engagement and outreach have expanded. Although the numbers may seem small when compared with larger government agencies, like the Department of Defense, FDA has succeeded in providing personalized and user-friendly products (i.e., content) to its audiences. The growth in FDA outreach reflects how implementing some basic strategies (e.g., an intent to convey more colloquial and personalized content to social media audiences[65]) has successfully yielded steady and dramatic increases in, more interaction with, and more questions from, those audiences.

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[59] An archive of all Basics Webinars resides at the following location: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm197102.htm. Accessed September 24, 2013.

[60] See http://www.fda.gov/Training/GuidanceWebinars/default.htm. Accessed September 24, 2013.

[61] See http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/ucm232821.htm. Accessed September 24, 2013.

[62] These materials are accessible at: http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm112724.htm. Accessed September 24, 2013.

[63] FDA.gov links to a large list of widgets that have been created: http://www.fda.gov/NewsEvents/InteractiveMedia/ucm200144.htm.[63] A search on FDA.gov gives even more results of current and past widgets: http://google2.fda.gov/search?q=widgets&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&output=xml_no_dtd&getfields=*&requiredfields=-archive%3AYes. Accessed September 24, 2013.

[64] See http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm247679.htm. Accessed September 24, 2013.

[65] In contrast to its former largely auto-generated posts, FDA's current posts are generally more colloquial and convey a personal voice. Additionally, FDA asks questions from the audience and also share news from its HHS colleagues and other collaborators.

Monitoring for the period from April 2012 to April 2013, for example, revealed the following trends in FDA's social media audiences:

- Twitter followers increased 261% (from ~7200 to 26,000), and Facebook fans increased 157% (from ~21,000 to 54,000). To accomplish these goals, typically at least one tweet per day with an average of three (depending on current events and initiatives) and at least two Facebook postings per day were sent out, and sometimes postings were also made on weekends.

- YouTube uploads increased over 78% (from 1.3 million to 2.3 million)

Recommendations

The Working Group for Initiative 7 makes the following recommendations:

1. *FDA should establish and implement a strategy to increase the dissemination of and audience for FDA compliance and enforcement data through social media.*

Because a substantial portion of the audience for FDA's presentation of its compliance and enforcement data prefers to acquire information through social media avenues, the Working Group believes it is becoming increasingly important that FDA devote resources to increasing and improving its use of social media. Given FDA's strong desire to increase public awareness and understanding of its compliance and enforcement data, as evidenced by much of the focus of its Transparency Initiative, the Working Group recommends that FDA call upon the social media assets and audiences it has developed to improve communication with the public regarding its compliance and enforcement efforts and the public availability and accessibility of substantial amounts of its compliance and enforcement data. So far, FDA's Web personnel have devoted less attention to expanding its social media presence with regard to compliance- and enforcement-related matters. Nevertheless, the tools to implement this recommendation already exist and are being continuously and consistently used to support many other FDA communication efforts.

The Working Group envisions that implementation of this recommendation would entail the following steps:

- **Step 1:** Once the appropriate offices create compliance and enforcement information, be it graphs, charts, new Web sites, infographics, or other types of information, it would likely live on a Web page that could eventually be sent out via social media.
- **Step 2:** The data's creators and/or owners would share the links to their data with the FDA social media owners, the Agency personnel administering the site.[66]
- **Step 3:** FDA social media owners would send out the data via Facebook, Twitter, Flickr, or YouTube, as appropriate.

Social media relies on links to official Web pages. An Agency commitment to ensure that such links to compliance and enforcement data are shared with FDA's social media sites for

[66] In other words, compliance and enforcement data originating and generated elsewhere would need to be shared with the site *owners* or administrators who would actually disseminate those data.

dissemination through social media avenues could enlarge the audience of such information to approximately 600,000 people. Furthermore, increasing use of social media to inform FDA's audiences about compliance and enforcement matters in the social media spaces in which they already participate would help support and further advance the President's Executive Orders on Transparency and Digital Government.

2. *FDA should enlist the assistance of its subject matter experts when responding to questions using social media*

The Working Group additionally recommends that FDA social media owners monitor social media sites for questions from FDA's audiences and pass them on to subject matter experts and that FDA institute procedures for identifying and calling upon those experts to assist in formulating posted answers to such questions.

