FOOD AND DRUG ADMINISTRATION TRANSPARENCY INITIATIVE:

EXPLORATORY PROGRAM TO INCREASE ACCESS TO THE AGENCY'S COMPLIANCE AND ENFORCEMENT DATA

TRANSPARENCY TASK FORCE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
JANUARY 31, 2012

I. Background

In a May 6, 2011, memorandum to the Department of Health and Human Services responding to a January 18, 2011, Presidential Memorandum on Regulatory Compliance,[1] FDA recounted the actions it had already implemented, as well those proposed or underway, to increase public accessibility of its regulatory compliance and enforcement information.[2] FDA stated that it would: (1) issue proposals for public comment, if it concluded that there were additional opportunities to increase the transparency of its compliance and enforcement data, within 150 days (by October 3, 2011), and (2) determine whether to adopt those proposals within 270 days (by January 31, 2012).

On October 3, 2011, 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," that advanced the following eight draft proposals to make FDA's publicly available compliance and enforcement data more accessible and user-friendly:[3]

> **Draft Proposal 1:** FDA should 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 should explore how frequently data should be updated in order for it to be useful to stakeholders.
>
> **Draft Proposal 2:** Although FDA's inspections database webpage currently provides an e-mail address where stakeholders can submit questions about the database, FDA should 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.

---

[1] Presidential Memoranda-Regulatory Compliance, Jan. 18, 2011, 76 Fed. Reg. 3825 (Jan. 21, 2011).

[2] Memorandum from John M. Taylor, Acting Principal Deputy Commissioner of the FDA, to HHS, dated May 6, 2011, http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM272653.pdf

[3] See http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf at pp. 9-10.

Draft Proposal 3: FDA should 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 webpages, and to encourage data analysis.

Draft Proposal 4: FDA should 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.

Draft Proposal 5: FDA should 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.

Draft Proposal 6: FDA should 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.

Draft Proposal 7: FDA should 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.

Draft Proposal 8: FDA should provide appropriate context for the compliance and enforcement data that it discloses, to help ensure that the data is not misinterpreted or 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)), and
- A statement explaining that the website'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).

In announcing the availability of this report on October 4, 2011, FDA sought public comment on these proposals by December 2, 2011. 76 Fed.Reg. 61367 (October 4, 2011). The Agency stated that its Transparency Task Force would ultimately recommend specific draft proposals to the Commissioner of Food and Drugs (the Commissioner) for consideration based on the comments it received, the feasibility of each draft proposal, relative priority, and available resources, and that the Commissioner would determine whether to adopt any of these draft proposals by January 31, 2012.

Seventeen (17) public comments were received in response to these proposals from various stakeholders, including manufacturers, trade associations, an academic center, animal rights advocates, and consumers. The Task Force reviewed the comments received from all of these stakeholders. The public comments were largely, although not universally, supportive of FDA's proposals, albeit sometimes with qualifications. For example, while expressing support for FDA's transparency efforts, one comment remarked on the importance of ensuring an accurate and current database, posted with appropriate context, in a manner consistent with current laws governing the preservation of confidential and proprietary information.

Based on a review of the recommendations of the Transparency Task Force, the Commissioner is adopting all eight of the draft proposals published in October 2011, thereby committing the Agency to exploring numerous avenues for increasing the transparency and public accessibility of its compliance and enforcement data.

II. Initiatives Promoting Greater Access to the Agency's Compliance and Enforcement Data That FDA Will Explore to Increase Transparency

Following are the initiatives the Commissioner has determined merit exploration:

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.

Summary of Public Comments

Several comments voiced support for more frequent and/or timely updating, provision, and/or posting of compliance and enforcement data from FDA's inspection database, including, without limitation, those relating to classifications of completed inspections. Some comments argued for increased or timelier access to redacted FDA

483 Forms[4] and Establishment Inspection Reports.[5] Some comments maintained that data and information will be helpful only if current, timely and consistently subject to a disclosure schedule. Addressing data quality issues, one comment recommended that quality control be performed to ensure the accuracy and consistency of information contained in multiple databases.

