

**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**

**TRANSPARENCY TASK FORCE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
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On January 18, 2011, President Obama issued a Presidential Memorandum on Regulatory Compliance,¹ requiring federal agencies to make publicly available compliance information easily accessible, downloadable, and searchable online, to the extent feasible and permitted by law. In that memorandum, the President observed that:

Greater disclosure of regulatory compliance information fosters fair and consistent enforcement of important regulatory obligations. Such disclosure is a critical step in encouraging the public to hold the Government and regulated entities accountable.²

The President also highlighted the achievements of the Environmental Protection Agency (EPA) and the Department of Labor (DOL) in developing websites (www.epa-echo.gov and <http://ogesdw.dol.gov>, respectively) that make their regulatory compliance information more accessible to the public.³

The Food and Drug Administration (FDA or Agency) responded to the Presidential Memorandum on Regulatory Compliance in a memorandum to the Department of Health and Human Services (HHS), on May 6, 2011 (FDA Response).⁴ The FDA Response summarized the actions that the Agency already had implemented, as well as those that were underway or proposed, to make its regulatory compliance and enforcement information more accessible to the public. FDA took those actions in response to the Presidential Memorandum on Transparency and Open Government,⁵ which the President issued in January 2009, and as part of FDA's own Transparency Initiative, which FDA's Commissioner, Dr. Margaret A. Hamburg, launched in June 2009.

In the FDA Response, the Agency also committed to examining the manner in which EPA and DOL disclose compliance and enforcement information to determine whether there are additional steps FDA could take to make comparable information more accessible. Specifically, FDA stated that it would: (1) within 150 days (by October 3, 2011), issue proposals for public comment, if it concluded that there were additional opportunities to increase the transparency of its compliance and enforcement data, and (2) within 270 days (January 31, 2012), determine whether to adopt those proposals.⁶

After meeting with EPA and DOL to discuss their methods for making compliance and enforcement data more accessible, FDA has determined that there are additional steps that it could take to make its own information more transparent and accessible to the public. Therefore, the Agency is issuing this report, which contains a number of draft proposals for public comment. Section I of this report summarizes the status of the actions that FDA has implemented, undertaken, or proposed, to date, to make its compliance and enforcement data more transparent and accessible; section II summarizes

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

² *Id.*

³ *See id.*

⁴ Memorandum from John M. Taylor, Acting Principal Deputy Commissioner of the FDA, to HHS, dated May 6, 2011 (FDA Response), <http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM272653.pdf>

⁵ Presidential Memorandum on Transparency and Open Government, Jan. 21, 2009, 74 Fed. Reg. 4685 (Jan. 26, 2009).

⁶ *See* FDA Response, at 9.

the EPA and DOL activities that have promoted greater public access to their enforcement and compliance data; and section III lists FDA's draft proposals, for public comment.

I. Status of FDA's Current Efforts to Increase Transparency by Promoting Greater Access to Compliance and Enforcement Data

The Commissioner launched FDA's Transparency Initiative⁷ in June 2009. As part of the Transparency Initiative, the Commissioner formed an internal task force (the "Task Force") to develop recommendations for enhancing the transparency of FDA's operations and decision-making processes. Since its inception, the Task Force has held two public meetings, launched an online blog, and proceeded with the Transparency Initiative in three phases:

- Phase I: *FDA Basics*⁸ – In January 2010, FDA launched a web-based resource called *FDA Basics*, which provides the public with basic information about FDA.
- Phase II: Public Disclosure⁹ – In May 2010, the Task Force released a report (Phase II Report) with draft proposals to increase FDA transparency, while protecting confidential information.
- Phase III: Transparency to Regulated Industry¹⁰ – In January 2011, the Task Force released a report (Phase III Report) with action items and draft proposals to make FDA more transparent and to foster a more efficient and cost-effective regulatory process.

In the Phase II and Phase III Reports, the Task Force identified 45 draft proposals and action items to improve transparency. FDA is responsible for a broad range of compliance and enforcement activities, and a number of the Phase II and Phase III draft proposals and action items were intended to expand or improve disclosure of information about FDA's compliance and enforcement activities.

Although the Commissioner is still considering the public comments on some of the draft proposals, as well as their operational feasibility, resource requirements, and relative priority, the Commissioner already has begun to implement some of the draft proposals related to compliance and enforcement.

⁷ See Transparency Initiative Homepage, FDA, <http://www.fda.gov/AboutFDA/Transparency/default.htm>

⁸ FDA Basics, FDA, <http://www.fda.gov/AboutFDA/Transparency/Basics/default.htm>

⁹ FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration (Phase II Report), FDA, <http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure/ExecutiveSummary/default.htm>

¹⁰ FDA Transparency Initiative: Improving Transparency to Regulated Industry, dated Jan. 2011 (Phase III Report), FDA, <http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/default.htm>

In a May 26, 2011 news release,¹¹ the Agency announced that it already has implemented the following Phase II draft proposals:

- (1) Draft Proposal 3 – Previously, FDA generally posted press releases on its website regarding the filing and resolution of enforcement actions filed by the Department of Justice on FDA’s behalf. However, there was no comprehensive list of these press releases available to the public. The Agency has implemented Draft Proposal 3 by developing a centralized webpage where stakeholders can easily access these press releases.¹² FDA also has developed and implemented standard operating procedures to ensure that the Agency is posting these press releases more systematically. Disclosing this information in one location provides the public with a more complete picture of industry activities that jeopardize the public health and about the actions that FDA is undertaking to protect the public health;
- (2) Draft Proposal 6 - FDA has posted a searchable inspections database that allows users to search by firm name, geographic information, the date of inspection, the FDA-regulated product involved (*e.g.*, by Center and inspection type), and the final inspectional classification.¹³ Disclosing this information increases the public’s understanding about the actions FDA is undertaking to protect the public health, and it may serve as an incentive for firms to correct violations and improve compliance efforts; and
- (3) Draft Proposal 7 - FDA has posted summaries of the most common inspection observations of objectionable conditions to better inform industry compliance efforts.¹⁴

In the same news release, FDA also announced that it has developed a web portal, entitled “Information about FDA Compliance and Enforcement Actions,”¹⁵ so that stakeholders can access information about key transparency activities related to enforcement and compliance in one place. The web portal provides links to the enforcement action press release webpage, the inspections database, and the common inspection observations discussed above. The portal also discloses, among other things, that FDA has placed a number of enforcement-related datasets on the Data.gov website.¹⁶ These include datasets for major food recalls, including the peanut and shell egg recalls, and the dataset providing information about websites that are, or were, illegally

¹¹ “FDA to make enforcement and compliance activities accessible online,” News & Events, FDA Note to Correspondents, May 26, 2011, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm256875.htm>

¹² See 2011 Enforcement Actions, FDA, <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm272028.htm>

¹³ See Inspections Database, FDA, <http://www.fda.gov/ICECI/EnforcementActions/ucm222557.htm>

¹⁴ See Inspection Observations, FDA, <http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm>

¹⁵ See “FDA to make enforcement and compliance activities accessible online,” News & Events, FDA Note to Correspondents, May 26, 2011, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm256875.htm>; see also Information About FDA Compliance, FDA, <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm254426.htm>

¹⁶ See US Food and Drug Administration Datasets, Data.gov, <http://www.data.gov/list/agency/25/28/catalog/raw/page/1/count/50>

marketing unapproved, uncleared, or unauthorized products related to the 2009 H1N1 flu virus. In addition, the web portal notes that the Agency has launched a redesigned webpage and phone app to permit consumers to search more easily and quickly for food and other product recalls, market withdrawals, and safety alerts.¹⁷

In the May 26, 2011 news release,¹⁸ FDA also announced that by the end of 2011, the Agency will begin to disclose additional information about FDA evaluations of filers, support industry efforts during a food recall to inform consumers about products that are not subject to the recall, in appropriate situations, and expand disclosure of untitled letters. These actions are intended to implement the following draft proposals from the Phase II Report:

- (1) Draft Proposal 5 – FDA will disclose the outcome of the filer evaluation for importers or third parties working on behalf of importers. Currently, importers, or third parties working on behalf of importers, file information about products offered for import into the United States. FDA conducts evaluations of those filers who submit information electronically to ensure that they are submitting accurate data, but those evaluations have not been made public, previously. Disclosing the evaluations may increase the accuracy of information submitted to FDA and decrease the number of potentially violative products firms try to import into the United States. It is important for other federal agencies with jurisdiction over FDA-regulated products, as well as for other companies in the supply chain, to have information about the compliance history of these entities;
- (2) Draft Proposal 19 – If FDA is aware of confusion in the marketplace about products that may be implicated in a food outbreak, and information gathered by industry or other sources may serve to alleviate that confusion, FDA will support efforts by industry and others to communicate information to consumers about products *not* subject to a recall when sufficiently reliable information about products not connected with the recall exist, if FDA concludes that disclosing the information is in the interest of public health; and
- (3) Draft Proposal 21 – FDA will expand its posting of untitled letters on the Internet,¹⁹ and it will post a recipient’s response to an untitled letter on the Internet, if the recipient requests it, as appropriate. Currently, FDA posts warning letters on the FDA website, and they are accessible in a searchable database or in various compilations organized by release date, company, issuing office, or subject matter, *etc.*²⁰ However, only some of the Centers post untitled letters on

¹⁷ See Improving Recall Information for Consumers, FDA,

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm249087.htm#improved>

¹⁸ See “FDA to make enforcement and compliance activities accessible online,” News & Events, FDA Note to Correspondents, May 26, 2011, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm256875.htm>

¹⁹ FDA issues an untitled letter to request that the recipient voluntarily correct any violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) listed in the letter. FDA uses untitled letters for violations that are not as significant as those that trigger warning letters. Unlike a warning letter, an untitled letter does not include a statement that warns the recipient that failure to promptly correct a violation may result in an enforcement action. FDA, generally, is under no legal obligation to warn individuals or firms about violations before taking enforcement actions.

²⁰ See Warning Letters, FDA, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

FDA's website. Expanded posting of untitled letters on the Internet may increase public accountability of firms, which may deter future violations and increase compliance with the law.

Since the May 26, 2011 news release, the Agency also has implemented Draft Proposal 4 in the Phase II Report. The proposal called for FDA to post the Office of Regulatory Affairs Annual Field Workplans that are older than five years, starting with 2001, on the FDA website. These workplans contain information regarding the Agency's planned enforcement priorities. FDA actually has exceeded the draft proposal, and is now posting all of the workplans from 2001-2010.²¹ Notably, workplans that are more than five years old (2001-2005) have been posted without redaction. However, any information in the more recent workplans that may interfere with ongoing inspection or enforcement activities has been redacted.²²

FDA is also working to implement Action Item 16 in the Phase III Report, which directed the Agency to establish a system that would permit interested stakeholders to receive e-mail notifications when an Import Alert is posted on the FDA website, or an existing Import Alert is updated. FDA expects to complete this action item shortly.

In addition, FDA has made considerable progress in implementing other draft proposals and action items in the Phase II and Phase III reports that are not directly related to compliance and enforcement activities. The Agency is in the process of creating a webpage that would allow stakeholders to track FDA's progress as we continue to increase transparency.

II. Summary of EPA and DOL Activities that Have Promoted Greater Access to Compliance and Enforcement Data

In the Presidential Memorandum on Regulatory Compliance, the President highlighted the achievements of EPA and DOL in making compliance and enforcement information more accessible to the public on EPA's Enforcement & Compliance History Online (ECHO) website (www.epa-echo.gov) and DOL's Enforcement Data 2.0 website (<http://ogesdw.dol.gov>).²³

This summer, FDA met with the champions of both websites in an effort to learn from, and build upon, their experiences. The conception, maintenance, and enhancement of both websites has required long-term commitment from senior leadership at EPA and DOL, who, like FDA senior leadership, recognize that transparency can drive good behavior and promote regulatory compliance.

EPA first launched ECHO in 2002. ECHO is a web interface that integrates EPA and state compliance and enforcement data for approximately 800,000 regulated facilities in

²¹ See Office of Regulatory Affairs Annual Field Workplans, Office of Regulatory Affairs (ORA) Workplans, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/ucm180154.htm>

²² FDA, generally, posts/updates workplans around the start of the new fiscal year.

²³ See Presidential Memoranda-Regulatory Compliance, Jan. 18, 2011, 76 Fed. Reg. at 3825.

the United States. The ECHO site allows users to find inspection, violation, enforcement action, informal enforcement action, and penalty information from the last three years about facilities regulated under the Clean Air Act (CAA) Stationary Source Program, Clean Water Act (CWA) National Pollutant Elimination Discharge System (NPDES), Resource Conservation and Recovery Act (RCRA), and Safe Drinking Water Act (SDWA). ECHO also includes SDWA data, Toxics Release Inventory data, National Emissions Inventory data, and Water Quality Data.²⁴

ECHO is innovative in its graphic display of inspection and enforcement data. ECHO uses maps to pinpoint inspection and enforcement data from specific regulated facilities. For example, ECHO's homepage contains an ECHO widget, under "ECHO In My Community," which allows users to search by zip code. When the user types in a zip code, the database will pull up a map pinpointing regulated facilities in the area.²⁵ These maps use color coding to show each facility's compliance status and numbers to show the number of years since the facility's last inspection. The user can obtain more detailed information by clicking on a particular facility with a mouse.

Another map on the website, among many others, allows the public to get information on all EPA enforcement actions and cases from 2010 in the United States.²⁶ This map uses color coding to show which environmental statutes are applicable to facilities in a given geographical area. As with the "Echo In My Community" map, the user can obtain more information about a particular facility by clicking on the facility.

ECHO's homepage also allows users to "mouse-over" certain icons to review state-by-state analytics and trends, as well as other contextual reports and information.²⁷ Although EPA launched ECHO in 2002, its champions noted that the site is a work in progress. They constantly strive to maintain and enhance the interface.

DOL's Enforcement Data 2.0 database is an aggregation of datasets from five separate agency systems (*i.e.*, Employee Benefits Security Administration (EBSA), Mine Safety & Health Administration (MSHA), Office of Federal Contract Compliance Programs (OFCCP), Occupational Safety & Health Administration (OSHA), and the Wage & Hour Division (WHD)). The database posts information about closed cases that includes inspections and violations data. Users can search by agency, state, zip code, company name, violation,²⁸ penalty amount, industry type (*e.g.*, various types of farming, manufacturing and services),²⁹ and year, and then, download the results into an Excel file for further manipulation and refinement. Notably, the database helps users analyze compliance information from related companies with predictive name searches.³⁰

²⁴ See ECHO Homepage, EPA, <http://www.epa-echo.gov/echo/index.html>; see also Frequently Asked Questions, ECHO, EPA, <http://www.epa-echo.gov/echo/faq.html>

²⁵ See ECHO Homepage, EPA, <http://www.epa-echo.gov/echo/index.html>

²⁶ See, *e.g.*, ECHO Annual Results Maps, Fiscal Year 2010, EPA, http://www.epa-echo.gov/echo/annual_maps.html

²⁷ See ECHO Homepage, EPA, <http://www.epa-echo.gov/echo/index.html>

²⁸ Users can search for facilities where there was or was not a violation; they cannot search by specific statutory or regulatory violation. See Search & Share, DOL Enforcement Data 2.0, DOL, <http://ogesdw.dol.gov/search.php>

²⁹ DOL utilizes the North American Industry Classification System or the Standard Industrial Classification, depending upon the dataset. See FAQ, Enforcement Data 2.0, DOL, <http://ogesdw.dol.gov/faq.php#search2>

³⁰ Search & Share, Enforcement Data 2.0, DOL, <http://ogesdw.dol.gov/search.php>

Similar to ECHO, DOL's Enforcement Data 2.0 often displays data graphically, and it uses a map to depict the location and types of OSHA and MSHA inspections and violations. As with the ECHO maps, the user can obtain more detailed information by clicking on a particular facility on the DOL OSHA/MSHA violation map with a mouse.³¹

DOL launched the Enforcement Data website in April 2010, and the Department acknowledges that its website, like EPA's, is a work in progress. In fact, DOL recently launched the 2.0 version (Enforcement Data 2.0), which added the following features: (1) the map displays of OSHA and MSHA inspection and violation data mentioned above, (2) viewable inspections records and enforcement history for specific companies or mines, (3) keyword searches with year, violation, or penalty filters, (4) a "Labs" section where visitors can create visualizations and animations using historical MSHA data, and (5) downloadable search results and datasets.³²

DOL's website also has a "Coming Soon" page announcing that DOL will add new functionality and features over the coming months, including: (1) new search criteria, (2) a mashup competition inviting the public to find innovative ways to use DOL's enforcement data, and (3) data that is better integrated with enforcement data from other federal and state agencies.³³ The "Coming Soon" page also solicits comments on additional ways to improve the site. Any user with a comment can click on a link entitled "feedback,"³⁴ and then can choose whether to submit a comment via e-mail, Twitter, or Facebook.³⁵

Although the data on EPA's and DOL's enforcement websites was publicly available through Freedom of Information Act (FOIA) requests, prior to the creation of the websites, the information was not available in a searchable web format. Accordingly, ECHO and Enforcement Data 2.0 made it much easier for the public to obtain the data, and this has a number of benefits. EPA noted that with ECHO, the public can better monitor environmental compliance in communities; firms can better monitor compliance across facilities that they own; and investors can more easily factor environmental compliance into investment decisions.³⁶ In addition, DOL observed that Enforcement Data 2.0 reduces the number of FOIA requests, the responses to which can be time-consuming and resource-intensive.

During the meetings, EPA and DOL shared the following approaches to data processing and data presentation, as well as general observations, which have helped them make their compliance and enforcement data more accessible to the public.

³¹ See Homepage, Enforcement Data 2.0, DOL, <http://ogesdw.dol.gov/index.php>

³² See "US Department of Labor improves enforcement databases," News Release, DOL, <http://www.dol.gov/opa/media/press/opa/OPA20111256.htm>

³³ See Coming Soon, Enforcement Data 2.0, DOL, http://ogesdw.dol.gov/coming_soon.php

³⁴ See *id.*

³⁵ See Feedback, Enforcement Data 2.0, DOL, <http://ogesdw.dol.gov/feedback.php>

³⁶ See also ECHO Frequently Asked Questions, EPA, <http://www.epa-echo.gov/echo/faq.html>

- (1) Posting current and high quality data increases transparency, and a number of process controls can be implemented to improve data quality and expedite disclosure, including:
 - Better field technology can speed disclosure – The more quickly inspectors can enter data into the database, the more quickly the agency can disclose it to the public.
 - Agencies can improve data quality and expedite data entry by implementing administrative incentives – For example, EPA field investigators do not get credit for inspections unless the field office certifies that the data has been properly recorded in a timely manner.
 - Increasing transparency, itself, provides an opportunity to improve data quality – Greater transparency reveals data errors and provides an opportunity to improve data quality if appropriate mechanisms for error reporting and data correction are in place.

For example, there is a “Report Error” button at the top of each ECHO Detailed Facility Report. If a firm or an individual identifies an error in the report, the firm or individual can click the “Report Error” button to flag the data error. The data error will remain publicly “flagged” until the issue has been investigated and resolved.

- (2) Presenting data graphically and providing mobile applications of databases increase transparency by driving more users to the website.
- (3) Integrated databases with specific search criteria permit stakeholders and the media to analyze data more easily and better understand compliance and enforcement trends.
- (4) Data analysis and/or different compilations of the same data, prepared by the agency/department, also help stakeholders and the media better utilize data and understand compliance and enforcement trends.
- (5) All compliance and enforcement data that is disclosed should be placed in context to ensure that the data is not misinterpreted or misused.

III. Draft Proposals to Increase Transparency by Promoting Greater Access to FDA’s Compliance and Enforcement Data

After meeting with the EPA and DOL champions of ECHO and Enforcement Data 2.0, the Task Force developed the following draft proposals to further improve the transparency of FDA’s compliance and enforcement activities and make its data more accessible to the public.

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,³⁷ 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.

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 observations³⁸ or the warning letter compilations,³⁹ 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

³⁷ See Inspections Database, FDA, <http://wcms.fda.gov/FDAgov/ICECI/EnforcementActions/ucm222557.htm>

³⁸ See Inspection Observations, FDA, <http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm>

³⁹ See Warning Letters, FDA, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

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).

FDA is soliciting public comment on these draft proposals for 60 days via www.regulations.gov. The Task Force will recommend specific draft proposals to the Commissioner for consideration based on the public comments, the feasibility of the draft proposal, relative priority, and resource constraints. The Commissioner will determine whether to adopt any of these draft proposals by January 31, 2012.⁴⁰

⁴⁰ See FDA Response, at 9.