INITIATIVE 8

***Initiative 8*:**

FDA will provide appropriate context for the compliance and enforcement data that it discloses to help ensure that the data are not misinterpreted or misused. Depending on the circumstances, appropriate contextual information may include, without limitation:

- Information regarding how frequently the data is updated,
- Information regarding the reliability of the data,
- Information regarding the average lapse of time between the inspection and the posting of inspection classification information,
- Definitions of inspection classification types (i.e., official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI)), and
- A statement explaining that the Web site's lack of information regarding a particular facility does not imply compliance or non-compliance (i.e., users should not infer that facilities that have not been inspected recently, or at all, are (or are not) in compliance with FDA laws and regulations).

Background and Overview

Initiative 8 involves compliance and enforcement information that was made publicly available during earlier phases of the FDA Transparency Initiative effort. Its task was to outline steps to improve the information and to ensure that the compliance and enforcement data FDA discloses are not susceptible to misinterpretation.

Currently, FDA posts data that show inspection classifications (based on observations made during inspections)[67] for firms it inspects and data that enumerate commonly observed violations, underscoring enforcement trends. FDA began posting information about inspections to increase transparency about its enforcement efforts. The goal was to enhance the public's understanding of these efforts while serving as a tool for the public to gauge compliance with applicable laws and regulations of a firm with which they may want to conduct business. In addition, posting commonly observed violations gives industry an opportunity to understand the trends that FDA is seeing in facilities it inspects and to take steps to ensure that its facilities are meeting relevant laws and regulations.

[67] Inspections are classified as NAI, VAI or OAI. An *NAI inspection classification* occurs when no objectionable conditions or practices were found during the inspection, or the significance of the documented objectionable conditions found does not justify further actions. A *VAI inspection classification* occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance. Inspections classified with VAI violations are typically more technical violations of the Food, Drug, and Cosmetic Act. An *OAI inspection classification* occurs when significant objectionable conditions or practices were found and regulatory action is warranted to address the establishment's lack of compliance with statutory or regulatory requirements.

FDA has a long history of sharing with industry the importance of producing products that are safe and of high quality. By sharing with the public the classifications that result from facility inspections, FDA has created a window through which they can view a firm at a given moment in time. Posting classifications may also incentivize industry to make sure it is in compliance and to correct outstanding problems expeditiously. Providing a better explanation on FDA's Web site of the enforcement and compliance data that FDA already discloses will not only provide for greater clarity of the information, but also will help improve the public's understanding of how FDA works to protect the public health.

Recommendations

The Working Group for Initiative 8 advances the following recommendations for FDA:

1. *FDA should create a frequently asked questions (FAQ) guidance document to provide appropriate definitions and context for compliance and enforcement data.*

The Working Group noted that the Web pages for the Inspection Classification Database[68] and Inspection Observations[69] already include a significant amount of explanatory information, such as definitions. The Working Group found, however, that this explanatory information could be enhanced to further promote use and understanding of the data.

The Working Group also found that much of the contextual information was difficult to locate. For example, to find appropriate definitions, the user has to click on multiple Web links leading to different locations on the FDA Web to find the appropriate definition. This makes it difficult to navigate back to the original Web page with the data subject to the definition. In other cases, contextual information appears on a Web page, the location of which is not intuitively obvious, or that cannot be linked to from a another page. Therefore, the Working Group recommends that FDA create a single FAQ guidance document for the compliance and enforcement data disclosed through the Inspection Classification Database and the Inspection Observation Web pages. The FAQ guidance should not only consolidate the definitions and other explanatory information concerning these data in one location, but also ensure that the answers be written in plain language and include additional contextual information, including the following:

- Clarifying the significance of the presence or absence of a facility in the database
- The frequency of data updates
- How the information is compiled
- The time between final inspection classification and its availability in the database
- What the various inspectional classifications mean

The Working Group believes this recommendation will improve the current system by enabling users to:

- Be better educated and, therefore, more confident as they navigate the Web site
- Be able to more effectively use the compliance and enforcement data provided for its intended purpose

[68] See http://www.fda.gov/ICECI/EnforcementActions/ucm222557.htm.

[69] See http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm.

- Have a better understanding of the data provided and be less likely to misuse or misinterpret those data

In addition, the FAQ guidance should provide new definitions and explanatory data not currently available to further enhance transparency.