Discussion

The Agency is committed to exploring possible activities to improve the timeliness of its compliance and enforcement data disclosures, including:

- establishment of more automated and centralized processes for capturing, verifying, and sharing data in lieu of labor-intensive and time-consuming manual entry, extraction, review, cross-checking, reconciliation, dissemination, and electronic posting of such information obtained from multiple sources;

- furnishing investigators handheld and other portable devices, including tablet computers, as well as leading edge technologies such as bar code printers to effect significant gains in timeliness, productivity, and efficiency, as well as quality assurance; and

- institution of administrative incentives to induce timely and accurate completion and classification of inspections and entry at multiple Agency levels of associated data.

FDA will also explore how it can enhance data quality by refining and standardizing data definitions across the Agency and through modernization of its information technology infrastructure by transitioning from more error-prone manual review, cross-checking, and reconciliation to an automated process for detecting and correcting inaccurate data.

Initiative 2: Although FDA's inspections database webpages currently provide 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

[4] The FDA Form 483, "Inspectional Observations," is a form FDA investigators use to list observations of objectionable conditions found during inspections. It is presented to, and discussed with, senior management at facilities at the conclusion of inspections.

[5] Investigators working out of the Agency's field offices conduct FDA inspections of establishments in which FDA-regulated products are manufactured, processed, packed or held. Clinical investigators are also inspected in connection with the testing of investigational drugs or devices. All inspections generate an Establishment Inspection Report.

compliance and enforcement data, and (2) the Agency can implement procedures for investigating potential errors and correcting data, when appropriate, that would enable it to remedy the errors more expeditiously.

Summary of Public Comments

One comment stated that manufacturers should have a mechanism for disputing incorrect or unclear information, and FDA's databases should clearly indicate that its publicly available compliance and enforcement information is currently under review for accuracy. Several comments supported installation of error reporting buttons enabling stakeholders to identify and focus the Agency's attention on potential errors in such information. One comment, however, stated that the overall focus should be on ensuring that data are accurate when they are posted rather than developing systems enabling the public to correct the data. Two comments advocated that reporting buttons be supplemented with a mechanism providing feedback to error reporters that acknowledged receipt of error reports and any subsequent corrections. One of these comments also recommended that FDA define a timeline in which errors can be expected to be resolved.

Discussion

FDA will explore the feasibility of allowing stakeholders to alert the Agency to potential errors in its compliance and enforcement information through installation of error reporting buttons. The Agency will additionally investigate whether to supplement these tools with mechanisms to notify error reporters of receipt and, where applicable, subsequent correction of errors. As part of this initiative, the Agency will investigate the resources needed to establish and sustain a group of data stewards charged with the ongoing responsibility for correcting erroneous data in the Agency's compliance and enforcement data systems.

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 webpages, and to encourage data analysis.

Summary of Public Comments

Some comments argued that FDA should attach greater priority to the publication, quality, relevance, and/or usefulness of its compliance and enforcement data than to its graphic presentation**.** One comment stated that investing in graphics and mobile web applications is a luxury and that FDA can make better use of its resources. Another urged FDA to minimize analysis relative to the specific deficiencies it identifies from inspections; companies should perform any analyses. Other comments similarly recommended that FDA provide access to the raw or source data online or in secure file format to allow stakeholders to perform their own analyses. One comment suggested that user feedback be solicited to determine what types of graphics would be most useful.

Discussion

While FDA agrees with the need to ensure the quality, utility, and reliability of its underlying compliance and enforcement data, the Agency believes that improved, more user-friendly and accessible graphic presentation of those data will better inform stakeholders about compliance and enforcement matters by drawing more users to its compliance and enforcement webpages. At the same time, the Agency intends to investigate the feasibility of continued investment in IT enhancements designed to encourage data analysis by making more source data available to stakeholders for extraction, retrieval, and individualized analyses. (See Discussion under Initiative 4 below). In the hope of improving stakeholder access to its compliance and enforcement webpages, FDA is also committed to developing content ready for viewing on mobile devices.

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.

Summary of Public Comments

One comment supported integrating compliance and enforcement data in a more user-friendly format based on input solicited from industry on how best to present the data. One comment observed that, because many of FDA's compliance and enforcement databases are not linked together, navigation between them is often difficult. It recommended that FDA consolidate its enforcement and compliance data into a single source incorporating relevant data fields and search criteria that would allow users from different constituencies and industries quickly to locate and obtain information of interest. Another argued that all of FDA's Center-specific databases should be integrated to draw from the same core data sources. Another comment maintained that it is not possible for food safety managers, regulators, and public health scientists to access and make efficient and timely use of multiple import refusal entries from FDA's Operational and Administrative System for Import Support (OASIS) database. It also encouraged FDA to make records of all inspections available in this database, including both positive and negative drug residue test results. One comment urged FDA to focus on the timely availability of actual data and leave detailed analysis to external stakeholders, such as companies and trade publications. Focusing on establishment identifiers in FDA's databases, another comment stated it would be helpful for researchers possibly to link FDA data to data from other agencies. One comment suggested that it would be useful for academic researchers to be able to query the compliance and enforcement database and export/download large files.

Discussion

While FDA has integrated some of its compliance and enforcement data from multiple FDA systems into its existing regulatory reporting, analysis, and decision support system, efforts are still underway to better integrate the Agency's databases as

much of the compliance and enforcement information is still stored in separate database systems. Additionally, its webpage development, posting, and communications processes remain largely decentralized by Agency component. Because FDA lacks a single authoritative core data source, data redundancy is one of the major issues that its multiple regulatory data systems confront. To the extent permitted by available resources, FDA is committed to exploring the feasibility of further centralizing and thereby integrating its compliance and enforcement data collection, data terminology/characterization, analysis, reporting, and dissemination processes. Initiative 4 informs investments FDA has under consideration to create an IT data repository or warehouse into which its current multiple regulatory data systems could be migrated and consolidated in order to improve how the Agency captures, integrates, and shares its operational compliance and enforcement data. Through a public-facing portal, a data warehouse could be designed to facilitate and ease data retrieval by stakeholders conducting analyses and generating reports customized to their individualized needs and preferences.

FDA works with multiple external partners, including state and local regulatory agencies, other federal agencies, and foreign governments. As FDA works to further enhance the transparency of its compliance and enforcement activities to the public, it also seeks to improve its transparency to, and data sharing and integration with, such partners.

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.

Summary of Public Comments

Comments generally supported making the inspection database's search functionality more robust and user-friendly. One comment maintained that the capabilities to search for compliance and enforcement data are currently very limited, while another recommended that FDA evaluate the potential to provide innovative methods for searching and filtering data that would improve the user's ability to identify and sort data and information in an accurate and user-friendly manner. One comment urged exploration of more "foolproof" search criteria; *i.e.*, a search system that would yield desired information in the event of search term misspellings or punctuation inaccuracies. Another comment expressed security concerns about FDA's making product-specific information available in an easily searchable database that would permit linking a warehouse location with the pharmaceuticals stored there, since, it argued, this could assist criminal elements in targeting where valuable pharmaceuticals are warehoused.

Discussion

FDA will explore improving the search capabilities for the public-facing portals in its IT systems to the extent that available resources permit. Among other things, this will encompass investigating:

- the introduction of predictive search query suggestions;
- the consistent application of commonly defined metadata[6] terms across the Agency;
- the establishment of a means for clustered search results or the automatic organization of search results into sets of results that have something in common, be it themes or related keywords, all of which could assist searchers in zeroing in on their goal; and
- development of dynamically generated webpages from the Agency's databases; that is, webpages prepared with fresh information for each individual viewing that changes with the time (e.g. new content), the user (e.g. preferences in a login session), the user interaction, the context (e.g. parametric customization), or any combination thereof and is automatically provided from a database.

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.

Summary of Public Comments

One comment supported Initiative 6 when it was presented in October 2011 as a draft proposal if it complements the disclosure of meaningful raw data. It and one other comment urged FDA to give priority to providing meaningful raw data rather than compilations or analyses. With such data, one of those comments maintained, companies can perform their own analyses. Another comment suggested use of consistent terminology to characterize violations emanating from very similar fact patterns or conditions and urged that external data miners assign a uniform nomenclature to enumerate charges for violating Agency regulations. One comment stated that analyses as well as graphics based on the language from the automated reporting system used to generate FDA 483 Forms and Establishment Inspection Reports (EIRs) are of limited value and that FDA should instead provide redacted 483 Forms in addition to the official inspection classification. Noting that the FDA Form 483 does not constitute the Agency's final determination on a violation, this comment added that publishing only a

[6] Metadata literally means "data about data" and describes how and when and by whom a particular set of data was collected, and how the data is formatted.

copy of the redacted Form 483 will not achieve full and fair disclosure or provide the appropriate contextual balance to prevent misinterpretation. The Agency should not only release the redacted version of the Form 483, but, if the company grants prior consent, the comment contended, the redacted company response.

Discussion

FDA will explore whether posting additional data compilations or analysis would increase transparency and better inform stakeholders about its compliance and enforcement activities. This inquiry will include an assessment of the informational value of compilations and analyses the Agency currently posts and of the need for and feasibility of undertaking and posting additional compilations and analyses. All of this is in addition to exploratory efforts to make compliance and enforcement databases more serviceable to stakeholders wishing to conduct their own analyses based on direct access to one or more data repositories. The Agency will also explore whether or to what extent it should adopt more consistent regulatory terminology to characterize potentially violative conduct associated with inspectional findings.

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.

Summary of Public Comments

One comment stated that FDA should consider use of social media to communicate compliance and enforcement data, as it may provide FDA opportunities to receive feedback and questions. Other comments argued that FDA should defer such use until it has effectively managed or otherwise optimized its compliance data. One of these comments also implied that social media may not be appropriate here, as it implicates security concerns and provides opportunities for misinformation/confusion. Another comment encouraged FDA to pay particular attention to context in the social media arena.

Discussion

The Agency believes that social media may enhance the Agency's efforts to communicate its compliance and enforcement data and activities to the public. This builds on efforts the Agency has already initiated with its FDA Transparency Blog, which is transferrable to Facebook and Twitter. See http://fdatransparencyblog.fda.gov/. Accordingly, the Agency will explore how it can improve and, if appropriate, increase its utilization of social media to impart important compliance and enforcement information to its stakeholders and the public at large.

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 misused. Depending upon 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 website'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).**

Summary of Public Comments

Several comments supported this initiative when presented in draft proposal form. For example, one comment "heartily" supported FDA's posting the frequency of data updates. Some comments expressed concern that transparency be achieved consistent with laws and regulations protecting trade secrets and confidential information. One comment urged that the Agency adopt and enforce a strict or narrow definition of confidential business information and encourage companies, for example, to release data on failed or abandoned compounds. Another comment, addressing how long the Agency takes to finalize inspection classifications, offered that the average lapse time between inspection and the posting of inspection classification information may be a useful performance metric for FDA to monitor and that establishing and disclosing specific timeframes or standards for posting inspection classification information would benefit users. One comment urged that FDA provide more robust explanations of what inspectional findings it found violative, while another similarly recommended that definitions of such findings be expanded to spell out the nature of cited violations. Another comment maintained that providing only the most common inspection observations would be of marginal utility to the regulated community should listed observations not be sufficiently detailed. One comment suggested that technical terms—for example, Warning Letter or recall—be clearly explained for the lay reader. It further urged FDA to:

- caution against using Medical Device Reporting (MDR) reports to assess rates of adverse events where it is not known how many devices are used in clinical practice;

- make full Additional Manufacturer Narrative on MDR reports and manufacturers' redacted responses to Warning Letters available and linked to original reports; and

- caution that a Warning Letter citing Good Manufacturing Practice (GMP) violations does not imply that devices are unsafe.

Decision

FDA is committed to helping prevent public misinterpretation or misuse of the compliance and enforcement data it publicly discloses by providing appropriate contextual information of the types referenced in Initiative 8. The Agency will also explore the necessity and feasibility of changing the manner in which it characterizes potentially violative inspectional findings. The Agency will additionally examine whether it needs to provide more contextual information surrounding its disclosure of MDR reports.[7] In carrying out this initiative, the Agency will act consistent with laws and regulations protecting trade secrets and confidential commercial information.

[7] When providing Manufacturer and User Facility Device Experience (MAUDE) data derived from such reports, the Agency currently cautions that such information "is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices." See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm.