

**FDA TRANSPARENCY INITIATIVE:
IMPROVING TRANSPARENCY TO REGULATED INDUSTRY**

**TRANSPARENCY TASK FORCE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
JANUARY 2011**

TABLE OF CONTENTS

I.	LETTER FROM CHAIR OF THE TRANSPARENCY TASK FORCE	1
II.	EXECUTIVE SUMMARY	2
III.	FDA TRANSPARENCY INITIATIVE.....	5
	A. BACKGROUND.....	5
	B. APPROACH	5
	C. PROGRESS TO DATE AND FUTURE PLANS	6
IV.	ACTION ITEMS AND DRAFT PROPOSALS FOR IMPROVING TRANSPARENCY TO REGULATED INDUSTRY, BY TOPIC AREA	9
	A. COMMUNICATING INFORMATION ABOUT AGENCY PROCEDURES	9
	B. PRODUCT APPLICATION REVIEW PROCESS	19
	C. GUIDANCE DEVELOPMENT	30
	D. REGULATIONS DEVELOPMENT.....	33
	E. IMPORT PROCESS	36
V.	OTHER TOPICS.....	43
	A. ADVISORY OPINION PROCESS	43
	B. AGENCY INTERACTIONS WITH MANUFACTURER REGARDING PUBLIC COMMUNICATION ABOUT EMERGING SAFETY ISSUES WITH A MANUFACTURER’S PRODUCT.....	45
VI.	NEXT STEPS.....	45
VII.	APPENDIX A: LIST OF ACTION ITEMS	47
VIII.	APPENDIX B: LIST OF DRAFT PROPOSALS.....	50
IX.	APPENDIX C: GLOSSARY OF ACRONYMS AND ABBREVIATIONS.....	51

I. Letter from Chair of the Transparency Task Force

January 2011

In response to President Obama's commitment to openness in government and the U.S. Department of Health and Human Services making transparency a priority, FDA Commissioner Dr. Margaret Hamburg launched FDA's Transparency Initiative in June 2009. Since that time, FDA has created a new webpage, *FDA Basics*, with questions, answers, and videos for the public that has been viewed by more than 900,000 people, established an online program performance program, FDA-TRACK, with monthly metrics on more than 100 FDA offices, and proposed for discussion a series of steps to provide more public understanding of FDA decision-making and promote innovation.

Today marks the next milestone in the transparency process at the Agency. The Task Force is releasing its report on transparency to regulated industry. From our first public comment period in 2009, we have heard from small and large companies about the need for FDA to more clearly communicate about its standards and expectations—both for regulated products generally and for specific applications. Clarity and consistency are pillars of an effective regulatory system that efficiently regulates products essential to health.

This report describes 19 steps FDA is taking to improve its transparency to regulated industry. One of these steps—a new website called *FDA Basics for Industry* (www.fda.gov/FDABasicsforIndustry)—launches today. Our goal is for this site to save many companies time and resources in understanding how to work with the agency. We encourage feedback and are committed to making this site as helpful as possible.

In addition, FDA is setting the expectation of responding to email questions about the regulatory process within 5 days, whenever practicable, or acknowledge receipt of the question and provide an estimated time for response. FDA is also making agency presentations at key meetings widely available and taking a range of other steps to improve transparency to manufacturers and the importing community.

FDA is proposing for comment five additional steps, including publishing on FDA-TRACK a timeline for high priority guidances that includes dates for publication of the draft guidance, receipt of public comments, and publication of the final guidance. The Agency recognizes the importance of clarity about the regulatory process, and we are interested in comments on these proposed approaches.

We look forward to your continued engagement in the agency's transparency efforts.



Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner, Chair of the Transparency Task Force

II. Executive Summary

Regulated industry provides the public with food, drugs, medical devices, cosmetics, and other widely used and important consumer products. FDA's mission is to protect and promote the public health through oversight of these products.

In order to succeed, FDA must clearly communicate standards and expectations to industry. Communicating requirements and expectations to industry in a more accessible manner promotes understanding of, and compliance with, rules set up to protect the supply of food and medical products.

In response to a request for input from FDA, regulated companies requested additional transparency about the standards to which their products are held, the process for soliciting guidance from the agency, and the progress of regulatory efforts at the agency. In this report, FDA outlines 19 action items and five draft proposals to improve transparency to regulated industry.

Better communication. A critical part of FDA's mission is to disseminate information about FDA policies and procedures in a manner that can be accessed by all interested members of industry. Six action items commit the agency to improving communication to industry about agency procedures:

- FDA will develop a web-based resource called *FDA Basics for Industry* that will provide basic information online about the regulatory process governing FDA-regulated products, and include information that is frequently requested by industry.
- FDA will update the agency organizational charts and senior leadership personnel changes on the FDA Web site on at least a quarterly basis and ensure that the level of detail provided on the organizational charts is consistent across the agency.
- FDA will provide links to the processes available for industry to submit general regulatory questions to each Center.
- FDA will also aim to respond to general questions about an existing policy, regulation, or the regulatory process that are submitted via email, whenever practicable, within 5 business days or acknowledge receipt of the inquiry and provide an estimated time for response.
- FDA will issue a final version of the "Strategic Priorities FY 2011-2015" by March 2011.
- FDA will post on the FDA Web site slide presentations that are delivered by FDA employees to external audiences at events sponsored by, or co-sponsored by, the agency.

A More Transparent Review Process. Four action items focus on improving transparency during the product application review process:

- FDA will compile all FDA Center guidance and standard operating procedures on FDA employees meeting with sponsors about product applications on the web-based resource, *FDA Basics for Industry*.
- FDA will describe the types of notifications the agency provides to industry with respect to the product application review process. FDA will provide an overview of the processes used to strive for consistency of product application review.
- FDA will also communicate general expectations about the circumstances, if any, under which it is appropriate to use secure email between FDA and a manufacturer when there is a question involving the manufacturer's product.
- FDA will explain how a sponsor is informed about whether the review of its product application is on track to meet the target date for FDA action on the application. FDA is also willing to hold further discussions with industry about application tracking systems, and explore the feasibility of implementing such a system at FDA.

Guidance and Regulations. Timely, relevant guidance supports efforts by industry to comply with the law and develop novel products that may benefit the public health. Two action items focus on greater transparency around the guidance development process and two action items focus on transparency of the regulations development process:

- Commissioner Hamburg has formed a cross-agency workgroup to identify the best practices for improving the agency's work on guidance.
- FDA will describe the ways in which interested individuals can provide input to the agency about guidance development. Links that provide industry with a list of guidance documents that have been withdrawn during the past year as well as possible topics for future guidance development or revision also will be made accessible in one location on the FDA Web site.
- After FDA issues a final rule, FDA will conduct outreach to the affected stakeholders as part of implementing the final rule if the rule imposes substantial new obligations.
- FDA will also work with the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB) to improve the accuracy of the timetables included in the agency's regulatory agenda published as part of the *Unified Agenda*.

Communications with Importers. Five action items focus on improving transparency to the importing community:

- FDA will provide contact information for points of contact within each District to whom to direct questions about the import regulatory process.
- FDA will allow interested members of the public to receive email notifications when an Import Alert is posted on the FDA Web site, or an existing Import Alert is updated.
- As part of the agency's efforts to implement the forthcoming Strategic Import Plan, FDA will develop and execute a project to promote more uniform processes and procedures across districts, when appropriate. This project will be tracked on FDA-TRACK, the FDA's agency-wide performance management system.
- FDA will aim to respond to general questions about the import process, if practicable, within 5 business days or acknowledge receipt of the inquiry and provide an estimated time for response. The Division of Import Operations and Policy (DIOP) in the Office of Regulatory Affairs (ORA) will compile a list of answers to questions frequently asked by industry and post this information on the FDA Web site.
- FDA will work with U.S. Customs and Border Protection (CBP) to explore developing a process by which brokers and filers can correct inadvertent data errors submitted about imported products and FDA should post that process online.

In addition to the above steps, FDA is requesting comments on five draft proposals to improve transparency to regulated industry. These draft proposals for public comment include: (1) disclosing, for certain high priority guidance documents in development, a timeline from the start of the agency's work on the draft guidance to publication of the final guidance, (2) posting on the FDA Web site a list of presentations given by FDA employees to external audiences, (3) informing submitters if an appeal request will be reviewed by the FDA Commissioner and when a decision may be expected, (4) reviewing existing procedures to evaluate importers, or third parties working on behalf of importers, who file information electronically about products offered for import, and (5) initiating a planning process to develop a web-based system that provides information about importing requirements.

III. FDA Transparency Initiative

A. Background

On January 21, 2009, President Obama issued a Memorandum to the Heads of Executive Departments and Agencies on Transparency and Open Government. The Memorandum called for “creating an unprecedented level of openness in Government” and noted that “[o]penness will strengthen our democracy and promote efficiency and effectiveness in Government.” The Memorandum pledges that the Administration “will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use” and instructs executive departments and agencies to “solicit public feedback to identify information of greatest use to the public.” On December 8, 2009, the Director of the Office of Management and Budget (OMB) issued the Open Government Directive.

Transparency is also a top priority for Secretary of Health and Human Services Kathleen Sebelius. Secretary Sebelius has formed a group that is dedicated to promoting transparency and openness at the U.S. Department of Health and Human Services (HHS) and is coordinating an overall HHS response to the Administration’s Open Government Directive.

Following the leadership of the President and the Secretary, the Commissioner of the U.S. Food and Drug Administration, Dr. Margaret A. Hamburg, launched the FDA’s Transparency Initiative in June 2009.

Commissioner Hamburg formed an internal task force to develop recommendations for enhancing transparency of FDA’s operations and decision-making processes. At the time of the announcement, she stated, “President Obama has pledged to strengthen our democracy by creating an unprecedented level of openness and public participation in government, and the FDA looks forward to participating in this process.” Commissioner Hamburg expressed that “increasing our openness will help us more effectively implement our mission to promote and protect the public health.”

Commissioner Hamburg asked Dr. Joshua Sharfstein, the Principal Deputy Commissioner of the FDA, to chair FDA’s internal task force, whose members include five of the Agency’s center directors, the Chief Counsel, the Associate Commissioner for Regulatory Affairs, and the Chief Scientist. The Task Force was charged with submitting a written report to the Commissioner on the Task Force’s findings and recommendations.

B. Approach

To solicit public input on improving agency transparency, the Task Force held two public meetings, launched an online blog, held listening sessions with

members of regulated industry, and opened a docket to which comments could be submitted.

At the first public meeting, the Task Force solicited comments on how the agency could improve transparency overall.¹ Thirty five individuals provided comments during the meeting and 335 people attended in person or watched the live webcast of the eight hour session.

At the second public meeting, the Task Force solicited comments on three specific issues related to transparency at the agency: (1) early communication about emerging safety issues concerning FDA-regulated products, (2) disclosure of information about product applications that are abandoned (no work is being done or will be undertaken to have the application approved) or withdrawn by the applicant before approval, and (3) communication of agency decisions about pending product applications.² Sixteen individuals participated in the groups convened to discuss each issue as well as during the open public session. One hundred seventy four people attended the meeting in person or watched the live webcast.

The online blog and the docket received over 1,500 comments.³ The blog, which is ongoing, has offered an opportunity for exchange about specific ideas for transparency at the agency.