Since 2010, FDA's office that is now the Office of Enforcement and Import Operations (OEIO) has maintained the Inspections Classification Database and Inspection Observations Web pages that provide inspection classification results for inspections conducted since October 2008 and inspection observation summaries completed since 2006. The Working Group believes that the consistent and ongoing effort to disclose these inspection results will ensure that definitions and explanatory information remain current. The Working Group recognizes that including in the FAQ's guidance new definitions and explanatory information may present resource challenges. Nevertheless, the minimal need for additional resources will be outweighed by the advantages of such a document as it fosters greater public understanding of the information and more effective use of the data presented.

2. *FDA should make the compliance and enforcement data it discloses more prominent on the main Web site.*

The Working Group believes that FDA's compliance and enforcement data can and should be made more prominent on FDA's various Web pages. As previously discussed under Initiatives 4 and 6, it is difficult to locate postings of these data because they are not sufficiently highlighted on FDA's home Web site, nor is it cross-linked with information that is available on other center-specific pages. Given the importance of and public interest in posted compliance and enforcement data, the Working Group for Initiative 8 agrees that these data warrant greater prominence on the FDA home page and each center's product-specific tab on the FDA home page.

Making the data more prominent on the Web site generally will ease user frustration, further inform the public about FDA's important regulatory activities, and bring increased use and understanding of the data.

3. *FDA should improve the organization and consistency of its posted compliance and enforcement data and develop an editorial board dedicated to the www.fda.gov/iceci Web site. This Web page should be clearly accessible from the FDA's home page and contain links to all such available data FDA discloses.*

The Working Group noted that the main FDA and center Web sites do not present the postings for their compliance and enforcement data in a consistent manner, and it can be difficult to find all of the compliance and enforcement data to which their Web sites have afforded stakeholders access. The links on the Transparency Initiative page, where the information currently can be accessed (i.e., under Information about FDA Compliance and Enforcement Actions[70]), are not comprehensive. And, although each center's product-specific tabs include compliance and enforcement data, presentation of the data is inconsistent, making it difficult to readily identify the data.

[70] See http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm254426.htm. Accessed September 25, 2013.

Consistent with recommendations from the Working Group for Initiative 4, the Working Group for Initiative 8 recommends that FDA develop an editorial board to maintain and curate the Compliance and Enforcement page at www.fda.gov/iceci. The Compliance and Enforcement page should be accessible from FDA's home page, be all-inclusive, and provide links to all enforcement data posted on FDA's various sites, regardless of the source of the data. Additionally, each center's compliance and enforcement page should list all links to compliance and enforcement data it posts. Each center page should not list any compliance and enforcement data links that are not included on FDA's main Compliance and Enforcement data page. The Working Group believes that enhancing the organization and consistency of its compliance and enforcement data will greatly improve the current presentation.

In summary, implementing these recommendations will enhance the presentation of the compliance and enforcement data and give users the tools they need to use those data to their fullest potential. Making the information easy to find, appropriately contextualized, and fully accessible will promote use of the data. Enforcement and compliance is an important aspect of FDA's regulatory activities and improving how these data are presented will not only improve transparency, but foster greater understanding of how these activities advance FDA's mission to protect public health.

Conclusion

Implementation of the recommendations advanced in this report to enhance transparency of the Agency's compliance and enforcement data that the working groups developed in response to initiatives the FDA Commissioner directed be explored will largely depend on the availability of resources. All of these recommendations are being referred to the Transparency Task Force, which, after assessing their relative priority in the context of one another as well as other Agency priorities, will consult with senior FDA leadership about the feasibility of implementing them to the extent available resources permit.

APPENDIX 1: INITIATIVE 3 – ENVIRONMENTAL SCAN OF CENTERS

Center	How are Compliance and Enforcement data presented?	Any data being	Files available	Search engines	Mobile
ORA	• Searchable databases • Tables and spreadsheets	Graphics in annual reports	Database data available for download via Excel	Number of searchable databases	Government wide app for recalls. No specific ORA app
CDER	• Searchable databases • Much of the data is presented on Web pages • Podcasts • YouTube Videos • Email alerts • Twitter	• Basic charts and tables • Metric displayed in PP slides • YouTube Videos	Database data available for download via Excel	Number of searchable databases	None
CBER	• Searchable database • Most of the data is presented on Web pages	Graphics in annual reports	None	Guidance, Compliance & Regulatory Information (Biologics)	None
CVM	• Searchable database: • Majority of data is presented as Web pages and downloads / pdfs	None	Database data available for download via Excel	• BSE Ruminant Feed Inspections Firms Inventory • Guidance	None
CDRH	• Searchable Databases	Graphics in annual analysis and FDA Track data	Database data available as pipe delimited files for download	• Large number of databases with simple and advanced searches. • Specific enforcement ones include recalls and inspection conclusions	MedWatcher app
CTP	• Searchable Database • Compliance	• Contract to display WL and CMPs	Database data available for download via Excel	WL and Civil Money Penalty Complaints	Mobile Texting Pilot Program

	Webinars • Podcasts • Widgets • Twitter	data via state maps • Pledge to Protect Kids from Tobacco shows data via a map	

APPENDIX 2: AGENCY- AND CENTER-OPERATED DATA SYSTEMS AND REPORTS

A. ORA Data Systems/Databases and Reports

The Office of Regulatory Affairs (ORA) operates all FDA-wide compliance and enforcement ***data systems***, including the following:

Operational and Administrative System for Import Support (OASIS): OASIS is the primary import operations system. It is a mission-critical system that fully automates the screening of product lines received daily from U.S. Customs and Border Protection (CBP) and supports the manual review and decision process for those products, returning the results to CBP. OASIS operates in conjunction with CBP's Automated Commercial System (ACS).

Field Accomplishments and Compliance Tracking System (FACTS): FACTS is ORA's primary domestic operations system. It serves as a central data repository for workload management, sample collections, sample analyses, information about firms regulated by the FDA, investigative operations, and compliance operations.

Compliance Management System (CMS): CMS, a Web-based system, is a collection of modules supporting FDA compliance management and workflow for compliance-related activities. CMS assembles inspection and import data from FACTS and OASIS to support work and case activities, including the publication of import bulletins, import alerts, and warning letters. Along with these activities, CMS can track and store compliance work from any FDA center. For example, CDER, CBER, CFSAN, and CVM use CMS to review results of foreign inspections. To some degree, CMS incorporates the centers' disparate compliance processes into a single system. CMS also enables field and center compliance officers to identify a compliance action and associate information in or outside FACTS. CMS also enables the association of all evidence needed to support compliance actions such as warning letters, regulatory meetings, seizures, and injunction, along with certain post-enforcement documentation. CMS organizes and centralizes establishment inspection reports and associated forms (e.g., FDA 483 Forms), helping ensure attachments and exhibits are accurate and uploaded in accordance with FDA (including FDA district) procedures. CMS also processes inspections for final review and classification. It can electronically transmit such information to the appropriate organizational units based on their business practices.

Recall Enterprise System (RES): RES is a centralized database for all recall activity. RES has substantially reduced the time needed to collect, process, and track recall information. RES eliminated the need for a variety of hard copy recall recommendations.

Turbo Establishment Inspection Report (Turbo EIR): An automated off-line reporting application, Turbo EIR provides the investigator a database of citations and helps the investigator prepare FDA Form 483 and, eventually, the establishment inspection report EIR). Turbo EIR loads FDA Form 483 data to a database for subsequent analysis (some FDA Form 483s, are still manually prepared and not available in this format).

Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT): Replacing the automated import admissibility screening portion of OASIS, PREDICT creates a risk-based import screening tool to improve the efficiency and productivity of the entry review and inspection process by targeting high-risk imports and leveraging automated verification of

product compliance with center databases. A Web-based system, PREDICT automatically flags potentially risky shipments, such as raw seafood, and gives lower-risk scores to products with good histories based on data provided by importers and entry filers, allowing the products to be rapidly cleared through FDA inspection.

There are a number of ***ORA-generated compliance and enforcement reports*** derived from ORA's above-listed systems, some of which are available to and used by other FDA components as well as the public. These include the following:

Inspections Classification Database and Search: Derived from the Field Accomplishments and Compliance Tracking System (FACTS), this data set discloses final classifications for inspections conducted of clinical trial investigators, institutional review boards (IRB), and facilities that manufacture, process, pack, or hold a currently marketed FDA-regulated product, when such inspections do not implicate matters subject to planned enforcement actions. During FDA's assessment, classifications may be subject to change after a review of all relevant information.[71]

Inspections Observation: Derived from ORA's Turbo EIR system, this data set is based on conditions or practices ORA inspectors list as objectionable and potentially violative of FDA requirements on FDA 483 Forms.[72] In addition to a summary, the site also includes certain downloadable inspectional observation data sets in Excel format. Spreadsheets summarizing the areas of regulation cited on FDA's system-generated 483 Forms, which are available by fiscal year, indicate how many times they were cited in those forms during FDA inspections.

Warning Letters: FDA's FOIA office reviews and manually posts redacted FDA warning letters, tobacco retailers warning letters, and drug marketing and advertising warning letters are posted to http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm. Warning letters related to health fraud are also housed on the ORA-owned health fraud scams Web page under the compliance actions section.[73]

Enforcement Report: As part of FDA's efforts to the increase the transparency of its compliance and enforcement data, the Enforcement Report's format was modified in June 2012 to offer downloadable recall data on a weekly basis in a usable, consumer-friendly format. Exported from RES universe, it is loaded into a Web application service without recall staff or contractor intervention. The report supplies information on all recalls and uses a tab format to provide information by the categories of Biologics, Devices, Drugs, Food/Cosmetics, and Veterinary and for product type, product description (including product and event details), code information, recall **c**lassification, reason for recall, and recalling firm.[74]

Recall, Market Withdrawals, and Safety Alerts: ORA provides a list gathered from press releases and other public notices about certain recalls of FDA-regulated products. In addition to furnishing information for recalls, the list provides information addressing general topic area

[71] For more on the classification of inspections, see the Establishment Inspection Report (EIR) Conclusions and Decisions ORA Field Management Directive 86. Accessed September 25, 2013.

[72] See http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm. Accessed September 25, 2013.

[73] See http://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/ucm255474.htm. Accessed September 25, 2013.

[74] See http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm. Accessed September 25, 2013.

(i.e., food, drugs, animal health, biologics medical devices and cosmetic) as well as date (sortable), brand name (sortable), product description, reason/problem, company (sortable), details (press releases), and photos (when available). This information is derived from metadata assigned to press releases allowing FDA's Web content management system to display the graphical table and sorting available on this Web page.[75]

FDA Debarment List: The following site links to a FDA Debarment List for drug product applications for persons who have been debarred: http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm. The following site links to an FDA Debarment List for food importation for persons debarred pursuant to sections 306(b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(3)): http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm194263.htm

Enforcement Statistics: ORA annually posts enforcement statistics/activity at: http://www.fda.gov/ICECI/EnforcementActions/ucm247813.htm. A slide set is available that includes fiscal year or multi-year statistics for seizures, injunctions, warning letters, recall events (total and by class), recalled products (total and by class), and debarments. These data are extracted from the Compliance Management System (CMS) and the Recall Enterprise System (RES).

Clinical Investigators—Disqualifications Proceedings: ORA consolidates information at one searchable database on disqualification proceedings for clinical investigators that until recently was made available in seven Web pages. This information, which was not previously tracked in a database, is now accessible at: http://www.fda.gov/ICECI/EnforcementActions/ucm321308.htm.

Import Alerts: See http://www.accessdata.fda.gov/cms_ia/ialist.html. Import alerts are automatically generated from CMS.

Import Refusals: See http://www.accessdata.fda.gov/scripts/importrefusals/. Import refusals are updated from OASIS data on a monthly basis.

B. Center-specific ORA Data Systems/Databases and Reports

Some centers have created and use their own independent systems to acquire, generate, and/or track compliance and enforcement data tailored to their needs.[76]

CBER

Direct Recall Classification (DRC): DRC refers to CBER personnel's direct classification of biologics recalls in lieu of more traditional and time-consuming recall classifications undertaken by FDA personnel located in FDA's district offices. DRC was designed to use current

[75] See http://www.fda.gov/Safety/Recalls/default.htm. Accessed September 25, 2013.

[76] Sometimes, however, centers commingle some ORA compliance and enforcement data with non-ORA data that have been entered into their own systems/databases. For example, to monitor recalls, CDRH uses, but then augments, data it receives from ORA's Recall Enterprise System (RES). Similarly, CFSAN has an internal system to monitor recalls that includes, but is not limited to, data from RES.

information technology to streamline recall classifications of biologics. The DRC program gives establishments the opportunity to electronically report recall-related information directly to CBER. Through the use of an electronic interface between Agency databases, the time and resources previously needed to review and classify recalls or biologics have been greatly reduced.