The Task Force also solicited feedback from FDA's Risk Communication Advisory Committee about communicating to the public about product recalls and emerging safety issues with FDA-regulated products.

Dr. Sharfstein attended a listening session, hosted by the White House Office of Science and Technology, to hear comments from the health care investor community on how transparency at FDA can foster investment in the life sciences and medical product innovation.

For this report, the Task Force reviewed the comments received about ways to improve transparency to regulated industry. The comments were used by the Task Force to inform the proposals in this report. The Task Force also identified ways to improve transparency that are reflected in this report.

C. Progress to Date and Future Plans

The Task Force is proceeding with the Transparency Initiative in three phases.

¹ A transcript from the public meeting is available on the FDA Web site, <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/ucm170422.htm#meetingtranscript>.

² A transcript of the public meeting is available on the FDA Web site, <http://www.fda.gov/downloads/AboutFDA/WhatWeDo/FDATransparencyTaskForce/UCM189845.pdf>.

³ The online blog is available at <http://fdatransparencyblog.fda.gov/>. The online docket is available at <http://www.regulations.gov>.

- Phase I: FDA Basics
- Phase II: Public Disclosure
- Phase III: Transparency to Regulated Industry

Phase 1: FDA Basics. The first phase is intended to provide the public with basic information about FDA and how the agency does its work. In early January 2010, FDA launched a web-based resource called *FDA Basics*. This resource now includes (1) 158 questions and answers about FDA and the products that the Agency regulates, (2) nine short videos that explain various agency activities, and (3) conversations with fourteen agency officials about the work of their Offices.

Visitors to *FDA Basics* can rate how helpful the information provided is and suggest additional questions for inclusion in *FDA Basics*. Feedback provided by the public is used to update the resource. Forty-four new questions have been added to the site, based in part on feedback provided by the public.

Each month, senior officials from FDA product centers and offices host online sessions about a specific topic and answer questions from the public about that topic. Each of these sessions is announced on the FDA Web site.

As of November 30, 2010, 957,008 visitors have viewed the FDA Basics site and left 8,781 comments.

Phase 2: Public disclosure. The second phase relates to FDA's proactive disclosure of information the agency has in its possession, and how to make information about agency activities and decision-making more transparent, useful, and understandable to the public, while appropriately protecting confidential information. As required by the Administration's Open Government Directive, the Task Force inventoried the information that is not currently available to the public and considered whether the public health would benefit from disclosure of some of this information.

On May 19, 2010, the Task Force released a report containing 21 draft proposals about expanding the disclosure of information by FDA while maintaining confidentiality for trade secrets and individually identifiable patient information. The Task Force solicited comment on the content of the proposals, as well as on which draft proposals should be given priority, for 60 days. Not all these proposals will necessarily be implemented. Some may require changes in law or regulation; some may require substantial amounts of resources.

The Task Force is reviewing the comments received and will recommend specific proposals to the Commissioner for consideration. The Task Force's

recommendations will consider feasibility and priority, considering other agency priorities that require resources.

Phase 3: Transparency to regulated industry. The Task Force held listening sessions and solicited comments about ways to improve transparency to regulated industry. The Task Force received comments from industry requesting additional clarity in standards and processes of the agency as well as additional transparency about the regulatory process.

The action items and proposals in this report address ways that FDA can become more transparent to regulated industry in order to foster a more efficient and cost-effective regulatory process. FDA will begin to implement the 19 action items outlined in this report in 2011. The Task Force is seeking public comment on the content of the five proposals in this report and may recommend specific proposals to Commissioner Hamburg for consideration.

IV. Action Items and Draft Proposals for Improving Transparency to Regulated Industry, by Topic Area

A. Communicating Information about Agency Procedures

1. Background

FDA has established various methods to inform industry about FDA's procedures. Information is communicated at workshops and meetings, as well as online on the FDA Web site. A section of the FDA Web site, accessible via the main home page, contains information relevant to industry, including information about FDA's dispute resolution process and access to all of FDA's published guidance documents.⁴

In April 2010, FDA launched a web resource called FDA-TRACK that allows the public to track the agency's progress on a range of measures.⁵ These measures are developed by the program offices across the FDA and reported on a monthly basis. Each quarter, monthly performance data is analyzed and senior managers present this data to FDA senior leadership. FDA-TRACK includes measures relevant to industry. For example, industry can track whether the agency is hitting its targets for completing reviews of product applications.

In addition, FDA has established a subscription service whereby members of the public can register to receive updates about FDA activities via email. For example, interested members of the public can receive emails notifying them when FDA warning letters are posted or when guidance documents are posted on the site. A list of the items for which members of the public can receive updates is accessible on the FDA home page by clicking "Email Updates."

FDA also posts organizational charts for the entire agency and its seven centers and offices.⁶ This information is updated on a quarterly basis. In general, the organizational charts for the six Centers, one research center, and the Office of Regulatory Affairs (ORA) include information down to the office-level, and include the names of senior leadership in that office. Information about additional levels of the organization (e.g., divisions within a center and offices within that division, if applicable) is typically available elsewhere on the FDA Web site.⁷

⁴ See, e.g., Industry, available at <http://www.fda.gov/ForIndustry/default.htm>.

⁵ For a further description of FDA-TRACK, see the video on the subject, available at <http://www.fda.gov/AboutFDA/Transparency/track/ucm222320.htm>. FDA-TRACK is available at www.fda.gov/fdatrack.

⁶ About the FDA Organizational Charts, available at <http://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/default.htm>.

⁷ See, e.g., CBER Key Staff Directory, available at <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm123224.htm>; CDRH Management Directory by Organization, available at

FDA has developed activities aimed at assisting and increasing communication about FDA's procedures with the smaller members of regulated industry who interact with FDA. These activities include the establishment of the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) in the Center for Devices and Radiological Health (CDRH), Small Business Assistance Programs in FDA regional offices, and staff in the Centers who handle inquiries from industry, including small businesses. These units provide technical assistance to small companies, hold exchange meetings to hear the views and perspectives of small businesses, conduct educational workshops, develop informational materials, and provide an accessible, efficient channel through which small businesses can acquire information from the FDA. FDA has also posted a "Small Business Guide for FDA" on the FDA Web site.⁸

Slide presentations used by FDA employees are provided to members of the public upon request. In some limited cases, slides used by FDA employees at meetings for external audiences are posted on the FDA Web site. For example, the Center for Drug Evaluation and Research (CDER) has posted a limited set of presentations on the FDA Web site.⁹

All data provided on the FDA Web site, including slide presentations, must be in a form that can be accessed by all members of the public, including individuals with disabilities. Section 508 of the Rehabilitation Act requires that federal departments and agencies make electronic and information technology accessible to people with disabilities, unless an undue burden¹⁰ would be imposed on the department or agency.¹¹ As a result of this requirement, all presentations must be made "508 compliant" prior to posting on the FDA Web site. In general, FDA does not make slide presentations given by FDA employees to external audiences available on the FDA Web site because of the time and resources needed to make them 508 compliant and post them.

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm127854.htm>; CDER Offices and Divisions, available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm075128.htm>; CVM Phone Directory XLS file. Link to the file is available at <http://www.fda.gov/AboutFDA/CentersOffices/CVM/default.htm>.

⁸ "Small Business Guide for FDA", available at <http://www.fda.gov/downloads/ForIndustry/SmallBusinessAssistance/SmallBusinessGuidetoFDA/UCM081030.pdf>.

⁹ CDER Presentations, available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm074833.htm>.

¹⁰ "Undue burden" means the activity entails significant difficulty or expense. 36 C.F.R. § 1194.4. The regulation provides that "[i]n determining whether an action would result in an undue burden, an agency shall consider all agency resources available to the program or component for which the product is being developed, procured, maintained, or used."

¹¹ 29 U.S.C. § 794d. If making electronic and technology information accessible would impose an undue burden, the department or agency must provide an alternative means of access to the information for individuals with disabilities so that the individual can use the information and data.

Some Centers provide training information about the regulatory process via learning modules that are accessible online. For example, CDRH has developed an online industry education tool called “CDRH Learn.”¹² CDRH Learn is a series of training modules describing many aspects of medical device and radiological health regulation, covering both premarket and postmarket issues. CDER offers online educational tutorials on specific topics in a series called “CDERLearn.”¹³

FDA has established electronic and telephonic means for members of the public, including industry, to contact FDA with questions about the regulatory process. The contact information for each FDA Center is accessible by clicking on the “Contact Us” link on the bottom of any FDA Web page. On the resulting Web page, selecting the applicable “area of concern” from the drop-down box leads visitors to contact information for the appropriate FDA Centers. Visitors can also select a Center by name from the list provided on the page under the heading “FDA Centers and Offices.” Questions sponsors may have about specific product applications are dealt with via the review process, described in Section B.

Below is a description of the process used to handle inquiries about the regulatory process for specific product areas.

Animal and Veterinary

Members of the public can submit questions to an email inbox or call the Center for Veterinary Medicine (CVM) with an inquiry.¹⁴ If additional expertise is required, CVM’s Office of Communication refers the inquiry to a CVM employee who will respond to the requestor. CVM has target time frames for responding to questions.

Biologics

The Center for Biologics Evaluation and Research (CBER) Manufacturers Assistance and Technical Training Branch responds to requests for information regarding CBER policies and procedures. Blood and tissue banks, clinical investigators, and other members of regulated industry can submit questions by email or by phone.¹⁵ If additional expertise is required, the inquiry is forwarded to the appropriate office for additional information. The response is then conveyed to the requester either by the Manufacturers Assistance and Technical Training Branch or by the appropriate product office. There are target time frames for responding to questions.

¹² CDRH Learn, available at <http://www.fda.gov/Training/CDRHLearn/default.htm>.

¹³ CDERLearn, available at <http://www.fda.gov/Training/ForHealthProfessionals/default.htm>.

¹⁴ About the Center for Veterinary Medicine, available at <http://www.fda.gov/AboutFDA/CentersOffices/CVM/default.htm>.

¹⁵ Manufacturers Assistance (CBER), available at <http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ManufacturingQuestions/default.htm>.

Devices

CDRH, as required by statute, has created a small manufacturers assistance program in the Division of Small Manufacturers, International and Consumer Assistance (DSMICA).¹⁶ Members of industry can call a general telephone number or submit an email with a question. Contact information for DSMICA employees is provided online and industry can contact a DSMICA employee directly with specific questions. Most DSMICA employees can answer questions in all medical device related areas. However, a list of DSMICA employees with their areas of expertise is also posted on the FDA Web site.¹⁷ DSMICA has target time frames for responding to questions.

Drugs

The CDER Division of Drug Information (DDI) is responsible for calls that come in from companies and industry consultants to the drug information telephone number or email address.¹⁸ Questions related to specific products are directed to the review division responsible for handling the product application. Questions are directed to subject matter experts as appropriate. DDI has target time frames for responding to questions. If a response will not be provided within the established timeframe, an interim response is provided via phone or email.

Foods

The Center for Food Safety and Applied Nutrition (CFSAN) has an email inbox dedicated to questions from industry.¹⁹ Questions that require interpretation of existing policy or that are extremely technical in nature are referred to a program specialist. CFSAN informs the inquirer when questions are referred to a specialist. CFSAN has target time frames for responding to questions. CFSAN also receives many questions of a regulatory nature via the Center's toll free information line. Most telephone inquiries are answered as they are received.

2. Summary of Public Comments

Comments noted that it is important for information about the regulatory process and agency policy to be broadly disseminated. One comment noted that it is important to bear in mind that providing information to industry trade associations is helpful, but is not sufficient to assure transparency to regulated industry.

¹⁶ Section 10 of the Medical Device Amendments of 1976 (P.L. 94-295) required FDA to create "an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices" 42 U.S.C. § 3512.

¹⁷ Manufacturers Assistance Staff, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ucm142656.htm#DSMICA_Staff.

¹⁸ CDER Contact Information, *available at* <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ContactCDER/default.htm>.

¹⁹ CFSAN Contact Information, *available at* <http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/ContactCFSAN/default.htm>.

Comments offered a range of suggestions for broadly disseminating information, such as providing webcasts of certain meetings hosted by industry trade associations to allow for broader access of the information, online training sessions for individuals who cannot attend training sessions in person, a web portal that provides answers to questions frequently asked by industry, conducting more presentations to industry at the regional level, and posting slides and speaker notes used by FDA employees when giving presentations to external audiences on the FDA Web site.

Several comments suggested that FDA add more detailed FDA organizational charts online so that it is easier for industry to find the right contact person at the agency to talk to about specific regulatory issues, and update organizational charts in a timely fashion when changes in organizational structure or personnel occur.

A couple of comments suggested FDA reinstate its practice of publishing the agency's strategic plan, with a list of FDA's priorities for promoting and protecting the public health.

Comments requested that FDA provide information on whom to contact at FDA when a member of industry has a question or an issue. One comment suggested that FDA develop a "triage" system for quickly and accurately answering industry questions about specific regulatory issues.

Comments also noted that FDA should respond in a timely manner to industry input on vital regulatory issues of concern to industry and the agency. Comments requested that a system be developed so that questions could be directed to the "FDA expert" on a particular topic and that questions should be answered within a week.

3. *Considerations*

The Task Force agrees that it is a critical part of FDA's mission to disseminate information about its policies in a form that can be accessed by all interested members of industry. FDA personnel should conduct and participate in as many industry training opportunities as resources allow.

The Task Force also agrees that information about FDA policies should be disseminated promptly to facilitate compliance, and increased access to presentations provided by FDA employees to industry may improve understanding of and compliance with FDA requirements. Industry should receive timely responses to regulatory questions.

In determining how to improve dissemination of information to industry, the Task Force considered the information that is currently available to regulated

industry about the agency's procedures. There are currently several mechanisms available to inform industry about FDA processes, including FDA employee participation in meetings sponsored by the agency or members of industry, industry-specific information available on the FDA Web site, the email notification system for new information posted on certain pages on the FDA Web site, and FDA-TRACK, the agency's performance management system. In FY 2009, agency employees participated in at least 100 meetings sponsored by the agency or members of industry. There are also additional cost-effective means the agency can undertake to provide information to industry.

The Task Force considered whether existing information could be made more accessible to regulated industry and updated on a more frequent basis, weighing the resources required to provide increased access to information online. A consideration was the resources involved in making materials 508 compliant for posting online.

In addition, the Task Force considered whether transcripts from public meetings could be disseminated sooner. FDA employees must review meeting transcripts for accuracy prior to posting online. The Task Force discovered that requesting an expedited transcript from a transcription service costs significantly more money; for example, for one company the agency has worked with in the past, it would cost 50% more for the agency to receive a transcript in 5 days, as compared to the typical processing time of 10 days (for simple requests).

The Task Force considered the diverse set of responsibilities faced by some employees and the need to balance those responsibilities in order to ensure an efficient regulatory process. For example, FDA medical reviewers are often responsible for reviewing premarket applications, working on guidance documents in their area of expertise, and participating in training workshops to educate the public about FDA's standards and expectations. These same employees may also be the subject matter experts capable of providing an answer to a specific question.

4. Actions and Draft Proposals

ACTION 1:

FDA will develop a web-based resource called *FDA Basics for Industry* that will provide basic information online about the regulatory process governing FDA-regulated products, and include information that is frequently requested by industry.

Reasoning: Ready access by industry to information online that sets forth FDA's standards as well as expectations regarding regulated products may

improve the efficiency of the regulatory process. Less time will be spent searching for information; time that is better spent using this information to make more products that treat, diagnose, cure, and prevent disease available to the public. In addition, more people would be able to access that information if provided online.

The Task Force concluded that developing an online resource that includes basic information about the regulatory process will make important regulatory information more broadly available to members of regulated industry. In fact, the Task Force believes that this resource, which will be accessible to all members of industry, may in some cases meet the goal of wide dissemination of information more effectively than individual presentations by employees.

FDA Basics for Industry will serve as a portal to information that is frequently requested by industry. This web-based resource will include links to training modules for industry, such as CDRH Learn and CDERLearn. CBER is also developing an online training tool for industry, which is expected to launch in 2011.

The online resource for industry will be modeled on FDA's successful efforts with *FDA Basics*, a web-based resource launched January 2010. On *FDA Basics*, the public is provided with basic information about FDA and how the agency does its work. *FDA Basics* includes over 155 questions and answers, nine short videos that explain various FDA activities and 14 interviews with FDA officials about the work of their offices. The public is encouraged to rate the helpfulness of the content on the site and suggest additional questions to be added to the site. Since its launch, over 40 questions have been added to the site based on feedback provided by the public.

ACTION 2:

FDA will update the agency organizational charts and senior leadership personnel changes on the FDA Web site on at least a quarterly basis and ensure that the level of detail provided on the organizational charts is consistent across the agency.

Reasoning: FDA consists of six product centers, one research center and two offices. There are over 11,000 full-time equivalent employees working at the agency. Additional detail can be added to FDA's current organizational charts and the level of detail provided on the organizational charts should be consistent across the agency.

Given the size of the FDA, an organizational chart that includes contact information for key leadership, as well as information about the divisions and offices at the agency, is another way to inform the public about the work of

the agency. The updated organizational charts will be posted to the FDA Web site by March 2011.

In addition, the agency's organizational charts and information about senior leadership is only helpful if it is relevant and accurate. The process currently used by FDA provides for updates approximately every three months. Information on senior leadership personnel is requested from each Center, the organizational chart is manually updated, and then made 508 compliant. A text version of the organizational chart must also be updated. Given the multiple steps involved, by the time the "updated" information is posted online, it may no longer be accurate.

FDA will explore ways to automate the process used to update this information, in order to keep the information available to the public more current.

ACTION 3:

Each Center has a process for industry to submit general regulatory questions, and for directing inquiries to individuals with additional expertise, if necessary. Links to these processes will be made available on *FDA Basics for Industry*.

Reasoning: It is important to provide a clear mechanism for industry to ask questions about the regulatory process and receive answers. While each Center has telephone lines and email inboxes dedicated to this purpose, the Task Force received several comments requesting that the agency develop a system to answer questions from industry. The Task Force concluded that the agency does have the system in place but must make this information more prominent and accessible.

FDA has now instituted standardized email addresses for industry to submit questions about FDA-regulated products. The email addresses are standardized according to product type. The addition of these standardized email addresses does not disrupt the functionality of other email addresses that accepted questions from industry in the past.

ACTION 4:

If a general question about an existing policy, regulation, or the regulatory process is submitted to any of the email addresses specified below, whenever practicable, FDA should provide a response within 5 business days or acknowledge receipt of the inquiry and provide an approximate timeframe for response. This will be tracked on FDA-TRACK.

Reasoning: It is important to provide clear expectations to industry, which includes a time frame for response to general questions about the regulatory process submitted to the agency. The recently instituted standardized email addresses for industry are as follows:

Industry.Foods@fda.gov
Industry.Cosmetics@fda.gov
Industry.DietarySupplements@fda.gov
Industry.MedicalDevices@fda.gov
Industry.Radiological@fda.gov
Industry.AnimalVeterinary@fda.gov
Industry.Drugs@fda.gov
Industry.Tobacco@fda.gov
Industry.Biologics@fda.gov

As mentioned above, the addition of these standardized email addresses does not disrupt the functionality of other email addresses that accepted questions from industry in the past.²⁰

The Task Force concluded that questions submitted by applicants or sponsors about specific applications under review by the agency are best handled through the product review process. Product application review may involve complex issues of science and the Task Force concluded that those questions are best handled on a case-by-case basis.

ACTION 5:

In September 2010, FDA issued its “Strategic Priorities FY 2011-2015” in draft form for public comment. FDA will issue a final version of the “Strategic Priorities FY 2011-2015” by March 2011.

Reasoning: Interested stakeholders should be aware of FDA’s priorities for achieving its mission of protecting and promoting the public health. The Strategic Priorities FY 2011-2015 document outlines the goals and priority areas that will guide FDA through fiscal year 2015. FDA will finalize the Strategic Priorities FY 2011-2015 document in early 2011.

²⁰ The following email addresses still accept emails from industry, and whenever practicable, FDA will provide a response to an inquiry sent to any one of these email addresses within 5 business days, or acknowledge receipt of the inquiry and provide an approximate timeframe for response.

AskCVM@fda.hhs.gov (animal and veterinary)
matt@fda.hhs.gov (blood products, vaccines, other biologics)
druginfo@fda.hhs.gov (drugs)
industry@fda.gov (foods, dietary supplements, cosmetics)
dsmica@fda.hhs.gov (medical devices and radiation-emitting products)

ACTION 6:

FDA will post on the FDA Web site slide presentations that are delivered by FDA employees to external audiences at events sponsored by, or co-sponsored by, the agency.

Reasoning: Providing members of regulated industry access to information about agency policies and procedures presented at meetings to external audiences may lead to a more efficient regulatory process. Industry may be provided information that informs product submissions, leading to a smoother application review process. Information provided at these meetings may also inform a company's compliance efforts, contributing to FDA's efforts to protect the public health.

As suggested by the comments the Task Force received on this issue, one of the most direct means of expanding access to regulatory information presented by FDA employees to external audiences is by posting that information on the FDA Web site. The Task Force concluded that FDA should expand access to slide presentations delivered by FDA employees to external audiences. Providing access to all FDA presentations delivered to external audiences on the FDA Web site, however, requires making the presentations 508 compliant before posting the presentations online.

As a first step, FDA will post slide presentations delivered by FDA employees to external audiences at events sponsored by, or co-sponsored by FDA. FDA is also proposing to list presentations given by FDA employees to external audiences on the FDA Web site (see Draft Proposal 1 below). The Task Force believes that this list can be used by industry members to request presentations of interest.

DRAFT PROPOSAL 1:

FDA should maintain on the FDA Web site a list of presentations given by FDA employees to external audiences.

Reasoning: Hundreds, if not thousands, of FDA employees located in DC, in the 5 Regional Offices, 20 District Offices, 13 Laboratories and more than 150 Resident Posts and Border Stations located across the U.S., give presentations to external audiences each year. FDA does not currently centrally manage or collect presentations delivered by FDA employees to external audiences. As a result, FDA does not have a means of assessing the public's interest in presentations given by FDA employees to external audiences.

If FDA instituted a process to track presentations given by FDA employees, and a list of those presentations were posted online, members of the public will be informed about the presentations given by agency employees, and, if

interested, could request a copy from the agency. In that way, broader access may be provided to materials of interest to the public while allowing the agency to gain a better understanding of the type of information that is of interest to the public. Frequently requested presentations may be posted on the FDA Web site.

DRAFT PROPOSAL 2:

When the Office of the Commissioner (OC) receives a request to reconsider a scientific decision of an FDA employee from an interested person outside the agency pursuant to 21 C.F.R. § 10.75, OC should inform the submitter within three weeks whether OC will review the request, and should inform the submitter when a decision or an update on the status of the review may be expected.

Reasoning: FDA regulations set forth a basic process for an interested person outside of FDA to request internal agency review of a decision through the established channels of supervision or review.²¹ In certain circumstances, this process may include a review by the Office of the Commissioner (OC). While there are timeframes that govern the review of a decision through the established channels of supervision or review at the Center or Office level, there are not timeframes for any review that may be conducted by the Office of the Commissioner.

The Task Force concluded that OC should inform a requester when it has determined whether to review the request. If OC has decided that review will occur, the requestor should be provided with information about when a decision may be expected. Implementation of this proposal will support more consistent practices across the agency, while providing industry with more certainty regarding the regulatory process.

B. Product Application Review Process

1. Background

Each Center has systems in place to ensure consistency of product review across Divisions to the extent possible. These systems include the use of standard operating procedures and guidances that communicate policies and procedures governing product application review. Each Center has a comprehensive training program for new reviewers and makes additional training opportunities available for existing reviewers.

FDA encourages sponsors and applicants to attempt to resolve disagreements by starting with the review team within the division and then elevating the dispute, if necessary, to the Division Director. Sponsors may submit formal

²¹ 21 C.F.R. § 10.75.

dispute resolution requests for any decision made at the Division Director level or above.

An Ombudsman is also available to mediate disputes sponsors may have with agency employees during the product application review process. Sponsors can contact the Ombudsman at any time for consultation and guidance on the dispute resolution procedure or for assistance in resolving a complaint or dispute.

Timeframes Governing Product Application Review

Animal drugs

Performance goals associated with the complete review of animal drug product applications are set forth in the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

The product application review process usually begins with a pre-submission conference between CVM employees and the potential applicant. During this conference, agreements regarding the product application or studies needed to support approval may be made.²²

Most sponsors participate in the Center's phased review process. Phased review means that after the review of each technical section submission, the sponsor will receive a technical section complete letter or an incomplete letter. The incomplete letter describes the deficiencies the product review team noted in the application, and allows drug sponsors to address specific aspects of the application as the information becomes available. Once all of the technical sections are submitted and complete, the sponsor submits an administrative new animal drug application and the Center has 60 days to complete review.

When an application is submitted to FDA, a team is assigned to review that application. The Team Leader is the primary contact for any regulatory or science issues associated with the application. The contact information for that individual is provided to the sponsor. If that individual changes, the sponsor is notified.

Each new animal drug sponsor is assigned to a specific project manager. When the sponsor opens an application file and submits to the file certain information about a planned clinical study, the assigned project manager contacts the sponsor and provides his or her contact information. In addition, the project manager discusses the administrative process with the sponsor and explains the project manager role in those processes. If a project manager changes, the old and new project manager coordinate efforts to ensure that the sponsor is notified about the change. The assigned project manager is the primary contact for administrative issues.

²² 21 C.F.R. § 514.5.

After approval of an original new animal drug application or major supplemental application, the project manager contacts the sponsor and offers the sponsor an opportunity to attend a post-review meeting to discuss the review process.

Drugs for human use and biological products

FDA regulations provide that the FDA will make a determination about the approvability of a drug application within 180 days of receiving the application, unless the applicant and FDA have agreed otherwise or the sponsor has submitted a major amendment to the application.²³ A detailed timeline for review of a new drug application or biologics license application is set forth in guidance to industry and review staff entitled, “Good Review Management Principles and Practices for PDUFA Products.”²⁴ This guidance is available on the FDA Web site.

As set forth in this guidance, FDA sends the applicant an acknowledgement letter that notifies the applicant of the date of receipt of the application. This letter is sent within 14 days after the agency receives the application. Within 60 days of receipt of the application, the Center notifies the applicant of its decision regarding whether the application is sufficiently complete to permit a substantive review.²⁵ At this time, the Center also notifies the Center whether the application will be classified priority (or expedited) review or standard review. By the 74th day following receipt of the application, the Center communicates to the applicant issues identified during the filing review. Information about planned review activities, including, for example, whether there will be an Advisory Committee meeting, the timing for discussion of risk evaluation and mitigation strategies (REMS) and other post-marketing safety commitments, is also communicated to the applicant by this date.

During the review, FDA may contact the applicant with questions about the application. An internal mid-cycle meeting is held to discuss the progress of the application review. A request may be sent to the applicant within 30 days of the mid-cycle meeting if additional information or analyses are needed.

Each application that is submitted is assigned a regulatory project manager (RPM). Contact information for the RPM is provided in the letter sent to the applicant acknowledging receipt of the application. If the RPM is changed during the course of the review, the applicant is notified by the new RPM. Contact information for the RPM is included with every communication to the applicant.

²³ 21 C.F.R. § 314.100.

²⁴ Guidance for Review Staff and Industry: Good Review and Management Principles and Practices for PDUFA Products (Apr. 2005), *available at* , <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079748.pdf>.

²⁵ 21 C.F.R. § 314.101(a).

Medical devices

Performance goals associated with review of certain device submissions—premarket notification submissions (510(k)s), original premarket approval applications (PMAs) and premarket approval application supplements—are set forth in the Medical Device User Fee and Modernization Act, as amended by the Food and Drug Administration Amendments Act of 2007.²⁶

CDRH notifies the sponsor when a 510(k) or PMA has been received. Communication with the sponsor, application review, and coordination of any team review, if necessary, is handled by the primary reviewer. The reviewer notifies the sponsor that they are the reviewer for the application. If there is a change in reviewers in the midst of the review process, the new reviewer notifies the sponsor.

During the review, CDRH reviewers may contact the applicant with questions. For PMAs, a 100 day meeting or communication occurs with the sponsor about the status of the submission.

Electronic Product Application Regulatory Submissions

Some Centers accept certain formal regulatory submissions associated with the product approval process in electronic format. For example, CVM accepts Notices of Claimed Investigational Exemption for a New Animal Drug (NCIE) in electronic format.²⁷ CDER accepts new drug applications (NDAs) and abbreviated new drug applications (ANDAs) in electronic format.²⁸ CBER accepts biologics license applications (BLAs) in electronic format.²⁹ CDRH encourages sponsors of premarket medical device submissions to include a copy of their submission in electronic form along with the required

²⁶ See, e.g., Performance Goals for the Medical Device User Fee Amendments of 2007, available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM109102.pdf>.

²⁷ Guidance for Industry: How to Submit a Notice of Claimed Investigational Exemption in Electronic Format to CVM (June 2009), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052374.pdf>. Information about electronic submissions for CVM-related documents can be found here, <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/ucm2006508.htm>.

²⁸ Guidance for Industry, Providing Regulatory Submissions in Electronic Format — ANDAs (June 2002), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163188.pdf>; Guidance for Industry, Providing Regulatory Submissions in Electronic Format — NDAs (Jan. 1999), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163187.pdf>.

²⁹ Guidance for Industry, Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format — Biologics Marketing Applications (Nov. 1999), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM192413.pdf>.

paper copies³⁰ and accepts premarket notification applications (510(k)s) for in vitro diagnostic devices in electronic format.³¹

FDA has published a draft guidance that sets forth general considerations for members of industry that elect to submit electronic submissions to the agency. This draft guidance applies to all of FDA's centers.³²

In addition, some Centers have posted information regarding the Center's preferences regarding the use of secure electronic mail for communications associated with product applications. CBER, CDER, and CDRH have posted a policy outlining expectations for the use of secure email.³³

Communicating with Sponsors During Product Review

FDA has established avenues through which sponsors of medical products can meet with agency personnel during and after the review process. All Centers have published guidelines for meeting with sponsors of medical products. These guidelines provide sponsors with an understanding of the process used to manage meeting requests and the information needed in preparation for the meeting, as well as set expectations regarding the conduct of the meeting.

CVM, CBER, CDER, and CDRH have targets related to holding meetings with industry set forth in the ADUFA, AGDUFA, Prescription Drug User Fee Act (PDUFA), and Medical Device User Fee and Modernization Act (MDUFMA), respectively.

CVM has posted its Program Policy and Procedures Manual, which includes a chapter on procedures for scheduling and meeting with outside parties, on the FDA Web site.³⁴ CDRH has posted its guidelines for early collaboration

³⁰ Electronic Copies for Premarket Submissions, *available at* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>.

³¹ In Vitro Diagnostic Devices, *available at* <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107776.htm>.

³² Guidance for Industry, Providing Regulatory Submissions in Electronic Format — General Considerations (Oct. 2003), *available at* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM124751.pdf>.

³³ *See, e.g.*, Electronic Regulatory Submission and Review: Secure Email (discusses the appropriate use of email for drug applications), *available at* <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/default.htm#ESG>; CBER SOPP 8119: Use of Email for Regulatory Communications (discusses the appropriate use of email for biologics license applications), *available at* <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPs/ucm109645.htm>; CDRH, Guidance for Industry -- Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements (discusses the appropriate use of email for medical device submissions), *available at* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

³⁴ Center for Veterinary Medicine Program Policy and Procedures Manual: Scheduling and Holding Meetings with Outside Parties (Aug. 2006), *available at*

meetings with sponsors considering submitting a PMA or with any person planning on investigating the safety or effectiveness of a Class III product or implant.³⁵

CBER and CDER have issued a guidance titled “Formal Meetings Between the FDA and Sponsors or Applicants” that describes procedures for requesting, preparing, scheduling, conducting and documenting formal meetings held between FDA employees and product sponsors or applicants.³⁶ The guidance applies to applicants who have submitted an NDA or BLA to FDA for review. The CDER Office of Generic Drugs (OGD), in large part, also follows this guidance for meetings conducted with sponsors that submit an ANDA to FDA for review. However, the specific deadlines that have been negotiated as part of the PDUFA are not applicable to ANDAs, and thus, those provisions of the guidance are not followed by OGD.

As part of the Good Guidance Review Management Practices, CDER and CBER offer applicants submitting applications for new molecular entities and new biological products an opportunity to participate in a post-review teleconference or meeting.³⁷ Such meetings are used to discuss the quality of the application and to evaluate the communication process during the drug development and marketing application review process. The purpose is to learn from successful aspects of the review process. FDA encourages these meetings in order to improve future application submissions and the quality of the review process.

2. Summary of Public Comments

Several comments encouraged the use of electronic tools for routine communications between applicants and FDA staff. Some comments suggested that FDA consistently provide action letters to applicants via electronic communication. More specifically, one comment suggested that

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/UCM046890.pdf>.

³⁵ Early Collaboration Meetings Under FDAMA; Final Guidance for Industry and CDRH Staff (Feb. 2001), available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073604.htm>.

³⁶ Formal Meeting Between the FDA and Sponsors or Applicants (May 2009), available at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm153222.pdf>.

CBER has also posted online a Standard Operating Procedure and Policy (SOPP) regarding the scheduling and conduct of regulatory meetings between CBER employees and product sponsors and applicants to address issues relating to product development. SOPP 8101.1, Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants (May 2007), available at

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPs/ucm079448.htm>.

³⁷ See Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products at 25 (Apr. 2005), available at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079748.pdf>.

the primary reviewer on a product application should communicate with sponsors through email or telephone if sponsors have questions, or request clarification regarding FDA comments, to avoid delay in the review process.

Comments requested that the agency hold more meetings with the applicant during the review process. A commenter stated that meetings help ensure an adequate scientific dialogue and common understanding about what is expected during product development and that some meeting requests are not being granted. One comment suggested that FDA provide sponsors with the opportunity to participate in a mid-cycle review meeting that would highlight issues that arose during the review process. Another comment suggested that as part of the review process, a regular weekly or biweekly call should be incorporated to provide “timely scientific discipline clarifications as part of the review process.” The commenter stated that these calls can be cancelled when not needed. Another comment suggested that FDA offer sponsors the opportunity to participate in a post review meeting.

One commenter noted that not all questions necessarily require a formal meeting or letter for resolution. A comment suggested that FDA could improve its responsiveness, and decrease the need for full-scale meetings, by developing a process whereby a sponsor may raise and discuss a single issue rapidly and efficiently with the appropriate division. One commenter requested that the agency engage in more frequent consultations with applicants that are filing applications with FDA for the first time. One comment called for “informal communications” with FDA through the development and review process so that industry can receive timely answers to clarifying questions.

One comment requested that the agency provide applicants with a better understanding of what information to expect—and when—during the review. A commenter requested that FDA establish a “clear roadmap for sponsors about what actions will take place, and when, in the review of their application,” another commenter suggested that FDA ensure that major application review milestones are communicated to the sponsor early in the review cycle, and another commenter requested that FDA publish documents that describe procedures for interacting with sponsors during product review.

Other comments suggested that FDA develop an electronic system that would allow sponsors and applicants to track their application through the review process. Comments noted that this system may help eliminate redundant questions from sponsors and applicants regarding the status of their application.

Some comments noted that this system should only be developed if it could maintain the security of information contained within the system. As stated by one commenter who suggested FDA consider developing a tracking

system, “given the importance of protecting competitive and confidential commercial information, it is imperative that such a system provide access only to the sponsor and be operated under strict security guidelines.” Other comments noted that FDA should provide more clarity regarding the status of product reviews and include specific timelines in responses sent to industry.

To maintain continuity of any communications between FDA and industry, comments stated that FDA should inform sponsors, especially when they have an application pending, about any changes in personnel within a FDA division.

Several comments requested more information about the process the agency uses to assure consistency of the review process. One comment requested that FDA provide review staff, especially project management staff, with training in communication during review of applications.

3. *Considerations*

The Task Force agrees that meetings and informal communications between sponsors and FDA can provide useful information and greater predictability to sponsors and can help avoid unexpected or late-emerging problems in the review of an application. The cost of drug development may increase when timely answers to industry questions are not provided. FDA should provide as much information to sponsors as possible.

At the same time, the Task Force believes that a timely review process provides essential benefits to sponsors and patients. Meetings and frequent informal communications are resource and time-intensive and the FDA staff who prepare for and participate in meetings are oftentimes the same individuals who, among other responsibilities, review product applications. FDA review staff already spend tens of thousands of hours preparing for and holding meetings with sponsors and a significant number of meetings are held with industry each year. For example, in FY 2009, in response to 2,162 meeting requests from sponsors, the CDER Office of New Drugs scheduled 1,859 meetings with product application sponsors.

The Task Force therefore considered whether an increase in meetings and other less formal communications would lead to a decrease in review efficiency, i.e., more time would be needed for review, or would lead to a more efficient review process. The Task Force concluded that given current resources, it is not feasible to significantly increase the number of meetings and informal communications with FDA staff without decreasing review efficiency. Nevertheless, because of the importance of adequate communication between sponsors and FDA, this issue might be appropriately raised in the context of PDUFA negotiations.

The Task Force also considered the types of issues that may arise during the review of a product application and the methods FDA may use for timely resolution of those concerns. The Task Force considered whether the need for additional meetings and informal communications could be addressed to some extent, especially for small and first-time applicants, by providing general access to additional, detailed information about the review process. The Task Force believes that there are efficiencies that may be gained by clearly conveying expectations to sponsors about the process of reviewing applications and about what is needed to request and prepare for meetings.

The Task Force considered the usefulness of providing more information to industry through a tracking system and whether increased disclosure would lead to efficiencies in the review process. The Task Force also agrees that a workable tracking system could provide greater transparency to sponsors about the review of their applications and cut down on the number of communications with reviewers about the status of a sponsor's pending application. At the same time, product applications contain information that should be kept confidential, and the Task Force concluded that there must be a means available to keep that information secure. To explore the effectiveness and cost of such a system, members of the Task Force and agency employees involved in the product application review process participated in a teleconference with representatives of Health Canada to learn more about the electronic system used by that regulatory agency to track product applications.

4. Actions

ACTION 7:

FDA will compile all FDA Center guidance and standard operating procedures on FDA employees meeting with sponsors about product applications on the web-based resource, *FDA Basics for Industry*.

Reasoning: Meetings provide an opportunity for sponsors to ask questions about the product application process; the Task Force appreciates the benefits of providing timely answers to sponsor questions. But meetings consume a significant amount of agency resources, which constrains the number of meetings the agency can hold each year. FDA strives to meet the goals set forth in user fee negotiations with industry and will continue to assess that process to meet the user fee goals.

For the thousands of meeting requests FDA receives each year, sponsors that follow the agency's guidance on what is needed to request and prepare for meetings help ensure that the meetings are productive. Each Center that interacts with product sponsors has developed guidelines for meeting with sponsors. These documents are currently available on various pages on the FDA Web site. As a means for improving transparency, FDA will make this

information more easily accessible by compiling the information on a central location on the FDA Web site.

ACTION 8:

As part of the *FDA Basics for Industry* web-based resource, FDA will describe the types of notifications it provides to industry (e.g., letter acknowledging receipt of the application, mid-cycle review meetings) associated with the product application review process. FDA will explain its practice of providing the sponsor with the name and contact information of the individual who should be contacted with questions about the product application. FDA will provide an overview of the processes used to strive for consistency of product application review.

Reasoning: Explaining the product review process may give industry information that is helpful for business planning purposes and may lead to efficiencies in the review process. Providing this information in an easily accessible format may decrease the need for industry to contact FDA for this information and the need for more resource-intensive meetings.

Each Center has a process by which it reviews product applications that are submitted to the agency, and works to complete the review process in an efficient and timely manner. Each Center also has a process in place to strive for consistency of product application review; explaining this process may increase understanding of the agency's decision-making process. FDA's product application process will be summarized and made more easily accessible by compiling the information on a central location on the FDA Web site.

ACTION 9:

FDA will communicate on the web-based resource, *FDA Basics for Industry*, general expectations about the circumstances, if any, under which it is appropriate to use secure email between FDA and a manufacturer when there is a question involving the manufacturer's product.

Reasoning: FDA appreciates the potential efficiencies associated with the use of electronic communication. But, product applications submitted to FDA include proprietary information that should not be disclosed to the public. As a result, communications about product applications via electronic means must be conducted in a fashion that maintains the security of this information.

In some instances, Centers have established a means for sponsors to communicate about product application related matters via secure email, if they choose to do so. In these cases, there are processes governing the use of

secure electronic communication. Each Center's practice with respect to the use of electronic tools to communicate about product applications will be explained and made readily available on the FDA Web site.

ACTION 10:

FDA will explain via the *FDA Basics for Industry* web-based resource how a sponsor is informed about whether the review of its product application is on track to meet the target date for FDA action on the application. FDA is also willing to hold further discussions with industry about application tracking systems, and explore the feasibility of implementing such a system at FDA.

Reasoning: The agency has published milestones of key events during the course of the review process. Many product applications submitted to the agency are associated with performance goals for review. In most cases, the agency succeeds in meeting those target timeframes.³⁸

FDA communicates with sponsors as questions arise during the review process. FDA's requests for additional information provide a gauge of the agency's progress reviewing an application. Providing information to sponsors about this process may address some of sponsors' concerns articulated in comments to the Transparency Task Force.

FDA representatives participated in an initial discussion with representatives from Health Canada about the application tracking system used by that agency. FDA's initial sense was that the system did not provide a significant increase in the amount or quality of information available to a sponsor or applicant regarding their submission. The majority of the information available via the Health Canada tracking system is transmitted by FDA's review offices to the sponsor via email, telephone, or facsimile. Further, the security needs inherent in developing a tracking system for all applications that can be accessed by individual sponsors and yet keeps product application information confidential would require significant resources.

But Health Canada's experience implementing an application tracking system suggests that such a system could substantially reduce the need for communications between sponsors and FDA review staff concerning the status of applications. FDA is open to further discussions to gain a better understanding of the benefits to industry of an application tracking system and the feasibility of implementing such a system at FDA.

³⁸ See FDA-TRACK for product application review dashboards for new drugs, biologics, generic drugs, and medical devices, available at www.fda.gov/fdatrack.

C. Guidance Development

1. Background

FDA has issued regulations that govern the development, issuance, and use of guidance documents.³⁹ These regulations provide that as part of the agency's guidance development process, FDA will post on the FDA Web site a list of guidances the agency may work on during the next year.⁴⁰ This list, however, does not indicate the Center's priority topics for completion nor are timeframes through publication of the final guidance document provided.

Members of the public can also submit written comments to FDA about draft guidance documents (public comment is not solicited for guidance documents that set forth existing practice or minor changes in interpretation or policy).⁴¹ Interested members of the public can also suggest areas for guidance development,⁴² submit drafts of guidance documents for FDA to consider,⁴³ and suggest that FDA revise or withdraw an existing guidance document.⁴⁴

2. Summary of Comments

Many comments from industry stated that improvements are needed to the agency's guidance development process. Several comments stated the timeliness of the process must be improved, noting that "the process moves too slowly to provide meaningful information to industry." Some comments suggested that FDA formally track the agency's progress in drafting guidance documents, and include clear timelines and specific development stages. Comments further noted that if the guidance development process is delayed, stakeholders should be notified. Industry also requested that FDA inform stakeholders about the priority of guidances that the agency is planning on working on during the year.

Comments suggested that FDA create more opportunities for feedback from stakeholders during the guidance development process, including outside of the formal notice and comment mechanism. Comments suggested that once the agency receives input on a draft guidance document, FDA establish a transparent procedure for describing how it has evaluated those comments.

³⁹ See 21 C.F.R. § 10.115.

⁴⁰ 21 C.F.R. § 10.115(f)(5); see, e.g., Guidance Agenda: New Draft Guidances CDER is Planning to Publish During Calendar Year 2010, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079647.pdf>.

⁴¹ 21 C.F.R. § 10.115(g).

⁴² 21 C.F.R. § 10.115(f)(2).

⁴³ 21 C.F.R. § 10.115(f)(3).

⁴⁴ 21 C.F.R. § 10.115(f)(4).

Comments suggested that for guidance documents that have been in draft form for a specified period of time, e.g., longer than five years, FDA should reissue the guidance for public comment, so that the final draft reflects the most current knowledge of the subject matter and the guidance continues to be relevant. Comments also requested that FDA develop and communicate a work plan to finalize guidance that has been in draft form for many years.

Comments suggested that training and education should be part of the agency's guidance implementation process. Suggestions included holding public workshops where FDA employees review new guidances, holding webinars that allow for open public participation, and issuing question and answer documents about the guidance. Comments noted that training should occur early in the implementation process, preferably soon after a new policy or process is implemented.

Comments also requested that FDA issue more guidance documents.

3. *Considerations*

The Task Force agrees that it is critical that the agency provide relevant, timely guidance to industry in order to support efforts by industry to comply with the law and develop new products that may benefit the public health. The Task Force recognizes that the current guidance development process can be opaque, issuance of final guidance documents can be slow, and this can have negative effects on industry and the public.

In part because of competing, sometimes higher-priority, demands on agency staff, there are no simple solutions to such problems as lack of predictability about when a guidance document will issue. For example, if application review, regulation development and crisis management are all given a higher priority than guidance development, and the same staff are responsible for all of these activities, it may be impossible to predict when guidance documents will be completed. In addition, many of the problems, such as timeliness, cannot be addressed solely by greater transparency.

The Task Force considered the importance of providing clearer expectations about the guidance development process and better support for efforts by industry to satisfy agency recommendations. The Task Force considered the existing processes used to manage the guidance development process. The Task Force also considered the substantial resource issues involved in improving guidance development. The FDA staff who are responsible for guidance development are generally the same staff who are engaged in other agency priorities such as application review and regulation development.

The Task Force considered the effectiveness of the agency's current guidance development methods to provide useful and timely advice to industry. The

Task Force agrees that the timeliness of issuing final guidance documents is an area in need of improvement.

4. *Actions and Draft Proposals*

ACTION 11:

To examine suggestions for improving the guidance process, the Commissioner has formed a cross-agency working group under the leadership of the Office of Policy. This working group is examining the current process and will identify best practices for improving the agency's work on guidance. Topics include streamlining guidance development, reducing the time between issuance of draft and final guidance, and making it easier to find guidance documents on the FDA Web site.

Reasoning: The Commissioner has determined that to improve the guidance development process in a meaningful way, a broader, more in-depth review of the process is necessary. As a result, a working group of senior regulatory policy leads from across the agency has been convened under the leadership of the Office of Policy to identify best practices for improving FDA's efficiency at issuing final guidance documents. The working group will summarize their review of the guidance development process and make recommendations, as appropriate, by the end of FY 2011.

ACTION 12:

FDA will describe the ways in which interested individuals can provide input to the agency about guidance development as part of the web-based resource, *FDA Basics for Industry*. Links that provide industry with a list of guidance documents that have been withdrawn during the past year as well as possible topics for future guidance development or revision also will be made accessible in one location via *FDA Basics for Industry*.

Reasoning: Based on comments the Task Force received about providing input to the agency regarding guidance development, the Task Force decided to make explanations of the different ways in which the public can participate in, and learn about, guidance development, more accessible on the FDA Web site. As a result, FDA will provide this information on *FDA Basics for Industry*.

DRAFT PROPOSAL 3:

FDA will inform industry about the progress of certain high priority guidances in development by disclosing a timeline from the start of the agency's work on a draft guidance to publication of the final guidance.

Reasoning: FDA currently discloses a list of guidance documents the agency may work on during the next year. But priority items are not indicated and the target date for publication of the final guidance document is not provided. Timely, relevant guidance supports efforts by industry to comply with the law and develop novel products that may benefit the public health.

After consulting with HHS and OMB, FDA has decided to provide timelines associated with the guidance development process in an effort to provide more predictability and clarity. FDA will track the progress of certain high priority guidance documents⁴⁵ and will disclose the following milestone dates (including status of the milestone): (1) when FDA begins work on the guidance, (2) publication of the draft guidance, (3) the close of the comment period for the draft guidance, and (4) publication of the final guidance. This information will be tracked on FDA-TRACK. If implemented, an example of what would be provided is below.



Office of the Commissioner
Office of Policy

Key Projects	Milestone	Milestone Status	Milestone Completion Date
Office of Policy: Guidance			
Title: Guidance for Industry: Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages			
Description: The guidance, when finalized, will implement the provisions set forth in Section 505D of the Federal Food, Drug, and Cosmetic Act (the Act) regarding development of standardized numerical identifiers (SNIs) for prescription drug packages.			
1. Draft guidance started	3/1/2007	Completed	3/1/2007
2. Draft guidance issues	1/1/2009	Completed	1/16/2009
3. Comment period on draft guidance closes	4/16/2009	Completed	4/16/2009
4. Final Guidance Issues	3/27/2010	Completed	3/29/2010

D. Regulations Development

1. Background

Regulations are generally implemented using a two step process. First, the agency publishes a Notice of Proposed Rulemaking (NPRM) in the Federal Register and the public is given a specified period of time to comment on the rule. After the comments are reviewed and analyzed, the agency publishes the final rule.⁴⁶ If FDA determines that circumstances have changed significantly since the publication of a proposed rule, FDA may reopen the comment period

⁴⁵ A certain guidance document may be considered “high priority” if the content in the planned guidance would benefit public health (e.g., responds to a public health risk or provides information about clinical study design), is required by statute, would improve agency operations, or is included as part of user fee negotiations.

⁴⁶ The Administrative Procedure Act generally requires federal agencies to seek input from the public on proposed rules, and consider those comments when finalizing the rule.

to allow the public to submit additional comments before finalizing the proposed rule.

Pursuant to Executive Order 12866, FDA must publish a regulatory agenda that contains regulations under development or review at the agency. Regulations that the agency plans to work on during the next 12 months are included in the agenda.⁴⁷ This includes any plans to publish an Advance Notice of Proposed Rulemaking (ANPRM), a NPRM, or a final rule. For each planned regulation, FDA provides in its regulatory agenda, among other things:

- brief summary of the action,
- legal authority for the action,
- projected date for completion of at least the next step for the regulatory action (dates for all past steps are included),
- statutory deadlines, if any, and
- the agency's priority for the regulation.

Any actions or reviews of regulations that have been completed or withdrawn since the last regulatory agenda was published are also included.

Twice a year, the federal government issues the *Unified Agenda of Federal Regulatory and Deregulatory Actions*, a compilation of regulatory agendas published by federal agencies.⁴⁸

An informal survey of the projected dates for regulatory action included in regulatory agendas published by FDA since May 2005 indicates that FDA should work with the Department of Health and Human Services and the Office of Management and Budget to better manage the regulations development process so that the projected timetables are more accurate. A review of 68 proposed regulations included in FDA's regulatory agenda during this time period reveal that only 7 regulations were published by the date projected in the regulatory agenda. Six regulations were published within 6 months of the projected date, but the vast majority of the regulations were published two years or more after the projected date (some of these regulations are yet to be published).

⁴⁷ FDA can elect to include activities that have a next action beyond 12 months if disclosure of the rule in the regulatory agenda would provide a benefit to users.

⁴⁸ See Executive Order 12866, Regulatory Planning and Review, 58 Fed Reg. 51735 (Oct. 4, 1993). The Unified Agenda is made available online, available at <http://www.reginfo.gov>.

FDA hosts training workshops for industry to explain agency procedures. FDA employees also frequently participate in educational events hosted by others. These events occur as the need arises, and oftentimes occur during the implementation of final rules.

2. *Summary of Public Comments*

Comments stated that the agency may publish a proposed rule, solicit comment, and then “is silent for years about whether and when it intends to finalize the document.” One comment stated that “companies may be confused about what rules and policies to follow in the interim.” Comments suggested that FDA provide more information about the status of pending rules and urged FDA to publish final rules reasonably quickly. Comments stated that the rulemaking process should include clear timelines, and if a proposed rule has not been finalized within a reasonable amount of time, FDA should either re-open the comment period for that proposed rule, or re-issue the rule for public comment.

Comments also requested that FDA provide training to industry following the issuance of a final rule. One comment stated that any training should occur soon after new regulatory requirements are implemented. Another comment suggested that FDA should issue, on a more frequent basis, questions and answers about new rules. Industry stated that these actions would help increase understanding of, and compliance with, new requirements.

3. *Considerations*

The Task Force agrees that the current process used to develop regulations has failed to generate consistency and predictability in the process. Proposed rules are not finalized for years, and information provided to the public about timetables associated with the process has proved to be inadequate at times. The Task Force agrees that industry should be able to expect a more predictable regulations development process and the timetables put forth by the agency should be more reliable.

The Task Force considered the importance of providing clearer expectations about the regulatory development process and better support for efforts by industry to comply with the law. The Task Force considered the existing processes used to manage the regulations development process and the effectiveness of those methods.

The regulations development process involves many steps, including issuing a proposed rule for public comment, analyzing those comments, reviewing the proposed rule in light of those comments, and responding to those comments in a final rule. The Task Force recognizes the importance of finalizing proposed rules as soon as possible.

4. *Actions*

ACTION 13:

After FDA issues a final rule, FDA will conduct outreach to the affected stakeholders as part of implementing the final rule if the rule imposes substantial new obligations.

Reasoning: Providing industry with information on substantial new regulatory requirements benefits public health by informing industry about what is needed to comply with the law. Although it is agency practice to participate in outreach activities following the issuance of a final rule with substantial new obligations, there is no agency policy that outreach must occur in these situations. Conducting routine outreach in these situations is a cost-effective way to support industry's compliance efforts more effectively. By knowing what is expected, this will hopefully lead to improved compliance by industry. These outreach activities may help FDA more effectively protect the public health.

ACTION 14:

FDA, working with the Department of Health and Human Services and the Office of Management and Budget, will improve the accuracy of the timetables included in the agency's regulatory agenda published as part of the *Unified Agenda*.

Reasoning: Industry must follow the standards articulated in FDA regulations because they carry the force of law. The failure to finalize rules in a timely manner contributes to confusion among industry. FDA should improve the accuracy of projected dates provided in the agency's regulatory agenda.

E. Import Process

1. *Background*

The Office of Regulatory Affairs (ORA) is the lead office for all field activities conducted by the FDA. ORA Headquarters is comprised of the Office of Resource Management, the Office of Regional Operations, the Office of Enforcement, and the Office of Criminal Investigations. The Division of Import Operations and Policy (DIOP) within the Office of Regional Operations serves as the agency focal point for relationships between ORA Headquarters and the field on all import programs and operations.

DIOP's responsibilities include:

- Overseeing field import operations, including investigation and compliance activities
- Developing and reviewing FDA import policies, procedures, programs, and assignments
- Coordinating FDA import activities with United States Customs and Border Protection (CBP) and other federal agencies and foreign governments
- Training field import personnel

ORA staff are dispersed throughout the United States. Over 85 percent of ORA's staff work in the 5 Regional Offices, 20 District Offices, 13 Laboratories, and more than 150 Resident Posts and Border Stations located across the U.S.

Sections 801(a) and 536(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorize FDA to examine foods, drugs, cosmetics, tobacco products, devices, and radiation-emitting electronic products offered for import into the United States. FDA can refuse admission of imported products into the U.S. if, among other reasons, the product appears to be adulterated or misbranded. FDA works closely with CBP to prevent the importation of adulterated, misbranded, or otherwise violative products into the country.

In some cases, a product may be detained without physical examination (DWPE) when it is offered for importation into the United States. The DWPE decision is based on whether the agency has sufficient evidence or other information, other than from a physical examination, to refuse admission of an imported product. Such information could be based on, for example, a shipper or importer having a history of importing violative products such that future imports of the product appear to not be in compliance with the FD&C Act. When a product is detained, the owner or consignee has an opportunity to show that the product meets FDA requirements.⁴⁹ In some situations, FDA may allow the importer to recondition a product that is violative.

FDA uses Import Alerts to identify and disseminate import information to FDA personnel. Import Alerts identify problem commodities and/or importers and provides information and direction to FDA personnel regarding

⁴⁹ Regulatory Procedures Manual, Chapter 9: Import Operations and Actions, at 9-18 (Mar. 2010), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf>.

the importation of those commodities as well as information to FDA personnel regarding the companies noted in the alert.

As part of the importation process, importers must file information about the product with CBP, and other agencies with jurisdiction. Importers can file this information themselves, or may use the services of a licensed customhouse broker to facilitate submission of the required documentation. FDA conducts evaluations of filers who participate in FDA's electronic entry processing program to determine if filers are submitting accurate data to FDA.

Requirements and other information regarding importing products are set forth in the FD&C Act, FDA regulations, and in numerous documents and guidances issued by the agency. In addition, a section of the FDA Web site is dedicated to information of interest to the importer community.⁵⁰

FDA employs an import screening tool, the Operational and Administrative System for Import Support (OASIS), to help manage and oversee import operations. OASIS is an automated FDA system for processing and conducting admissibility screening determinations for imported FDA-regulated products.⁵¹ FDA's Import Trade Auxiliary Communications System (ITACS) is an extranet application that will be available to any trade user with a valid entry number. It will enable a trade user to retrieve entry review status, to provide product availability information, and to submit documentation. ITACS is expected to be deployed in the next few months.

FDA also plans to issue a *Strategic Plan for Imports* (Strategic Plan) that will identify and address critical issues and performance gaps in current import operations. This Strategic Plan will address the entire life cycle of FDA-regulated products imported into the U.S., with a goal of increasing uniformity, and improving effectiveness and efficiency across the country. This will result in a more modern approach to import operations that focuses on prevention, intervention and response.

2. Summary of Public Comments

The Task Force received one submission from a trade association containing suggestions for improving transparency of the import process. The comment requested that ORA headquarters consider ways to provide FDA districts with guidance that results in more uniform processes and procedures, including developing a policy about how importers can correct data that has been submitted about products.

⁵⁰ "Import Program," available at <http://www.fda.gov/ForIndustry/ImportProgram/default.htm>.

⁵¹ A new risk-based screening tool, the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), is in development and will replace the admissibility screening function OASIS.

The comment also suggested a variety of ways to facilitate communication with the importer community, including (1) methods of allowing specific trade issues to be brought to the attention of ORA headquarters, (2) publishing contacts in each District with whom brokers who are not physically located at the port can communicate, and (3) providing the option to receive an email notification when new Import Alerts are issued or procedural updates to the Regulatory Procedures Manual are made.⁵²

The comment also made recommendations about how FDA can provide timely and useful responses to industry questions about imports, including establishing an email address for each District and committing to respond to phone or email contacts within 24 hours. It was noted that developing the ITACS system of notification and communications will help the agency provide timely responses to questions.

The comment also proposed ways in which FDA could better inform the importer community about regulatory requirements, including development of a web database system that provides basic requirements related to importing a specific commodity.

The comment also suggested that FDA review the existing procedures used to conduct evaluations of importers, or third parties working on behalf of importers, who file information electronically about products offered for import into the United States.

3. Considerations

The Task Force agrees that FDA could improve its communications with importers in many of the ways proposed. FDA agrees that where possible, and when appropriate, industry should be given the means to correct inadvertent data errors submitted about imported products.

In determining which actions would be most effective to improve transparency to importers, the Task Force considered the need for flexibility to adapt to local conditions as well as different FDA-regulated products, and the efficiencies that may result from a more uniform system.

The Task Force also considered the information currently provided to the importer community, and whether improvements in how that information is presented would improve transparency. The Task Force considered whether the means available for the importing community to get information about

⁵² The Regulatory Procedures Manual (RPM) is a reference manual for FDA personnel that the agency posts on the FDA Web site. It provides FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. It does not create or confer any rights for, or on, any person and does not operate to bind FDA or the public. The RPM is available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>.

importing requirements could be made more accessible. The Task Force also considered the current responsibilities of FDA employees to protect the public health. The Task Force sought to determine efforts that the agency could undertake to improve communication, given the agency's competing priorities and limited resources.

4. *Actions and Draft Proposals*

ACTION 15:

FDA will publish on the FDA Web site contact information for each Import Program Manager and update that list on a regular basis.

Reasoning: Fostering effective communication channels between the importer community and FDA contributes to a more efficient and cost-effective regulatory process. Import Program Managers are managers based in FDA district offices that serve as the point of contact for issues related to import operations. Providing contact information for Import Program Managers online will provide the importer community with an individual to whom to direct questions about the import regulatory process within each District. These individuals can manage the process so that importers can receive responses to questions related to import operations.

ACTION 16:

FDA will allow interested members of the public to receive email notifications when an Import Alert is posted on the FDA Web site, or an existing Import Alert is updated.

Reasoning: Industry requested a means to get up-to-date information about Import Alerts from FDA. Placement of a product on an Import Alert for DWPE means that FDA has sufficient information to detain that product when it is offered for import into the United States.

Placement on an Import Alert for DWPE has significant implications for manufacturers and distributors of those products. Based on the information in the Import Alert, FDA may refuse admission of the product unless the importer demonstrates that the product is in compliance with applicable laws before FDA will admit the product into the country or FDA allows the importer to recondition the product.

Companies whose products are on a FDA Import Alert have an incentive to remedy the issue quickly so that they are removed from the list as soon as possible. The Task Force concluded that real-time notification can assist with this process and that FDA should permit interested members of industry to

sign up to receive email notifications when an Import Alert is posted on the FDA Web site, or an existing Import Alert is updated.

ACTION 17:

As part of FDA's efforts to implement the forthcoming Strategic Import Plan, FDA will develop and execute a project to promote more uniform processes and procedures across districts, when appropriate, and inform industry of district and port-specific practices and procedures. This project will be tracked on FDA-TRACK.

Reasoning: As described above, ORA staff are dispersed throughout the United States, with most of the ORA staff working in regional and district offices. This nationwide structure is needed since FDA-regulated products are found throughout the country. Different issues may arise in different areas of the country, so uniform procedures on all matters may not be appropriate. At the same time, the comment argued that there are cases in which identical products are handled differently in different districts. Processes and procedures should be uniform to the maximum extent possible to facilitate efficiency and predictability.

The Task Force concluded that there may be circumstances where the efficiencies to be gained from uniform processes are feasible and supportive of public health. FDA's implementation of the forthcoming *Strategic Import Plan* will address this issue.

ACTION 18:

If a general question about the import process or existing policy is submitted to the Division of Import Operations and Policy (DIOP) in the Office of Regulatory Affairs (ORA) or to a FDA field office, DIOP or the field office should provide a response, if practicable, within 5 business days or acknowledge receipt of the inquiry and provide an estimated time frame for response. DIOP will compile a list of answers to questions frequently asked by industry and post this information on the FDA Web site.

Reasoning: Setting an expectation for responses to general questions about the import process or existing FDA policy regarding imports helps bring clarity and more certainty to the process. The Task Force concluded that the importer community should expect a response to general questions about the import process or existing policy within 5 business days, or receive acknowledgment from FDA if a response cannot be provided within that timeframe. In the agency's experience, some questions may require additional expertise, and in those cases, the inquiry may be forwarded to the appropriate office or employee for additional information. In setting an expectation for

response to all general questions, the Task Force felt it was important to incorporate the reality that the vast majority of ORA employees are located in the field.

Further, in an effort to make more basic regulatory information about the import process broadly available, DIOP will post answers to questions that are frequently asked by industry on the FDA Web site.

ACTION 19:

FDA will work with Customs and Border Protection to explore developing a process by which brokers and filers can correct inadvertent data errors submitted about imported products and FDA should post that process online.

Reasoning: The accuracy of the information submitted by brokers and filers about imported products is important to FDA's work in protecting the food and medical product supply in the United States. The ability to correct such errors contributes to a more efficient and cost-effective regulatory system because decisions are made based on more accurate information.

Information submitted about imported products, however, is housed in different systems and owned by different regulatory agencies, which introduces challenges to any process to correct information that has been submitted. FDA should work with CBP to explore the feasibility of allowing brokers and filers to correct inadvertent data errors, when appropriate. If a process is developed, that information should be made broadly available by posting on the FDA Web site.

DRAFT PROPOSAL 4:

In order to foster a more uniform and efficient process, FDA should review existing procedures used to conduct evaluations of importers, or third parties working on behalf of importers, who file information electronically about products offered for import into the United States. This review of the overall process should include what to examine during the evaluation, the error rate classification, the process of discussing the findings with the firm, and the final classification. It should also include the process for handling evaluations of those filers who file entries without being physically located at the port where the product enters the United States.

Reasoning: Importers, or third parties working on behalf of importers, file information about the product offered for import at one of the ports of entry into the United States. The accuracy of this information is important to FDA's work to effectively protect the public from potentially harmful

products. Under FDA's current procedures, evaluations of filers who submit information electronically to FDA are conducted based on where the broker is physically located.

According to the importer community, however, an increasing number of filers are using the CBP Remote Location Filing Program, which permits importers to file information about products being presented for import at locations where the filer is not physically present. Given this trend, the Task Force concluded that FDA should review the existing procedures for filer evaluations to see if there should be any improvements made to the evaluation system.

DRAFT PROPOSAL 5:

FDA should initiate a planning process to develop a web-based system that would help importers more easily determine the proper requirements for importation, the correct data codes, and any special requirements. FDA will engage industry in the planning process.

Reasoning: Both FDA and the importer community have an interest in transparency with respect to regulatory requirements. The Task Force recognizes the need to clearly convey requirements and expectations to the importer community to promote understanding of, and compliance with, the rules and regulations set up to protect the food and medical product supply. Compliance with regulatory requirements in turn helps protect the public health because fewer violative products enter the U.S.

FDA should explore ways in which existing information about the import process can be made more accessible. Making existing information accessible through the website may allow limited agency resources to be used in other ways and may allow helpful information to be found more quickly and reliably by importers, leading to greater efficiencies for both FDA and industry.

V. Other Topics

A. Advisory Opinion Process

One group, representing several prescription drug manufacturers, requested that FDA create an advisory opinion process for "timely binding advice in response to a specific request on proposed promotional and scientific exchange practices." The group stated that the availability of an advisory opinion process at FDA would encourage greater industry compliance with FDA laws and regulations while providing improved communication to the public about important health information. It also noted that other federal agencies have established an advisory opinion process, including, the Office of Inspector General (OIG) at the

Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS), and the Federal Trade Commission (FTC).

FDA currently has a process in place for companies to receive advisory comments on specific promotional pieces for drug and biological products before disseminating those pieces.⁵³ Although these comments are not binding, if FDA subsequently changes its position on a promotional piece, the agency is required to provide notice to the submitter and a reasonable amount of time to correct the promotional piece before FDA will take enforcement action.

The Task Force concluded that the feedback FDA currently provides to pharmaceutical companies on the content of specific promotional pieces is within the agency's expertise and contributes to FDA's mission to protect and promote the public health. The request for FDA to issue binding advisory opinions may place inappropriate restrictions on FDA's ability to respond to emerging issues to best protect and promote the public health.

The Task Force also considered whether a binding advisory opinion process for food labeling would aid FDA in its mission to protect and promote the public health. As stated above, issuance of binding advisory opinion may limit the agency's flexibility to address emerging public health issues and to implement its statutory responsibilities. In addition, requestors may fail to provide, or subsequently change, claims or product formulations that might render the labeling at issue unlawful. But the company may mistakenly believe it can continue to rely on a favorable advisory opinion. This may have negative consequences for public health.

CFSAN's Office of Nutrition Labeling and Dietary Supplements (ONLDS) often responds to questions from food companies about labeling and promotional matters, such as the proper nomenclature for a food ingredient or "front-of-pack" labeling claims. In some instances, CFSAN also uses guidance to communicate with industry about such matters.⁵⁴

The Task Force is not recommending changes to current practice.

⁵³ See 21 C.F.R. § 202.1(j)(4).

⁵⁴ See, e.g., Draft Guidance for Industry, *Ingredients Declared as Evaporated Cane Juice* (Oct. 2009) (advising industry that, in FDA's view, 'evaporated cane juice' is not the common or usual name of any type of sweetener), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabeling/Nutrition/ucm181491.htm>; Guidance for Industry, *Letter Regarding Point-of-Purchase Food Labeling* (Oct. 2009), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabeling/Nutrition/ucm187208.htm>.

B. Agency Interactions with Manufacturer Regarding Public Communication about Emerging Safety Issues with a Manufacturer's Product

Comments requested that FDA communicate with companies in advance of disclosing safety information about their products publicly. Some comments suggested that FDA engage with the manufacturer of the product at least 48 to 72 hours prior to communicating emerging safety issues to the public; another comment suggested at least 72 to 96 hours notice. These comments noted that prior notice would allow time for companies to work with FDA to develop complimentary communications to the public and healthcare providers about the issue and allow the company time to prepare for questions from doctors, patients, and the media.

One comment from a trade association also requested that FDA share information with sponsors about the methods FDA used to conclude that there may be a safety concern with a product.

Discussions with industry are generally needed in advance of communicating with the public in order for FDA to gather additional information to further understand the potential safety issue. Those discussions provide notice to the company that FDA is exploring safety concerns with one of its products.

When appropriate, FDA works with the relevant manufacturer(s) regarding emerging safety information about its product or class of products. FDA may also notify the manufacturer and solicit input from the manufacturer prior to disclosing information to the public, for example, to confirm the accuracy of factual information or to assure consistent and non-confusing messages are communicated to the public. CDER aims to notify the relevant sponsor that emerging drug safety information about its drug will be posted on the FDA Web site at least 24 hours before the public communication is issued.⁵⁵ However, when necessary to protect public health, FDA may notify the public without first informing the manufacturer. As a result of the need for the agency to respond based on the specific facts at hand, the Task Force is not recommending any changes to current practice.

VI. Next Steps

The Task Force will solicit comment on the five draft proposals set forth in this report for 60 days. Comments will be solicited via www.regulations.gov. The Task Force is seeking comment on the content of the proposal, as well as which proposals should be given priority. Based on the Task Force's review of the comments received and internal assessment regarding what would be needed to implement the proposal, the

⁵⁵ Guidance for Industry, Drug Safety Information—FDA's Communication to the Public (Mar. 2007), *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072281.pdf>

Task Force will recommend specific proposals to the Commissioner for consideration. The Task Force's recommendations will consider feasibility and priority, considering other agency priorities that require resources.

FDA will begin to implement the action items in this report in 2011.

VII. Appendix A: List of Action Items

Communicating Information About Agency Procedures

1. FDA will develop a *FDA Basics for Industry* web-based resource that provides basic information online about the regulatory process governing FDA-regulated products.
2. FDA will update the agency organizational charts and senior leadership personnel changes on the FDA Web site on at least a quarterly basis and ensure that the level of detail provided on the organizational charts is consistent across the agency.
3. Each Center has a process for industry to submit general regulatory questions, and for directing inquiries to individuals with additional expertise, if necessary. Links to these processes will be made available on *FDA Basics for Industry*.
4. If a general question about an existing policy, regulation, or the regulatory process is submitted to any of the email addresses specified below, whenever practicable, FDA should provide a response within 5 business days or acknowledge receipt of the inquiry and provide an approximate timeframe for response. This will be tracked on FDA-TRACK.
5. In September 2010, FDA issued its “Strategic Priorities FY 2011-2015” in draft form for public comment. FDA will issue a final version of the “Strategic Priorities FY 2011-2015” by March 2011.
6. FDA will post on the FDA Web site slide presentations that are delivered by FDA employees to external audiences at events sponsored by, or co-sponsored by, the agency.

Product Application Review Process

7. FDA will compile all FDA Center guidance and standard operating procedures on FDA employees meeting with sponsors about product applications on the web-based resource, *FDA Basics for Industry*.
8. As part of the *FDA Basics for Industry* web-based resource, FDA will describe the types of notifications it provides to industry (e.g., letter acknowledging receipt of the application, mid-cycle review meetings) associated with the product application review process. FDA will explain its practice of providing the sponsor with the name and contact information of the individual who should be contacted with questions about the product application. FDA will provide an overview of the processes used to strive for consistency of product application review.

9. FDA will communicate on the web-based resource, *FDA Basics for Industry*, general expectations about the circumstances, if any, under which it is appropriate to use secure email between FDA and a manufacturer when there is a question involving the manufacturer's product.
10. FDA will explain via *FDA Basics for Industry* how a sponsor is informed about whether the review of its product application is on track to meet the target date for FDA action on the application. FDA is also willing to hold further discussions with industry about application tracking systems, and explore the feasibility of implementing such a system at FDA.

Guidance Development

11. To examine suggestions for improving the guidance process, the Commissioner has formed a cross-agency working group under the leadership of the Office of Policy. This working group is examining the current process and will identify best practices for improving the agency's work on guidance. Topics include streamlining guidance development, reducing the time between issuance of draft and final guidance, and making it easier to find guidance documents on the FDA Web site.
12. FDA will describe the ways in which interested individuals can provide input to the agency about guidance development as part of the web-based resource, *FDA Basics for Industry*. Links that provide industry with a list of guidance documents that have been withdrawn during the past year as well as possible topics for future guidance development or revision also will be made accessible in one location via *FDA Basics for Industry*.

Regulations Development Process

13. After FDA issues a final rule, FDA will conduct outreach to the affected stakeholders as part of implementing the final rule if the rule imposes substantial new obligations.
14. FDA, working with the Department of Health and Human Services and the Office of Management and Budget, will improve the accuracy of the timetables included in the agency's regulatory agenda published as part of the *Unified Agenda*.

Import Process

15. FDA will work with Customs and Border Protection to explore developing a process by which brokers and filers can correct inadvertent data errors submitted about imported products and FDA should post that process online.

16. FDA will publish on the FDA Web site contact information for each Import Program Manager and update that list on a regular basis.
17. FDA will allow interested members of the public to receive email notifications when an Import Alert is posted on the FDA Web site, or an existing Import Alert is updated.
18. As part of FDA's efforts to implement the forthcoming Strategic Import Plan, FDA will develop and execute a project to promote more uniform processes and procedures across districts, when appropriate, and inform industry of district and port-specific practices and procedures. This project will be tracked on FDA-TRACK.
19. If a general question about the import process or existing policy is submitted to the Division of Import Operations and Policy (DIOP) in the Office of Regulatory Affairs (ORA) or to a FDA field office, DIOP or the field office should provide a response, if practicable, within 5 business days or acknowledge receipt of the inquiry and provide an estimated time frame for response. DIOP will compile a list of answers to questions frequently asked by industry and post this information on the FDA Web site.

VIII. Appendix B: List of Draft Proposals

Communicating Information About Agency Procedures

1. FDA should maintain on the FDA Web site a list of presentations given by FDA employees to external audiences.
2. When the Office of the Commissioner (OC) receives a request to reconsider a scientific decision of an FDA employee from an interested person outside the agency pursuant to 21 C.F.R. § 10.75, OC should inform the submitter within three weeks whether OC will review the request, and should inform the submitter when a decision or an update on the status of the review may be expected.

Guidance Development

3. FDA will inform industry about the progress of certain high priority guidances in development by disclosing a timeline from the start of the agency's work on a draft guidance to publication of the final guidance.

Import Process

4. In order to foster a more uniform and efficient process, FDA should review existing procedures used to conduct evaluations of importers, or third parties working on behalf of importers, who file information electronically about products offered for import into the United States. This review of the overall process should include what to examine during the evaluation, the error rate classification, the process of discussing the findings with the firm, and the final classification. It should also include the process for handling evaluations of those filers who file entries without being physically located at the port where the product enters the United States.
5. FDA should initiate a planning process to develop a web-based system that would help importers more easily determine the proper requirements for importation, the correct data codes, and any special requirements. FDA will engage industry in the planning process.

IX. Appendix C: Glossary of Acronyms and Abbreviations

ADUFA: Animal Drug User Fee Act

AGDUFA: Animal Generic Drug User Fee Act

ANDA: Abbreviated New Drug Application

ANPRM: Advanced Notice of Proposed Rulemaking

BLA: Biologics Licensing Application

CBER: Center for Biologics Evaluation and Research

CBP: United States Customs and Border Protection

CDER: Center for Drug Evaluation and Research

CDRH: Center for Devices and Radiological Health

CFSAN: Center for Food Safety and Applied Nutrition

CMS: Centers for Medicare and Medicaid Services

CVM: Center for Veterinary Medicine

DDI: Division of Drug Information

DIOP: Division of Import Operations and Policy

DSMICA: Division of Small Manufacturers, International and Consumer Assistance

DWPE: Detained Without Physical Examination

FDA: United States Food and Drug Administration

FD&C Act: Federal Food, Drug and Cosmetic Act

FTC: Federal Trade Commission

HHS: United States Department of Health and Human Services

ITACS: Import Trade Auxiliary Communications System

MDUFMA: Medical Device User Fee and Modernization Act

NDA: New Drug Application

NCIE: Notices of Claimed Investigational Exemption for a New Animal Drug

NPRM: Notice of Proposed Rulemaking

OASIS: Operational and Administrative System for Import Support

OC: Office of the Commissioner

OGD: Office of Generic Drugs

OIG: Office of the Inspector General

OMB: Office of Management and Budget

OND: Office of New Drugs

ORA: Office of Regulatory Affairs

PDUFA: Prescription Drug User Fee Act

PMA: Premarket Approval

REMS: Risk Evaluation and Mitigation Strategies

RPM: Regulatory Project Manager