Biologic Product Deviation Reports (BPDRs).[77] BPDR data are housed in CBER's Biologics Compliance Information System (BCIS), which, in turn, has been interfaced with CBER's DRC system, thereby transferring BPDR data to CBER's DRC program. On occasion, as data populating the DRC system demonstrate, centers enter data that ultimately make their way into ORA's Agency-wide systems/databases. In May 2007, a bi-directional interface to share data between CBER and ORA was developed to provide a mechanism to automatically generate recall event records in ORA's Recall Enterprise System (RES) using data captured in the CBER BCIS application. Additionally, in March 2009, CBER's DRC Program provided a mechanism to automatically generate CBER-related recall event records for certain recalls in RES using data compiled in the CBER BCIS application. This interface enables the transfer of information into RES without requiring direct input from district recall coordinators. DRC records are classified and terminated without ORA involvement. Following classification, CBER recall data return to BCIS for reporting purposes. Thus, CBER contributes data to ORA's RES while importing ORA's RES data into BCIS.

Note: The regulations at 21 CFR 600.14 and 21 CFR 606.171 require biologics manufacturers to report BPDRs and related information. Reporting is required for events associated with the manufacture of a biologic in which there is a deviation or unexpected or unforeseeable event that may affect the safety, purity, or potency of a distributed product. In addition, 21 CFR 1271.350(b) requires the reporting of deviations in the manufacturing of distributed human cells, tissues, and cellular and tissue-based products (HCT/Ps) that relate to a core Good Tissue Practice (GTP) regulation and the prevention of communicable disease transmission or HCT/P contamination.

CDER

Establishment Evaluation System (EES): Inspection assignments in CDER's preapproval program are issued in EES. If an inspection is needed, the assignment is transmitted electronically via EES to FACTS.

Drug Quality Reporting System (DQRS): DQRS is a centralized reporting system that encourages health care professionals to voluntarily report observed or suspected defects or quality problems with marketed drug products. FDA receives such reports through the MedWatch Program. CDER evaluates and prioritizes drug quality reports to identify and follow-up on significant health hazards through assignment and review of investigative reports. Drug quality reports are also used to identify industry trends associated with pharmaceutical manufacturing, packaging, and labeling.

Substance Registration System (SRS): The goal of the joint FDA/United States Pharmacopeia (USP) Substance Registration System (SRS) is to support health information technology initiatives by generating unique ingredient identifiers (UNIIs) for substances in drugs, biologics,

foods, and devices. The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. The SRS Board oversees the procedures and management of the SRS and comprises experts from FDA and the USP.

Electronic Drug Registration and Listing System (eDRLS): Section 510(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(p)) now requires manufacturers to submit registration and listing information for human drugs electronically, unless a waiver is granted. CDER's eDRLS has replaced the older paper-based Drug Registration and Listing System (DRLS).

Document Archiving, Reporting & Regulatory Tracking System (DARRTS). DARRTS is a flexible, integrated, fully electronic workflow tracking and information management system to receive, log, track, assign, process, and manage official submissions with internal and external stakeholders. The system maintains the official submission records and manages and tracks communications and documentation concerning submissions.

In some instances, CDER relies on interfaces it has created involving some of its center-specific systems that enable data and information to be shared: DARRTS-EES-FACTS (drug review and establishment data and inspection assignment and outcome information) and DQRS-DRLS/eDRLS (DQRS interfaces with DRLS and eDRLS for relevant product, labeler and establishment data).

CDRH

CDRH Ad-Hoc Reporting System (CARS): CARS is a center-specific data warehouse permitting ad hoc queries and generation of user-customized analytical reports as well as canned reports.[78] Updated daily, CARS allows data from several transactional systems to be analyzed together without affecting those systems' performance. Within CARS, CDRH has integrated data from across the total product life cycle (TPLC), which brings together large volumes of compliance and enforcement and other data from several sources. TPLC includes data on all approvals and clearances, device problems, the applicable MAUDE records, and recalls. The data can be aggregated by any number of factors, including device type, FDA establishment identifier (FEI), district and medical specialty.

CARS pulls and integrates substantial volumes of data from ORA-operated and owned systems, and CDRH augments this information with additional data not available in ORA's systems for retrieval and analysis by its personnel. For example, its recall data set contains more data than are entered into RES. CARS also integrates data from other ORA systems such as FACTS as well as from multiple non-ORA systems, including CDRH'S Center Tracking System (a Web-based, flexible workflow tracking system designed, among other things, to ensure more accurate, more efficient, and faster reviews of certain industry submissions) and FDA Unified Registration and Listing System (FURLS/Device Registration and Listing Module (DRLM). CARS also features CDRH's TPLC repository as one of its primary constituents.

[78] CDRH is piloting some aspects of center-wide compliance and enforcement data base/data system integration at FDA.

APPENDIX 3: LOCATIONS OF COMPLIANCE AND ENFORCEMENT DATA ON THE FDA WEB SITE

The following links lead to compliance and enforcement data on FDA's Web site. Web pages were accessed on September 25, 26, and 27, 2013, and on October 18, 21, 22, and 23, 2013:

FDA-wide ORA compliance and enforcement data:

Inspection classifications:
http://www.fda.gov/ICECI/EnforcementActions/ucm222557.htm

Warning Letters:
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

Recalls (Enforcement Report):
http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

AIP list:
http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm

Debarment list:
http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm

Clinical investigator disqualified/restricted lists:
http://www.fda.gov/ICECI/EnforcementActions/DisqualifiedRestrictedAssuranceList/default.htm

Enforcement Story – NOTE: has not been published since FY2008:
http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/default.htm

Non-clinical labs (GLP inspections) – NOTE: does not appear that lists have been updated since approx. 2006 -2008:
http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/NonclinicalLaboratoriesInspectedunderGoodLaboratoryPractices/ucm2005399.htm

FDA BSE/Ruminant Feed Firms Inventory: **http://www.accessdata.fda.gov/BSEInspect/**

Inspection observations:
http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm

Enforcement statistics: **http://www.fda.gov/ICECI/EnforcementActions/ucm247813.htm**

Import Alerts:
http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm

Import Refusals:
http://www.fda.gov/ForIndustry/ImportProgram/ImportRefusals/default.htm

Compliance and enforcement data on center-specific Web pages:

CBER

Untitled Letters:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/ucm091551.htm ;
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/ucm091547.htm

Administrative Action Letters:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/AdministrativeActionsBiologics/default.htm

Clinical Investigator Inspection Lists:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm165743.htm

Certain biologic recall notifications (non-blood/plasma recall notifications prior to classification):
http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/default.htm

Biologic Product Deviation Report (BPDR) annual summaries:
http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129757.htm

Blood collection and transfusion fatality reporting annual summaries:
http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/default.htm

Human cells, tissues, and cellular and tissue-based product (HCT/P) inspection data:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm136342.htm

Recall statistics:
http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/ucm275723.htm

CTP

Tobacco retailer compliance check inspections database and listing of recent civil money penalty letters:
http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm

Other types of Warning Letters are available at FDA's Inspections, Compliance, Enforcement, and Criminal Investigations page:
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm#recent

Tobacco retailer compliance webinars:
http://www.fda.gov/TobaccoProducts/ResourcesforYou/BreakTheChain/ucm220111.htm

Tobacco retailer compliance podcasts:
http://www.fda.gov/TobaccoProducts/ResourcesforYou/BreakTheChain/ucm237677.htm

CVM

Advisory Action Letters:
http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/ucm042132.htm

CFSAN

Total Diet Study (contaminant levels in foods):
http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/TotalDietStudy/default.htm

Egg Farm Inspection Classification Lists: **http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/ucm227619.htm**

Untitled Letters
http://www.fda.gov/Food/ComplianceEnforcement/UntitledLetters/default.htm

CDRH

CDRH Medical Device Database Listings:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm, includes:

CDRH Inspections Classification Database:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/inspect.cfm

CDRH Recalls Database:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm

CDRH Total Product Lifecycle Report:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

CDRH Radiation-Emitting Electronic Products Corrective Actions:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/rh_res.cfm

CDER

Certain drug recall notifications (mainly Class I):
http://www.fda.gov/Drugs/DrugSafety/DrugRecalls/default.htm

Warning Letters and Notice of Violation Letters to Pharmaceutical Companies:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm

Cyber Letters:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/CyberLetters/default.htm

Enforcement Actions Sorted by Drug Class:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm

Unapproved Drug Actions Sorted by Firm:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm228670.htm

Unapproved Drug Actions Sorted by Private Label Distributor:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm228677.htm

Clinical Investigator Inspection Classification Database:
http://www.accessdata.fda.gov/scripts/cder/CLIIL/index.cfm

Compounding Warning Letters:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm