

**FDA TRANSPARENCY INITIATIVE:
DRAFT PROPOSALS FOR PUBLIC COMMENT REGARDING
DISCLOSURE POLICIES OF THE U.S. FOOD AND DRUG
ADMINISTRATION**

[G]overnmental decisions, particularly regulatory decisions, should be based on publicly available information. . . . This premise underlies the Freedom of Information Act, the Federal Advisory Committee Act, and the Government in the Sunshine Act. In enacting each of these statutes, the Congress implemented a basic principle of our political system: that people affected by governmental decisions have a right to know the basis on which they are made. Anyone who questions the wisdom of a regulatory decision should be able to examine the factual foundation of the decision.

FDA Commissioner Donald Kennedy, 1978

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

I.	LETTER FROM CHAIR OF TRANSPARENCY TASK FORCE	1
II.	EXECUTIVE SUMMARY	2
III.	TRANSPARENCY TASK FORCE	9
	A. BACKGROUND.....	9
	B. APPROACH	9
	C. PROGRESS TO DATE AND FUTURE PLANS.....	11
IV.	TRADE SECRETS	13
V.	DRAFT PROPOSALS BY TOPIC AREA	14
	A. ADVERSE EVENT REPORTS	14
	B. DOCKET MANAGEMENT PROCESS.....	20
	C. ENFORCEMENT PRIORITIES AND ACTIONS	21
	D. IMPORT PROCEDURES	25
	E. INSPECTIONS	27
	F. PRODUCT APPLICATIONS (INCLUDING INVESTIGATIONAL APPLICATIONS)	30
	G. RECALLS	50
	H. WARNING AND UNTITLED LETTERS	54
VI.	OTHER AREAS OF PUBLIC COMMENT	57
	A. ADVISORY COMMITTEE MEETINGS	57
	B. CITIZEN PETITION PROCESS	58
	C. COMMUNICATING ABOUT SAFETY CONCERNS AND EMERGING SAFETY ISSUES	58
	D. FREEDOM OF INFORMATION ACT	59
	E. INSPECTION RESULTS FROM FOOD FACILITIES	60
	F. MEDIA POLICY.....	61
	G. MEETINGS WITH STAKEHOLDERS.....	62
VII.	NEXT STEPS	63
	A. PHASE II.....	63
	B. PHASE III	63
VIII.	APPENDIX: GLOSSARY OF ACRONYMS AND ABBREVIATIONS	64

I. LETTER FROM CHAIR OF TRANSPARENCY TASK FORCE

May 2010

President Obama's Administration and the U.S. Department of Health and Human Services have made a priority of promoting openness in government. At the U.S. Food and Drug Administration (FDA), we recognize that the successful implementation of this principle will enhance our ability to promote and protect public health. The public, Congress, media, and industry should all understand how FDA operates and why the agency makes key decisions.

Last summer, FDA Commissioner Dr. Margaret Hamburg launched the Transparency Initiative. It has been my pleasure to chair an internal task force charged with developing recommendations for Commissioner Hamburg's review.

Today, as part of the second phase of this effort, FDA is releasing a draft report on the public disclosure policies of FDA. Our goal is to facilitate transparency that promotes public health and innovation.

The report proposes for public comment 21 specific draft proposals. These draft proposals reflect close review of more than 1,500 public comments and extensive consideration and discussion within FDA.

These steps would:

- Better explain FDA decisions. One proposal for comment is for the agency to explain the rationale when the agency declines to approve medical products. This explanation can support the development and approval of improved products.
- Provide more data to doctors and patients. A proposal would permit FDA to release summary data on safety and effectiveness from medical product applications when doing so would clear misconceptions or promote public health.
- Illuminate enforcement efforts. A proposal would have FDA post the classification of every inspection by agency staff. This information could be very useful to consumers and purchasers of medical products and food.
- Support innovation for rare diseases. A proposal would allow FDA to explain that an abandoned application for an orphan drug could represent a significant therapeutic advance. This could incentivize another company to continue with the application.

We invite public comment on these draft proposals, including input on whether we have struck the right balance between disclosure and confidentiality in support of public health. Because FDA cannot implement all of the proposals at once, we are asking for input on how to prioritize. Please visit www.fda.gov/transparency to provide your thoughts.

The Task Force will consider the public comments, the operational feasibility, priority, and resource requirements required to recommend specific proposals to Commissioner Hamburg for consideration.

We look forward to your continued participation in the Transparency Initiative.



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

II. EXECUTIVE SUMMARY

A. Introduction

Every day, the U.S. Food and Drug Administration (FDA) makes important health and safety decisions about foods, drugs, medical devices, cosmetics, and other widely used consumer products. Transparency in FDA's activities and decision-making allows the public to better understand the Agency's decisions, increasing credibility and promoting accountability. Transparency helps the Agency to more effectively protect and promote the public health.

In January 2009, President Obama issued a memorandum on Transparency and Open Government calling for an "unprecedented level of openness in Government" and directing the Director of the Office of Management and Budget (OMB) to issue an Open Government Directive instructing executive departments and agencies to take specific actions to implement the principles of transparent, collaborative, and participatory government. The Open Government Directive was issued in December. Under the leadership of Secretary Kathleen Sebelius, the U.S. Department of Health and Human Services has also prioritized transparency and openness. In June 2009, FDA Commissioner Dr. Margaret Hamburg launched FDA's Transparency Initiative to implement these efforts at FDA.

The initiative is overseen by a Task Force representing key leaders of FDA. The internal task force is chaired by the Principal Deputy Commissioner of the FDA and includes five of the Agency's center directors, the Chief Counsel, the Associate Commissioner of Regulatory Affairs, and the Chief Scientist. The Task Force is charged with submitting a written report to the Commissioner on the Task Force's findings and recommendations.

Over the last eleven months, the Task Force has held two public meetings,¹ launched an online blog (<http://fdatransparencyblog.fda.gov/>), and opened a docket. The online blog and the docket have received 1,572 comments.

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

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

Phase I: FDA Basics. The first phase is intended to provide the public with basic information about FDA and how the Agency does its work. This phase was unveiled in early January 2010 with the launch of a web-based resource called *FDA Basics* (www.fda.gov/fdabasics). The resource now includes (1) 126 questions and answers

¹ Transcripts and the webcast from both public meetings are available on the FDA Web site, www.fda.gov/transparency.

about FDA and the products that the Agency regulates, (2) nine short videos that explain various FDA activities, and (3) ten conversations with FDA officials about the work of their Offices. 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. Feedback provided by the public will be used to update this resource.

Phase II: Public Disclosure. The second phase relates to FDA’s policy on disclosure. The Task Force reviewed and considered all comments received from a range of stakeholders, many of which stated that FDA should disclose more of the information it has in its possession. The Task Force weighed the public interest in disclosure of additional information and the public interest in confidentiality (including potential competitive interests), and used the comments from the public to inform the draft proposals for public comment in this report. The Task Force also identified ways to improve transparency that are reflected in this report.

In this report, the Task Force makes available for public comment 21 draft proposals for changes in policy related to the disclosure of information FDA has in its possession, while supporting the redaction of trade secrets and individually identifiable patient information from all documents proposed for disclosure. Other topics, on which FDA plans to make changes or on which the Task Force is not proposing policy changes at this time, are discussed in the “Other Areas of Public Comment” section of the report.

The Task Force is soliciting comments from the public on the draft proposals set forth in this report for 60 days. In addition to input on the content of the proposals and whether the Task Force has struck the right balance with respect to the draft proposals, FDA is seeking input on how the Agency should prioritize the proposals since FDA cannot implement all of the proposals at once. To develop the broadest slate of proposals, the Task Force did not, at this stage of the review, consider the feasibility of implementing the proposals. Based on this input, the 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. Some of the draft proposals may require extensive resources to implement, and some may require changes to regulations and possibly even legislation. As a result, the Task Force may ultimately recommend some, but not all, of the draft proposals for implementation.

Phase III: Transparency to Regulated Industry. The third phase of the Transparency Initiative will address ways FDA can become more transparent to regulated industry, in order to foster a more efficient and cost-effective regulatory process. The Task Force solicited comments from the public on this topic and draft proposals from this phase are expected in the summer of 2010.

B. Draft Proposals for Public Comment

The draft proposals for public comment are organized in alphabetical order by topic.

Adverse Event Reports

For certain FDA-regulated products, FDA provides a mechanism for the public to quickly access public information from adverse event reports submitted to the Agency. Even where provided, however, such information is not now always accessible in a manner that allows users to generate summary reports of this information.

The Task Force proposes for public comment:

- 1. FDA should expand the areas in which it provides the public with online access to public information from adverse event reports about FDA-regulated products submitted to FDA, in a format that is searchable and allows users to generate summary reports of this information, including, if known and as applicable, the trade name and/or established name of the product, dosage, route of administration, description of the adverse event, and the health outcome. Adverse event report information should continue to be disclosed with a clear disclaimer about the limits of the information.**

Docket Management Process

FDA does not now routinely post comments from people who identify themselves as “individual consumer” when they submit comments using www.regulations.gov.

The Task Force proposes for public comment:

- 2. FDA should change its current practice so that comments submitted at www.regulations.gov from people self-identified as individual consumers are posted on that Web site in the same manner as other comments. In the Federal Register notice soliciting public comment, FDA should adequately inform commenters about the public disclosure of their comments on www.regulations.gov.**

Enforcement Priorities and Actions

Each year, FDA’s Office of Regulatory Affairs (ORA) issues a workplan that provides estimated resource allocations and information regarding planned target activities, such as inspections. This information is not disclosed due to a concern that it may provide regulated industry with information that may allow it to more easily avoid detection and circumvent the law. FDA generally makes available on its Web site press releases issued by the Department of Justice (DOJ) announcing when it files a case on FDA’s behalf, or the results of a case, but currently there is not a comprehensive list of the court actions pursued by FDA available to the public.

The Task Force proposes for public comment:

- 3. In the weekly FDA publication, FDA Enforcement Report, FDA should disclose when the U.S. Department of Justice files a case seeking enforcement action on FDA’s behalf in a court of law and the final determination of that case, if known.**

- 4. FDA should post on its Web site all Agency Workplans (i.e., the annual Office of Regulatory Affairs Annual Field Workplan) that are older than five years, starting with the FY 2001 Workplan.**

Import Procedures

Importers, or third parties working on behalf of importers, file information about products offered for import into the United States. FDA conducts evaluations of those filers who submit information electronically to FDA to determine if they are submitting accurate and truthful data to FDA. The outcome of the filer evaluation is not disclosed.

The Task Force proposes for public comment:

- 5. FDA should disclose the outcome of the filer evaluation for importers or third parties working on behalf of importers.**

Inspections

FDA conducts inspections of establishments that manufacture, process, pack, or hold FDA-regulated products before approving products and/or after products are on the market, to determine the establishment's compliance with laws administered by FDA. If objectionable conditions are observed, FDA provides the owner of the establishment with a document, called an FDA Form 483. If no enforcement action is contemplated, or after enforcement action is concluded, FDA provides inspected establishments with a final inspection report, called an Establishment Inspection Report (EIR). FDA proactively posts inspection reports (FDA Form 483s and EIRs) when a high level of public interest is anticipated. The Agency also posts "frequently requested" inspection reports.

The Task Force proposes for public comment:

- 6. FDA should disclose the name and address of the entity inspected, the date(s) of inspection, type(s) of FDA-regulated product involved, and the final inspectional classification—Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI)—for inspections conducted of clinical trial investigators, Institutional Review Boards (IRB), and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed. The disclosure of this information should be timed so as not to interfere with planned enforcement actions.**
- 7. FDA should generate, and share with the public, information about the most common inspectional observations of objectionable conditions or practices that are made during inspections of FDA-regulated establishments and post that information online on a regular basis.**

Product Applications (Including Investigational Applications)

FDA generally does not disclose any information about the existence, status, or contents of an investigational application submitted to the Agency, until the product has been approved, licensed, or cleared. Statutes and FDA regulations generally prohibit the release of information from or about an unapproved application.

The Task Force proposes for public comment:

- 8. FDA should disclose the existence and, when asked, confirm the existence or non-existence of investigational applications. For investigational applications, the disclosure should include the name of the application sponsor, the date the application was received, the proposed indication(s) or intended use(s) of the product, and the proposed proper and/or trade name of the product, if available.**
- 9. FDA should disclose: (1) whether an investigational new drug application (IND) has been placed on hold, terminated, or withdrawn, whether an investigational device exemption (IDE) has been terminated or withdrawn, or whether an investigational exemption for a new animal drug has been terminated and (2) if an IND has previously been placed on hold, whether and when the hold is lifted. A statement should be included that such actions may be taken for various reasons, only some of which relate to safety or effectiveness.**
- 10. FDA should disclose the fact that an NDA, NADA, ANDA, ANADA, BLA, PMA, or 510(k) application or supplement was submitted (or resubmitted) to the Agency at the time the application is received by FDA. The disclosure should include the name of the application sponsor, the date the application was received, the proposed indications or intended use of the product, and the proposed proper and/or trade name of the product, if available.**
- 11. FDA should disclose that an unapproved NDA, ANDA, NADA, ANADA, BLA, or PMA, or uncleared 510(k) has been withdrawn or, if FDA determines that the application was abandoned, abandoned by the sponsor. If the drug, biological product, or device is associated with a significant safety concern, FDA should provide a brief description of the product, the use for which approval was sought or obtained, and the identified safety concern.**
- 12. When an application for a designated orphan drug or a designated minor use/minor species animal drug has been withdrawn, terminated, or abandoned, FDA should disclose, if it determines, based on its review, that the application *was not* withdrawn, terminated, or abandoned for safety reasons and the product, if approved, could represent a significant therapeutic advance for a rare disease or for a minor animal species. A disclaimer that provides that FDA's expressed views about the product do not reflect whether a subsequent application involving the product will be accepted for filing or will be approved by FDA should accompany the disclosure of this information.**
- 13. FDA should disclose the fact that the Agency has issued a refuse-to-file or complete response letter in response to an original NDA, BLA, or an efficacy supplement for an NDA or BLA at the time the refuse-to-file or complete response letter is issued, and should, at the same time, disclose the refuse-to-file or complete response letter, which contains the reasons for issuing the letter.**

- 14. FDA should disclose the fact that the Agency has issued a refuse to approve letter in response to a NADA, or a supplemental NADA to add a new species or indication, at the time the refuse to approve letter is issued, and should, at the same time, disclose the refuse to approve letter, which contains the reasons for issuing the letter.**
- 15. FDA should disclose the fact that the Agency has issued a “not approvable” letter in response to a PMA for a medical device and the fact that FDA has issued an “additional information (AI)” letter in response to a 510(k) submission, and should, at the same time, disclose the “not approvable” letter or “additional information (AI)” letter, which contains the reasons for issuing the letter.**
- 16. FDA should disclose relevant summary safety and effectiveness information from an investigational application, or from a pending marketing application, if the Agency concludes that disclosure is in the interest of the public health, which includes when FDA believes it is necessary to correct misleading information about the product that is the subject of the application.**
- 17. FDA should convene a group of internal and external stakeholders to discuss the possible uses of non-summary safety and effectiveness data from product applications, the circumstances under which it would be appropriate for sponsors to disclose non-summary safety and effectiveness data from applications submitted to FDA, and if appropriate, the format and the method by which disclosure should occur.**

Recalls

When an FDA-regulated product is defective, potentially harmful, or mislabeled, recalling that product—removing it from the market or correcting the problem—is often the most effective means for protecting the public from products that violate the laws administered by FDA. Generally, FDA does not have mandatory recall authority (i.e., authority to order a manufacturer and/or distributor to recall a product), except under limited circumstances, but a firm may initiate a recall at any time. FDA issues a written notification that a recall is terminated to the recalling firm, but does not notify the public when a recall has been terminated.

The Task Force proposes for public comment:

- 18. When a system is set up that provides FDA with authority to require companies to submit certain information to the Agency when they initiate an action to recover or correct a product that is in the chain of distribution, FDA should disclose this information as soon as practicable after receiving this information from the firm.**
- 19. If FDA is aware of confusion in the marketplace about products that may be implicated in a food outbreak, and information gathered by industry or other sources may serve to alleviate that confusion, FDA should support efforts by**

industry and others to communicate information to the public about products that are not subject to the recall when sufficiently reliable information about products not connected with the recall exist, if FDA concludes that disclosure of this information is in the interest of public health.

- 20. If FDA determines that a recall is terminated, that information should be disclosed to the public. A recall is considered terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy and when it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.**

Warning and Untitled Letters

FDA may issue either a warning letter or an untitled letter to individuals or firms notifying them of violations of the Federal Food, Drug, and Cosmetic Act (FDCA) to allow them an opportunity to voluntarily comply with the law. The Agency posts warning letters on the FDA Web site and if the Agency can determine that a firm has fully corrected violations raised in a warning letter, FDA will issue an official “close-out” notice that will also be posted on the Web site. Some Centers proactively post untitled letters online.

The Task Force proposes for public comment:

- 21. FDA should post untitled letters on the FDA Web site, and, if requested by the recipient of the letter, the response to the untitled letter, as appropriate.**

III. TRANSPARENCY TASK FORCE

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.”

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, 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.² 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.³ 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 have received 1,572 comments.⁴ The blog 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.

The Task Force reviewed the comments received from all of these stakeholders—consumers, patients, regulated industry, health care providers, investors, and others. The comments were used by the Task Force to inform the draft proposals for public comment in this report. The Task Force also identified ways to improve transparency that are reflected in this report.

The draft proposals for public comment contained in this report have not yet been fully analyzed or prioritized by the Task Force. FDA is seeking public input on the draft proposals set forth in this report. FDA cannot implement the proposals at once, so as a result, FDA is seeking public input not only on the content of the proposals but on how the Agency should prioritize the proposals which are selected for implementation.

² A transcript from the public meeting is available on the FDA Web site, <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/ucm170422.htm#meetingtranscript>.

³ A transcript of the public meeting is available on the FDA Web site, <http://www.fda.gov/downloads/AboutFDA/WhatWeDo/FDATransparencyTaskForce/UCM189845.pdf>.

⁴ The online blog is available at <http://fdatransparencyblog.fda.gov/>. The online docket is available at <http://www.regulations.gov>.

The Task Force will review public comments received about each draft proposal and conduct a more in-depth analysis of what will be needed to implement each proposal, including resource requirements, information technology infrastructure, whether changes to statutes or regulations are needed, and operational feasibility, in order to arrive at proposals the Task Force will recommend for implementation.

C. Progress to Date and Future Plans

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

- 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*. The launch involved a media call and webinar with bloggers on FDA issues. This resource now includes (1) 126 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 ten 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*. The Agency has received over 4,500 comments from the public since the launch of the *FDA Basics* resource. Feedback provided by the public is used to update the resource.

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.

Early reaction to *FDA Basics* has been positive. One blogger wrote, “[t]he initiative can go a long way toward educating the public about what FDA does—and how—and also provide industry with real-time answers to their daily challenges, ultimately improving product quality and patient safety.” Another blogger wrote, “[i]t is really well put together, clear and works quite well. . . . The site is not only supportive of transparency, but is highly instructive and educational.”

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.

The Task Force is soliciting comments on the draft proposals in this report. To develop the broadest slate of proposals, the Task Force did not, at this stage of the review, consider the feasibility of implementing the proposals. FDA cannot implement all of the proposals at once so as part of the comment process, the Agency is seeking public input not only on the content of the proposals but on which draft proposals should be given priority, if implemented.

Based on this input, the 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. Some of the draft proposals may require extensive resources to implement, and some may require changes to regulations and possibly even legislation. As a result, the Task Force may ultimately recommend some, but not all, of the draft proposals for implementation.

Phase 3: Transparency to regulated industry. The third phase will address ways that FDA can become more transparent to regulated industry, in order to foster a more efficient and cost-effective regulatory process. Draft proposals from this phase are expected in the summer of 2010.

IV. TRADE SECRETS

FDA has adopted the following definition of trade secret:

A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.⁵

Trade secrets include such things as a company's manufacturing processes and precise product formulations. The Task Force believes that trade secrets have limited value for public disclosure, and that the value for public disclosure of other types of data, such as clinical trial results and adverse event reports, is significantly greater.

The Task Force believes that data relating to manufacturing methods and processes, which is the direct result of innovative efforts, deserves protection because keeping trade secret information confidential maintains investment in new product development and thus is important to fostering innovation.

As a result, the Task Force believes that trade secrets should remain confidential. Where such trade secrets exist in the documents proposed for public disclosure in the draft report that follows, the Task Force supports their redaction from the documents before the documents are disclosed.

FDA's current practice is to treat a substantial amount of the information that is submitted to FDA by companies and that does not fall under FDA's definition of trade secrets as confidential commercial information that is not publicly disclosed.

The Task Force examined the categories of information currently withheld as confidential commercial information. In some cases, the Task Force found that some firms are already disclosing certain information FDA currently treats as confidential commercial information. In those cases, the Task Force concluded that there may be little public benefit to withholding the information.

In other cases, the Task Force weighed the interests of the public in disclosure and the competitive interests that may be implicated by disclosure of the information currently considered confidential commercial information. Based on this assessment, the Task Force proposed how FDA should treat that information. In some instances, the Task Force is proposing that based upon this assessment, such information should be disclosed and, in other instances, the Task Force is proposing that FDA continue to treat the information as confidential. These draft proposals for public comment are discussed further in the body of this report.

Changes to statutes or regulations may be needed to implement some of the proposals.

⁵ 21 C.F.R. § 20.61(a); *see also Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983).

V. DRAFT PROPOSALS BY TOPIC AREA

The draft proposals for public comment are organized in alphabetical order by topic.

A. Adverse Event Reports

1. Background

Mandatory Reporting Requirements Applicable to Drugs and Biological Products

FDA regulations and statutory provisions establish adverse event reporting requirements for human drugs, including biological products, and animal drugs. These requirements apply to responsible persons as defined under each provision—generally manufacturers, packers, or distributors of the products in question, as well as holders of approved premarket applications (new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and biologics license applications (BLAs)), whether or not they also manufacture, pack or distribute.

Drugs for human use and biological products

In general, manufacturers, packers, distributors and applicants with approved applications for new drugs for human use, manufacturers, packers and distributors of licensed biological products, and persons identified on the label as the manufacturer, packer, or distributor of prescription drugs marketed for human use without an approved application are required to submit postmarketing safety reports of adverse drug experiences to FDA.⁶ A report of each adverse drug experience that is both serious and unexpected must be made to FDA as soon as possible, but no later than 15 days after receiving information about the event.⁷ Persons required to file such 15-day Alert reports are also required to investigate and submit any new information to FDA.⁸

Applicants with approved applications for new drugs or with biologics licenses must also report certain other adverse events to FDA on a periodic basis.⁹

Nonprescription (OTC) drugs marketed without an approved application are also subject to adverse event reporting requirements, under section 760 of the Federal Food, Drug, and Cosmetic Act. Manufacturers, packers, or distributors whose name

⁶ 21 C.F.R. §§ 310.305(c); 314.80(c); 314.98 (human drugs), 600.80(c) (biologics). To avoid duplication of reports, non-applicant manufacturers, packers, and distributors of drug and biological products having an approved application may submit all reports of serious adverse drug experiences to the applicant within 5 calendar days of receipt of information about the event, rather than submitting reports to FDA. See 21 C.F.R. §§ 314.80(c)(1)(iii), 600.80(c)(1)(iii). Similarly, packers and distributors of prescription drug products marketed for human use without an approved application may meet their postmarketing 15-day safety reporting obligations under 21 C.F.R. § 310.305 by submitting all reports of serious adverse drug experiences to the manufacturer within 5 calendar days of the receipt of information instead of reporting to FDA. Applicants/manufacturers receiving such data must then, in turn, submit a 15-day Alert report to FDA.

⁷ 21 C.F.R. §§ 310.305(c)(1); 314.80(c)(1)(i); 314.98(a) (human drugs), 600.80(c)(1)(i) (biologics). There are also certain specific reporting requirements concerning fatalities related to blood and blood products. 21 CFR §§ 606.170(b), 640.73.

⁸ 21 C.F.R. §§ 310.305(c)(2), 314.80(c)(1)(ii), 314.98(a) (human drugs), 600.80(c)(1)(ii) (biologics).

⁹ 21 C.F.R. §§ 314.80(c)(2), 314.98(a) (human drugs), 600.80(c)(2)(i) (biologics).

appears on the label of a nonprescription human drug product marketed without an approved application must report serious adverse events associated with their product to FDA within 15 business days.¹⁰

Animal drugs

For animal drugs, reports of product and manufacturing defects that may result in serious adverse drug events must be submitted by the applicant (or by non-applicant manufacturers, packers, distributors or labelers of the product through the applicant) to the appropriate FDA District Office or resident post within three working days of the company becoming aware that a defect exists.¹¹ In addition, a report of each adverse drug event that is both serious and unexpected must be submitted to FDA within 15 working days after the applicant first receives information about the event, no matter what the source of the information.¹² Applicants must promptly investigate each adverse drug event that is the subject of a 15-day alert report and provide any significant new information about the event to FDA.¹³ Additional drug experience information must be submitted to FDA at periodic intervals—every six months for the first two years following NADA or ANADA approval and yearly thereafter.¹⁴

Mandatory Medical Device Reporting (MDR) Requirements Applicable to Medical Devices Intended for Human Use

The MDR regulation requires adverse event reporting for manufacturers of medical devices, device user facilities (e.g., hospitals, nursing homes) and importers of medical devices.¹⁵

Manufacturers of medical devices must submit a report to FDA, no later than 30 calendar days after the day that they receive or otherwise “become aware” of information, from any source, that reasonably suggests that one of their marketed devices (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.¹⁶ Manufacturers of medical devices must also submit a report to FDA no later than five work days after the day that they “become aware” that (1) an MDR reportable event necessitates “remedial action” to prevent an unreasonable risk of substantial harm to public health; or (2) FDA has made a written request for the submission of such a report.¹⁷

Importers of medical devices must submit MDR reportable events to FDA, with a copy to the manufacturer, as soon as practicable, but no later than 30 calendar days after the day that they receive or otherwise “become aware” of information, from any

¹⁰ FDCA §§ 760(b) & (c).

¹¹ 21 C.F.R. § 514.80(b)(1).

¹² 21 C.F.R. § 515.80(b)(2)(i).

¹³ 21 C.F.R. § 514.80(b)(2)(ii).

¹⁴ 21 C.F.R. § 514.80(b)(4).

¹⁵ FDCA § 519, 21 C.F.R. Part 803.

¹⁶ 21 C.F.R. § 803.50(a).

¹⁷ 21 C.F.R. § 803.53.

source, that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury.¹⁸ Importers must also submit a report to the manufacturer as soon as practicable, but no later than 30 calendar days after the day that they receive or otherwise “become aware” of information, from any source, that reasonably suggests that one of their devices has malfunctioned and that the device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.¹⁹

Device user facilities, which include hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities, which are not a physician’s offices,²⁰ must also submit adverse event reports. As soon as practicable, but no more than 10 work days after the day that they “become aware” of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the device user facility, user facilities must submit a report to FDA and to the manufacturer of the device, if known.²¹ User facilities must also submit a report to the manufacturer of the device, if known, and, if the manufacturer is not known, to FDA, no later than 10 work days after the day that they “become aware” of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient in their facility.²² Device user facilities are also required to summarize all reportable events that occurred in the facility during the annual reporting year in annual reports submitted to FDA.²³

Reporting Requirements Applicable to Dietary Supplements

Manufacturers, packers, or distributors whose name appears on the label of a dietary supplement marketed in the United States must report serious adverse events associated with their product to FDA within 15 business days.²⁴

Voluntary Reporting

Anyone can submit reports to FDA about adverse events associated with any FDA-regulated products, including foods, drugs and medical devices. These reports can be submitted in a variety of ways. Adverse events that occur while using medical products (excluding vaccines), conventional foods and dietary supplements, cosmetics, and infant formula can be reported to the Agency’s MedWatch program. Anyone may report vaccine-related illness or injury to the Vaccine Adverse Event Reporting System (VAERS).²⁵

¹⁸ 21 C.F.R. § 803.40(a).

¹⁹ 21 C.F.R. § 803.40(b).

²⁰ 21 C.F.R. § 803.3 (definition of device user facility).

²¹ 21 C.F.R. § 803.30(a)(1).

²² 21 C.F.R. § 803.30(a)(2).

²³ 21 C.F.R. § 803.33.

²⁴ FDCA §§ 761(b) & (c).

²⁵ The National Childhood Vaccine Injury Act requires health care providers to report certain adverse events concerning vaccines through VAERS. 42 U.S.C. § 300aa-25(b).

Although FDA requests detailed information about the product and its usage in order to better characterize the adverse event and determine the likelihood it may be caused by the product, adverse event reports vary in the amount of information that can be provided or is known.

In some cases, FDA provides a mechanism for the public to quickly access information from adverse event reports submitted to FDA.

- The Agency’s Adverse Event Reporting System (AERS) collects information about adverse events, medication errors and product problems that occur after the administration of approved drug and therapeutic biological products. Individuals familiar with the creation of relational databases can download quarterly (noncumulative) data files from the AERS Web site, including, among other things, the trade name and/or established name of the product, dosage, route of administration, the adverse event, and the health outcome.
- Information about human vaccine adverse events is available online through the Vaccine Adverse Event Reporting System (VAERS).²⁶ VAERS collects information about adverse events that occur after the administration of vaccines licensed for use in the United States. Public VAERS records include, among other things, the vaccine, dosage, route of administration, the adverse event (including a narrative description), and the health outcome.
- Information about medical device adverse event reports is available online through the Manufacturer and User Facility Device Experience (MAUDE) database. Users can search the database for information on medical devices that may have malfunctioned or caused death or serious injury. Public MAUDE reports include, among other things, the trade name and/or established name of the product, the adverse event (including a narrative description), and the health outcome.

In addition, in some cases, the Agency alerts the public to new information about serious adverse events when it issues communications about an emerging safety issue.

2. Summary of Public Comments

In general, comments from individuals requested disclosure of more information about adverse events that are reported in connection with FDA-regulated products, including information about the type of event, the number of adverse events reported, and/or frequency of occurrence. Comments noted that the information should be provided to the public in an accessible, user-friendly format, and in a timely fashion. One comment urged the FDA to make adverse event reporting systems “straightforward to use” and to make information about adverse events “as easily retrievable as possible.”

²⁶ Vaccines Adverse Event Reporting System, available at www.vaers.hhs.gov. The VAERS system is co-sponsored by the Centers for Disease Control and Prevention (CDC) and FDA.

Some comments wanted FDA to post the frequency of adverse events associated with the use of veterinary products. Some comments noted that it would be helpful to have frequency information provided as a percentage of total adverse events reported; other comments suggested that the number of times an adverse event was reported should be disclosed.

One comment recommended that FDA harmonize and centralize its current adverse event reporting programs, stating that currently, adverse event reports are submitted to the Agency on several Web sites.

Comments that recommended the disclosure of adverse event information stated that public disclosure of adverse events associated with medical products was important to allow users of these products to make informed decisions about these products.

3. *Considerations*

The Task Force recognizes that there are public health benefits to providing the public with timely information about adverse events reported about FDA-regulated products. Additional disclosure will result in health care providers and patients having access to information that can be used to inform health care decisions.

The Task Force considered the public's interest in FDA providing adverse event information as soon as practicable, and even when the Agency has not determined whether the adverse event is likely associated with product. The Task Force considered the risk that the public may draw assumptions and possibly conclusions about a product based on incomplete information. The Task Force also considered that it is important for FDA to be transparent about the limited usefulness of adverse event reports that are disclosed when FDA has not analyzed their association to the FDA-regulated product. The Task Force considered whether, if preliminary information from adverse event reports is disclosed, a disclaimer should be included that cautions the public about drawing conclusions about products based solely on adverse event information because there is no certainty that the reported event was actually caused by the product and reports do not always contain enough detail to fully evaluate an event.

The Task Force also took into account the fact that although certain entities (generally manufacturers, packers, distributors and in some cases user facilities) are required to submit adverse event reports, other persons, including, in most cases, health care providers and patients, report adverse events voluntarily. Thus, there is no way of knowing the actual number of adverse events that may be associated with a product because of under-reporting. FDA also does not know the actual number of people or animals that have been exposed to a product because sales data and other available proprietary product distribution information, the best estimates available to FDA, do not necessarily equate to product use. The Task Force considered whether it would be misleading to disclose the frequency of adverse events reported as a percentage of total adverse events reported for a product or as a percentage of the exposed population. FDA does not receive information about all adverse events and may not have accurate data about the number of people or animals that are exposed to the

product, which is necessary to calculate accurately the frequency of adverse events for an exposed population.

The Task Force considered the Agency's current capability to quickly process adverse event reports for disclosure to the public. Regardless of any system used, adverse event reports (i.e., individual case safety reports (ICSRs)) must be reviewed for quality control purposes, entered into the system, and non-public information such as personal information redacted (e.g., name of the patient, or any other information that would identify the patient) before the ICSR describing the adverse event can be disclosed to the public.

4. Draft Proposal(s) for Public Comment

DRAFT PROPOSAL 1:

FDA should expand the areas in which it provides the public with online access to public information from adverse event reports about FDA-regulated products submitted to FDA, in a format that is searchable and allows users to generate summary reports of this information, including, if known and as applicable, the trade name and/or established name of the product, dosage, route of administration, description of the adverse event, and the health outcome. Adverse event report information should continue to be disclosed with a clear disclaimer about the limits of the information.

Reasoning: Individuals using, or who have an interest in using, an FDA-regulated product have a particular interest in receiving information about the safety of that product as soon as possible. For medical products, for example, this information can be used by prescribers, patients, public health officials, and consumers to inform decisions about the use of such products, and may help those who use the product to identify and report additional adverse events.

Public access to adverse event reports can provide industry with more complete information that can be used to assess the safety profile of products and may help industry determine more quickly whether additional actions are required to ensure the safe use of a product.

FDA is likely to have the most complete database of adverse event reports about a particular product because of the reporting systems described above. Making adverse event report information about FDA-regulated products more accessible to the public provides a window into FDA's post-marketing surveillance system. Disclosing some of the data FDA uses to monitor FDA-regulated products once they are on the market may lead to better understanding of the post-marketing surveillance system.

FDA has some experience providing the public with online access to adverse event report information quickly, as discussed in section 1 above. But in many circumstances, members of the public only have access to information from adverse event reports by submitting a Freedom of Information Request (FOIA) request to

FDA. This method does not provide broad access to the information nor is it efficient for Agency employees to provide this public information on a piecemeal basis.

FDA should provide adverse event reports for all FDA-regulated products in a similar manner. There is no compelling reason for providing differential access to adverse event reports for FDA-regulated products. FDA should aim to provide the public with increasing availability and accessibility of adverse event report information for all FDA-regulated products. Increased availability of this information can arm the public with information relevant to the safe use of products, free up Agency resources for other activities that improve public health, and further the goals of the Administration in achieving more transparent government.

B. Docket Management Process

1. Background

FDA maintains various dockets—each docket is a repository of information related to an FDA rulemaking or other matter. Dockets facilitate public participation in FDA rulemaking and in other matters by allowing the public to view information about these matters and submit comments on them. Comments can be submitted to the docket electronically, or in writing to FDA’s Division of Docket’s Management.

Most information in FDA’s dockets is available on www.regulations.gov. When FDA creates a docket for a rulemaking or other matter, the public can find, read, and comment on the matter on this site. FDA also has a docket reading room that contains most comments (confidential material is not available).

Due to concerns raised by some individuals about disclosing the personal information of individuals who submit comments to the docket, as a matter of Agency practice, FDA generally does not post on www.regulations.gov comments from people who identify themselves as an “individual consumer” when submitting a comment to www.regulations.gov. All comments, however, are considered by FDA, irrespective of whether the comment is posted online. FDA regulations set forth procedures for submitting comments to the Agency.²⁷

2. Summary of Comments

Comments requested that all comments submitted to www.regulations.gov, including individual consumer comments, be posted on the Web site.

3. Considerations

The Task Force considered whether FDA should post online all of the comments submitted to an Agency docket. The Task Force also considered the rationale for treating comments from individual consumers differently, in terms of whether they are posted online, from comments submitted by other members of the public.

²⁷ See 21 C.F.R. § 10.20.

The Task Force also considered the interest in not providing personal information about the commenter, such as the person's name or address, on a public Web site. The Task Force recognizes that public availability of this information may be more of a concern when a person is sending comments as an individual, as opposed to on behalf of an organization, business, or other entity.

4. *Draft Proposal(s) for Public Comment*

DRAFT PROPOSAL 2:

FDA should change its current practice so that comments submitted at www.regulations.gov from people self-identified as individual consumers are posted on that Web site in the same manner as other comments. In the Federal Register notice soliciting public comment, FDA should adequately inform commenters about the public disclosure of their comments on www.regulations.gov.

Reasoning: Publication of consumer comments will allow the public to learn about the viewpoints of individual members of the public, not only trade associations or academic institutions, for example. With respect to posting comments online, most comments from individual consumers should be treated in the same manner as comments submitted by others. But before doing so, FDA must adequately inform the public of the ways they can submit comments to the docket. The public should be adequately informed that comments submitted to www.regulations.gov are subject to disclosure online.

C. Enforcement Priorities and Actions

1. *Background*

Each year, the Office for Regulatory Affairs (ORA) issues ORA's Annual Field Workplan ("ORA Workplan"). The ORA Workplan provides resource allocation and information regarding planned target activities, such as inspections, for the upcoming fiscal year. The numbers provided are estimates—FDA may change its priorities and resource allocations during the year for different reasons, including in response to a public health emergency.

FDA has the authority to pursue enforcement actions against regulated firms, individuals, and products that fail to comply with the Federal Food, Drug, and Cosmetic Act and other laws FDA enforces. FDA authority includes the use of actions such as seizures,²⁸ injunctions,²⁹ civil monetary penalties,³⁰ and prosecution.

²⁸ FDCA § 304.

²⁹ FDCA § 302.

³⁰ See, e.g., FDCA §§ 303(b)(2) (imposing civil penalties for violating drug sample provisions), 303(f)(1)(A) (imposing civil penalties for device violations), but see FDCA § 303(f)(1)(B).

When the U.S. Department of Justice (DOJ) files a case on FDA's behalf, the enforcement action may be announced in a press release issued by DOJ. DOJ may also issue a press release announcing the result of a case. FDA generally makes these press releases available on FDA's Web site, but currently there is not a comprehensive list of the court actions pursued by FDA available to the public. FDA also shares information about trends in agency enforcement actions, such as the number of enforcement actions filed during a year, at relevant public meetings.

Prior to taking an enforcement action, FDA does not publicly disclose any information about its decision to bring such an action.

Under certain circumstances, FDA also has the authority to "debar" individuals and corporations from certain activities.³¹ For example, FDA has the authority to debar individuals and corporations convicted of certain felonies or misdemeanors from providing services in any capacity to a person with an approved application or a pending application at FDA.³² In addition, FDA has the authority to disqualify clinical researchers who engage in certain conduct from receiving investigational drugs, biological products, and devices.³³

Actions to debar individuals and firms are published in the Federal Register, and lists of disqualified individuals and debarred individuals and firms are posted on the FDA Web site.

2. Summary of Public Comments

Comments asked FDA to provide more information about enforcement actions on the FDA Web site in a timely, understandable, accessible manner. For example, some comments suggested that FDA include information about court cases filed and the final result of those cases in the weekly publication, *FDA Enforcement Report*. Another comment encouraged FDA to "continue and expand" the Agency's practice of publishing links to press releases issued by the United States Attorneys Offices about cases that involve FDA-regulated products. One comment suggested that debarments of individuals and companies, and disqualifications of clinical investigators should also be listed in the *FDA Enforcement Report*. One comment requested that FDA publish the names of firms under investigation by the Agency and another comment requested that FDA post information on any investigations of products that may not be safe to eat or safe to use.

One comment suggested that FDA provide information about the timeline for further enforcement action on the FDA Web site. Another comment stated that FDA should share trends in enforcement actions and discuss the rationale for those actions with relevant scientific groups during public meetings.

³¹ FDCA § 306.

³² FDCA § 306(a) & (b).

³³ 21 C.F.R. §§ 312.70, 511.1(c), 812.119.

Comments requested more information about FDA’s decision-making process regarding a decision to pursue an enforcement action. A comment requested information about the facts relied upon by FDA when determining whether to pursue an enforcement action. An industry group suggested that “FDA can do a better job explaining its operations and activities by making available a multi-year strategic plan and companion operational plan describing the tactics and objectives the agency plans to achieve.”

Comments requested more information about the resources FDA allocates for enforcement activities. For example, comments suggested that FDA provide “detailed budget and staffing figures at the program level,” “detailed employment information for these programs, such as number of inspectors,” and “information on the size of the various communities subject to FDA regulation.”

3. *Considerations*

The Task Force considered that the public interest is served when interested individuals can assess how FDA protects the safety of medical products and the food supply.

The Task Force considered whether additional disclosure would improve industry compliance with FDA requirements and help deter actions that could result in the marketing of products that harm the public.

The Task Force considered the accessibility of enforcement-related information, noting that information about enforcement actions are often public but may not be readily accessible by the public. The Task Force noted that the public is not able to get a complete picture of the court cases filed against FDA-regulated entities, and the results of those actions.

The Task Force considered the effect that additional public disclosure about pending and planned enforcement actions would have on FDA’s ability to enforce the law. The Task Force took into account the importance of frank deliberations among FDA employees about the merits of pursuing a particular enforcement action.

Further, the Task Force recognizes that disclosure of preliminary information, before FDA has decided to take an enforcement action and while the issue is still under investigation, may unfairly prejudice the company or individual at issue, particularly if the FDA’s final determination is that no enforcement action is warranted.

The Task Force considered the risk that disclosing detailed information about the FDA’s planned enforcement priorities and activities may be used to circumvent the law. The Task Force took into account the fact that FDA’s priorities and plans must be adaptable and able to shift in response to public health emergencies that may arise.

4. *Draft Proposal(s) for Public Comment*

DRAFT PROPOSAL 3:

In the weekly FDA publication, FDA Enforcement Report, FDA should disclose when the U.S. Department of Justice files a case seeking enforcement action on FDA's behalf in a court of law and the final determination of that case, if known.

Reasoning: Improved public access to information about prosecutions and other court cases pursued by FDA provides the public with current information about violative industry activities that jeopardize the public health. Additional access to this information provides the public with a better understanding of the activities FDA is undertaking to protect the public health.

In addition, ready access to this information may have a deterrent effect on related industries by making more apparent the consequences of failure to comply with the law.

DRAFT PROPOSAL 4:

FDA should post on its Web site all Agency Workplans (i.e., the annual Office of Regulatory Affairs Annual Field Workplan) that are older than five years, starting with the FY 2001 Workplan.

Reasoning: The public interest is served when interested individuals can assess how FDA protects the safety of the medical product and food supply. But disclosure of information about FDA's planned enforcement priorities may provide the public with information that allows regulated industry to more easily avoid detection and circumvent the law.

ORA Workplans should be disclosed after a certain amount of time has passed. Due to changing circumstances, it is highly unlikely that information from older workplans will allow individuals to predict how FDA would prioritize enforcement resources now. In other words, after a certain period of time has passed, the risk that regulated industry or individuals could use the information in the workplan to evade the law is substantially mitigated. Workplans from five years ago and older are sufficiently attenuated from FDA's inspection priorities now and can be disclosed.

Historical ORA Workplans provide the public with a better understanding of how FDA allocates limited resources to protect the public health and furthers the goal of the Administration to increase the public's knowledge of FDA and its operations. FDA has an interest in protecting contemporaneous enforcement data and Agency priorities (i.e., information within five years of the current year), but posting older ORA Workplans serves the public interest without compromising FDA's current enforcement activities.

D. Import Procedures

1. Background

Sections 801(a) and 536(a) of the Federal Food, Drug, and Cosmetic Act authorize FDA to examine foods, drugs, cosmetics, tobacco products, devices, and radiation-emitting products offered for import into the United States. As part of the importation process, importers must file information about the product with the United States Customs and Border Protection (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.

FDA can refuse admission into the U.S. of imported products if, among other reasons, the product appears to be adulterated or misbranded. As an initial step, FDA issues a notice to the owner or consignee informing them that their shipment has been detained and the basis of the detention. The owner or consignee is provided an opportunity to provide testimony regarding the admissibility of the product or, in some circumstances, to submit a proposal to recondition the product to bring it into compliance with applicable laws.³⁴ If the owner fails to show that the product is in compliance or fails to bring the product into compliance, FDA will issue a notice to the owner or consignee that the product was refused admission into the U.S. The product then has to be exported no later than 90 days after receipt of the notice, or it is subject to being destroyed by CBP.³⁵

FDA discloses the name of the foreign manufacturer responsible for the refused product, the date of refusal, and the description of the product, as provided by the manufacturer, on the FDA Web site.³⁶ This information is updated monthly and can be searched by country of origin or product.

FDA works closely with CBP to prevent the importation of adulterated, misbranded, or otherwise violative products into the country.

2. Summary of Public Comments

One comment requested that FDA post all responses, status, and correspondence related to products that are detained at the border as well as those that are subsequently released by FDA. Another comment stated that ORA import refusals should be posted in a searchable database so that information about refusals, by pathogen, year, or country can be easily retrieved.

³⁴ See FDCA § 801(a); 21 C.F.R. §§ 1.94, 1.95.

³⁵ FDCA § 801(a).

³⁶ Import Refusals, available at http://www.accessdata.fda.gov/scripts/ImportRefusals/ir_index.cfm.

3. *Considerations*

The Task Force considered whether additional disclosure of information about import procedures will give the public a better understanding of FDA activities to protect the food and medical product supply. The Task Force considered whether disclosure of more information about imported products or importers would deter future attempts by companies and individuals to import violative products into the United States.

The Task Force also considered the risk of confusing the public by disclosing additional information about imported products, particularly about the status of products that are detained at the border. Detentions do not mean that FDA has made a final determination with respect to the status of the product. Based on additional information, it may be determined that the products are compliant and should be allowed onto the U.S. market. The Task Force considered the public interest in disclosing information about products that currently are not, and may never be, sold on the U.S. market.

4. *Draft Proposal(s) for Public Comment*

DRAFT PROPOSAL 5:

FDA should disclose the outcome of the filer evaluation for importers or third parties working on behalf of importers.

Reasoning: Importers, or third parties working on behalf of importers, file information about the product offered for import. FDA conducts evaluations of the filers who submit information electronically to FDA to determine if they are submitting accurate information about products being presented for import into the U.S. Given their role in the import process, disclosing the results of these evaluations may increase the accuracy of the information submitted to FDA and decrease the number of potentially violative products firms try to import into the United States. It is important for other federal agencies with jurisdiction over FDA-regulated products imported into the U.S., as well as for other companies in the supply chain, to have information about the compliance history of these entities. To the extent that other regulatory entities conduct inspections using a risk-based approach, this information also may be helpful for setting priorities.

Disclosing the outcome of filer evaluations will likely increase accountability among actors in the supply chain. Filers will have an incentive to provide accurate information about imported products, which will allow FDA, CBP, and other federal agencies to more effectively protect the public from potentially harmful products. To the extent importers use third parties to file on their behalf, they will be armed with information that will allow them to select filers that have a track record of providing accurate information about imported products.

E. Inspections

1. *Background*

FDA conducts inspections of establishments that manufacture, process, pack, or hold FDA-regulated products, before approving products and/or after products are on the market, to determine the establishment's compliance with laws administered by FDA.³⁷ Upon completing the inspection, if objectionable conditions are observed, FDA provides the owner of the establishment with a document, called an FDA Form 483, which includes the name of the firm and the date(s) of inspection, and lists the observations made by the investigator during the inspection.³⁸

FDA provides initial classification of the inspection based on the observations noted during the inspection, the investigator's report, and FDA District Office supervisory personnel review. With the exception of instances where procedures indicate that the relevant product center has the right of final classification, the final classification of the inspection is made by the FDA District Office. An inspection classification reflects the compliance status of the establishment at the time of the inspection, based on the observations documented. The conclusions of the inspection are reported as Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI).

An **OAI** inspection classification occurs when significant objectionable conditions or practices were found and regulatory action is warranted to address the establishment's lack of compliance with statute(s) or regulation(s).

A **VAI** inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance. Inspections classified with VAI violations are typically more technical violations of the FDCA.

An **NAI** inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further actions.

If no enforcement action is contemplated, or after enforcement action is concluded,³⁹ FDA provides inspected establishments with a final inspection report, called an Establishment Inspection Report (EIR), which includes:

³⁷ See FDCA § 704.

³⁸ FDCA § 704(b).

³⁹ FDA's Information Disclosure Manual, Section III.D, explains how to determine whether an EIR is "closed," such that it no longer qualifies as a law enforcement record protected from public release under FOIA Exemption (b)(7)(A), 5 U.S.C. § 552(b)(7)(A). Among other things, "[a]n EIR is considered closed when FDA has concluded its review of the firm's activities and decides that no additional administrative or regulatory action is warranted or dictated. This generally does not occur until after FDA has issued a Warning Letter to the firm and the firm has responded." However, "[m]ere issuance of the Warning Letter does not close the EIR record, because a Warning Letter is informal and advisory and is not final agency action."

- Brief history of prior inspectional findings, including any action taken by FDA or corrective action taken by the firm in response to a previous inspection
- The investigator's narrative report
- Any refusals, voluntary corrections, or promises made by the firm's management
- Copies of forms the FDA issued to the firm during the inspection, including the FDA Form 483

FDA proactively posts inspection reports (FDA Form 483s and EIRs) in the ORA Electronic Reading Room when a high level of public interest is anticipated.⁴⁰ Also, FDA may post in the ORA Electronic Reading Room "frequently requested" inspection reports as defined by the Electronic Freedom of Information Act Amendments of 1996. FDA redacts non-public information, such as trade secrets, from the inspection report before posting it.

2. Summary of Public Comments

Several comments from both industry and consumer groups requested that FDA make all inspection reports available online in a timely fashion. Some comments suggested that inspection results should be posted within 24 hours after an inspection of a food facility is completed; another comment requested that FDA inspectional observations be posted and available for review within 30 days of the inspection being concluded. A comment from a consumer group suggested that FDA disclose a summary page of key inspection results after each food facility inspection and noted that this format appeared to be used successfully in another country.

Some comments specifically noted that the reports should only be posted after proprietary information has been redacted. A comment from industry noted that "these inspectional findings help industry to understand the expectations of the agency and are significant tools for industry to ensure that compliance training and programs are in step with FDA." Many comments bemoaned the time it takes to obtain inspection information through the FOIA process.

An industry comment suggested FDA provide additional information about inspection trends and "FDA's concerns that may drive inspectional observations and other citations."

3. Considerations

The Task Force recognizes that disclosing more information about FDA's inspectional findings will be helpful to industry seeking to comply with applicable

⁴⁰ See ORA FOIA Electronic Reading Room, available at <http://www.fda.gov/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/default.htm>.

laws and regulations. In addition, additional disclosures may provide the public with a better understanding of the supply chain for FDA-regulated products and inform decisions, by both consumers and industry, about which firms to purchase products from.

The Task Force considered the risk that the public may draw conclusions about firms based solely on the list of observations from the investigator's report though FDA may conclude that observations noted in a FDA Form 483 do not affect the public health and further action is not required. In addition, the Task Force considered that in FY 2008, FDA conducted approximately 14,800 inspections of foreign and domestic facilities that resulted in the issuance of an EIR. With additional funding, the Agency will conduct more inspections in the future, which will likely result in the issuance of more inspection reports.

The Task Force considered whether the usefulness of the inspection information would diminish if it was not provided in a timely fashion.

4. Draft Proposal(s) for Public Comment

DRAFT PROPOSAL 6:

FDA should disclose the name and address of the entity inspected, the date(s) of inspection, type(s) of FDA-regulated product involved, and the final inspectional classification—Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI)—for inspections conducted of clinical trial investigators, Institutional Review Boards (IRB), and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed. The disclosure of this information should be timed so as not to interfere with planned enforcement actions.

Reasoning: Disclosing information about the findings from establishment inspections increases public understanding about some of the ways FDA works to protect the public health. Disclosure of FDA's determination about the compliance status of establishments provides the public with a basis and rationale for enforcement actions FDA pursues against an establishment.

Public disclosure of this information makes firms accountable not only to FDA, but to the public at large. Disclosure of inspectional classification information may serve as an incentive to firms to correct violations.

Further, other firms are provided with information that will help them make more informed decisions about companies they choose to do business with. If FDA, for example, has concluded that a distributor has had significant objectionable conditions at its facility, this is important information to convey to manufacturers, schools, federal agencies, and other entities that may contract with that distributor. Market pressures may create incentives for firms to correct violations quickly or prevent violations from occurring in the future.

DRAFT PROPOSAL 7:

FDA should generate, and share with the public, information about the most common inspectional observations of objectionable conditions or practices that are made during inspections of FDA-regulated establishments and post that information online on a regular basis.

Reasoning: FDA should disclose summary information about common violations associated with FDA-regulated products; this is a method to provide firms with information that can be used to inform compliance efforts.

F. Product applications (including investigational applications)

1. Background

Investigational Applications/Notices

FDA receives and reviews applications seeking permission to conduct clinical investigations of unapproved human drugs (including unlicensed biological products) and significant-risk medical devices. To conduct certain clinical investigations of a human drug or biological product, a sponsor (either an individual or a company) must submit an Investigational New Drug Application (IND). An IND for a human drug or biological product goes into effect 30 days after it is submitted to FDA, permitting the initiation of the proposed investigation in human subjects, unless FDA informs the sponsor of the IND that it has been placed on “clinical hold.” FDA may place an IND on clinical hold before initiation of the investigation for several reasons, including if the Agency determines subjects would be exposed to an unreasonable and significant risk of illness or injury, or if the investigation does not otherwise comply with the regulations governing INDs.⁴¹

FDA can suspend an IND after a study has begun by putting it on clinical hold for the same reasons FDA can put it on hold before it begins. FDA may terminate an IND, among other reasons, if subjects would be exposed to an unreasonable and significant risk of illness or injury, the studies are being conducted in a manner substantially different from the protocols, or the sponsor is no longer complying with the regulations governing INDs.⁴² An IND under which no subjects are entered into any clinical studies for a period of 2 years or more, or all of the investigations are on clinical hold for 1 year or more, may be placed on inactive status.⁴³ A sponsor may also voluntarily withdraw an IND.⁴⁴

To conduct a clinical investigation on a significant-risk medical device, a sponsor must submit an Investigational Device Exemption (IDE).⁴⁵ A proposed investigation

⁴¹ 21 C.F.R. § 312.42(b).

⁴² 21 C.F.R. §§ 312.44(b) & (d).

⁴³ 21 C.F.R. § 312.45(a).

⁴⁴ 21 C.F.R. § 312.38(a).

⁴⁵ 21 C.F.R. § 812.20. Clinical investigations of non-significant risk devices are deemed to have an approved IDE, if certain requirements, including review by an Institutional Review Board (IRB), are met. 21 C.F.R. § 812.2(b)(1).

of a significant-risk medical device in humans may begin: (1) 30 days after FDA receives an IDE, unless FDA notifies the sponsor that the investigation may not begin or (2) when FDA has approved the IDE. An IDE may be disapproved, among other reasons, because there is reason to believe that the risks to subjects are not outweighed by the anticipated benefits, or because the investigation does not otherwise comply with the regulations governing IDEs.⁴⁶ After a study has begun, FDA generally may withdraw approval of an IDE for the same reasons it may disapprove it.⁴⁷

The information required for an IND or IDE varies depending on a number of factors, including the phase of clinical development, the known or suspected risks with the product, or the novelty of the product under investigation. Generally, the investigational application includes, among other things:

- Information about the nature of the product or device,
- Manufacturing information,
- Reports of prior investigations and marketing experience with the product,
- Animal pharmacology and toxicology studies (for INDs only),
- The investigational plan and protocol for the proposed study or studies,
- Information on the qualifications of the clinical investigators, and
- Commitments to obtain informed consent from research subjects, to obtain review of the study by an Institutional Review Board, and to adhere to the applicable regulations.⁴⁸

After an IND or IDE goes into effect, the following information is required to be submitted to or filed in the IND or IDE:

- Safety reports submitted by the sponsor, including reports of serious and unexpected adverse events in human subjects participating in the study or studies;⁴⁹
- Progress reports on the clinical study and, if a study is completed, a brief description of the results of the study;⁵⁰ and
- Letters reflecting FDA actions on the application.

⁴⁶ 21 C.F.R. § 812.30(b).

⁴⁷ 21 C.F.R. § 812.30(b).

⁴⁸ 21 C.F.R. §§ 312.23(a), 812.20(b).

⁴⁹ 21 C.F.R. §§ 312.32(c), 812.150(b)(1).

⁵⁰ 21 C.F.R. §§ 312.33, 812.150(b)(5) & (7).

Prior to shipment of a new animal drug for clinical investigational use in animals, the sponsor of an investigation must submit to FDA a “Notice of Claimed Investigational Exemption for a New Animal Drug” (NCIE) containing certain information about the study.⁵¹ The information required in an NCIE includes, among other things:

- Identity of the new animal drug,
- Labeling and other pertinent information to be supplied to the investigators,
- Name and address of each clinical investigator, and
- Approximate number of animals to be treated (or if not available, the amount of new animal drug to be shipped).⁵²

This information is maintained in an investigational new animal drug (INAD) file. FDA can terminate an exemption that permits shipment of a new animal drug for clinical investigational use in animals if FDA finds that the sponsor of the investigation has failed to comply with any of the conditions governing exemptions, continuing the investigation would be unsafe or otherwise contrary to the public interest, or the drug is being used, or has been used for purposes other than bona fide scientific investigation.⁵³ In such instances, FDA will notify the sponsor and permit the sponsor to have an opportunity to correct. If the sponsor fails to correct, prior to terminating the exemption, the sponsor will be given an opportunity for a hearing before the FDA.

Current Disclosure Policies for INDs, INAD files and NCIEs, and IDEs: At the present time, FDA generally does not disclose any information about the existence, status, or contents of an investigational application or exemption submitted to the Agency, until the product has been approved, licensed, or cleared.⁵⁴ Generally, FDA’s regulations prohibit it from disclosing that it has INDs, INAD files or NCIEs, or IDEs in-house, unless the existence of the INDs, INAD files or NCIEs, or IDEs has been publicly acknowledged by the sponsor. FDA’s regulations prohibit it from disclosing any of the information in or about the IND, INAD file or NCIE, or IDE, including whether it has put an IND on clinical hold, whether it has terminated an IND or an investigational exemption for a new animal drug, whether it has approved, disapproved, or withdrawn an IDE, or whether the IND has been voluntarily withdrawn by the sponsor or placed on inactive status.

FDA regulations create limited exceptions to this general prohibition on the release of information about IDEs: (1) FDA may release a summary of selected portions of the safety and effectiveness data in a pending application if: (a) the existence of the

⁵¹ 21 C.F.R. § 511.1(b)(4).

⁵² 21 C.F.R. § 511.1(b)(4).

⁵³ 21 C.F.R. § 511.1(d).

⁵⁴ 21 C.F.R. §§ 312.130, 514.12, 601.50, 812.38(a) & (b)(3); *but see* 21 C.F.R. §§ 314.430(d)(1), 514.11(d), 601.51(d)(1), 812.38(b)(2).

application has been disclosed and (b) the information is relevant for public consideration of a specific pending issue;⁵⁵ and (2) upon request, a detailed summary of information concerning the safety and effectiveness of banned devices that are the subject of the IDE will be disclosed.⁵⁶

FDA regulations also create limited exceptions regarding the release of information about INDs and INAD files and NCIEs: (1) the Commissioner of FDA may release summaries of selected portions of safety and effectiveness information in a pending application if: (a) the existence of the application has been publicly disclosed and (b) the information is relevant for public consideration of a specific pending issue;⁵⁷ and (2) safety and efficacy information from INDs and INAD files is required to be disclosed under certain circumstances, unless extraordinary circumstances exist.⁵⁸ In practice, the first exception is rarely invoked for information in INDs and INAD files and NCIEs, and the second has been difficult to implement.

With the passage of the Food and Drug Administration Amendments Act (FDAAA) in 2007, sponsors became subject to expanded requirements (found in Title VIII of FDAAA) to publicly disclose information about certain clinical trials being conducted by them. The sponsors are required to submit this information to ClinicalTrials.gov. ClinicalTrials.gov, a federally mandated databank for certain drug, biological product, and medical device clinical trials, provides the public with access to basic information about these clinical trials. The site includes information about, among other things:

- The disease or condition being studied
- The drug or therapy under study
- A summary of the purpose of the study
- The recruiting status of the trial
- Criteria for patient participation
- The location of the trial and specific contact information
- Study design
- The phase of the trial (for drugs and biological products).⁵⁹

⁵⁵ 21 C.F.R. § 812.38(b)(2).

⁵⁶ 21 C.F.R. § 812.38(b)(1).

⁵⁷ 21 C.F.R. §§ 314.430(d)(1), 514.11(d).

⁵⁸ See FDCA §§ 505(l)(1), 512(p)(1); 21 C.F.R. §§ 314.430(f), 514.11(f).

⁵⁹ 42 U.S.C. § 282(j)(2)(A)(ii).

In most cases involving certain drug clinical trials, this information is posted online shortly after the first patient is enrolled in the trial.⁶⁰ Title VIII of FDAAA also includes provisions for considering whether clinical trial results should be submitted to ClinicalTrials.gov for unapproved products.⁶¹

FDA will continue to work with the National Institutes of Health/U.S. National Library of Medicine (NIH/NLM) to implement the provisions in Title VIII of FDAAA and ensure that companies are complying with existing requirements in the law.

The International Committee of Medical Journal Editors (ICMJE) also requires that clinical trials be registered in a public clinical trials registry before an article is considered for publication in an ICMJE member journal.⁶² The ICMJE policy requires clinical trial registration, at the time of patient enrollment, or earlier. Significant, well-respected journals are members of ICMJE, including the Journal of the American Medical Association (JAMA), the New England Journal of Medicine (NEJM), and The Lancet.

In addition, PhRMA has issued principles encouraging the posting of certain clinical trials and results information on a public registry. PhRMA's "Principles on Conduct of Clinical Trials" provides that member companies "commit to the timely submission and registration on a public database of summary information about all clinical trials that we conduct involving the use of our marketed or investigational products in patients."⁶³ The principles explain that 21 days after patient enrollment is an appropriate standard for timely submission of the clinical trial to a public database. Finally, companies sometimes disclose, on company Web sites and in press releases, the company's product development pipeline, including the product's stage of development (e.g., for drugs, Phase 1, 2, or 3).

Marketing Applications

FDA receives and reviews applications seeking permission to market human drugs, animal drugs, biological products, and significant-risk medical devices. To obtain permission to market a human drug, the manufacturer must submit a New Drug Application (NDA) for an innovator drug, or an Abbreviated New Drug Application (ANDA) for a generic drug.⁶⁴ To obtain permission to market a biological product, the manufacturer must submit a Biologics License Application (BLA).⁶⁵ To obtain permission to market a medical device, a manufacturer must submit either a Premarket Approval Application (PMA) or a 510(k), unless the device is exempt from premarket notification requirements.⁶⁶ To gain permission to market an animal

⁶⁰ 42 U.S.C. §§ 282(j)(2)(C) & (D).

⁶¹ 42 U.S.C. § 282(j)(3)(D)(ii)(II).

⁶² See Clinical Trial Registration: A Statement From the International Committee of Medical Journal Editors, *available at* http://www.icmje.org/clin_trial.pdf.

⁶³ PhRMA, Principles on Conduct of Clinical Trials at 20 (April 2009).

⁶⁴ 21 C.F.R. Part 314.

⁶⁵ 21 C.F.R. Part 601.

⁶⁶ 21 C.F.R. Part 814 and Part 807, Subpart E.

drug, a manufacturer must submit a New Animal Drug Application (NADA) for an innovator drug, or an Abbreviated New Animal Drug Application (ANADA) for a generic drug.⁶⁷

The contents of a marketing application vary somewhat depending on the type of application, but generally include:

- Proposed labeling for the product, which includes proposed indications and how the product is to be administered;
- Information about the components, physical characteristics, and/or chemistry of the product;
- Information about how the product will be manufactured;
- Marketing history of the product, if any; and
- Information from all relevant laboratory, animal and clinical studies supporting the approval or clearance of the application.

Depending on the type of marketing application, the investigational application may also be incorporated by reference.

If the marketing application for a drug, biological product, or device is not accepted for filing by FDA because the Agency determines the application is not sufficiently complete to allow for substantive review of the application, FDA sends a “refuse to file,” “refuse to accept,” or “refuse to receive” letter to the sponsor of the application, depending on the type of application. These letters are not sent in response to 510(k) submissions.

If, after reviewing an application, FDA determines that it cannot approve or clear the application in its current form, FDA sends a letter informing the sponsor of this decision. For NDAs, BLAs, and ANDAs, this letter is called a “complete response” letter. For NADAs and ANADAs, this letter is called a “refuse to approve” letter. For PMAs, it is called a “not approvable” letter. For 510(k)s, it is called an “additional information (AI)” letter.

In some cases, a sponsor may voluntarily withdraw a pending application before FDA has reached a final determination. If no activity is seen on an application for some period of time and it appears no work is being done or will be undertaken by the sponsor on a pending application, it may be considered abandoned.

If, after reviewing an application, FDA determines that the application meets the requirements for approval (for NDAs, ANDAs, NADAs, ANADAs, BLAs, or PMAs)

⁶⁷ 21 C.F.R. Part 514.

or clearance (for 510(k)s), FDA sends a letter informing the sponsor of this decision. Additionally, for NADAs and ANADAs, FDA publishes in the Federal Register a regulation prescribing the conditions under which the new animal drug may be used and sends the applicant a copy of the proposed Federal Register publication.

If, after the product is approved, FDA determines that the product no longer meets the requirements for marketing approval, e.g., is no longer safe and effective, FDA may send a notice informing the sponsor that FDA intends to withdraw approval or licensure, and offering the sponsor an opportunity for a hearing. A sponsor may also voluntarily request that FDA withdraw the approval, license, or clearance of an application.

Current Disclosure Policies for Marketing Applications. FDA does not disclose the existence of a marketing application for a drug, biological product, or a premarket approval application for a device unless the application has been previously publicly disclosed or acknowledged by the sponsor.⁶⁸ FDA does not disclose the existence of a 510(k) for a device unless the device is on the market or the submitter of the 510(k) has disclosed its intent to market the device.⁶⁹

FDA's regulations generally prohibit the release of information from or about a pending application. As a result, FDA generally cannot disclose that it has issued a "refuse to file," "refuse to accept," "refuse to receive," or "additional information (AI)" letter to the sponsor of the application.⁷⁰ If the marketing application cannot be approved or cleared, FDA does not disclose the complete response, not-approvable, refuse to approve, or "not substantially equivalent (NSE)" letters.

If and when the drug application, biologics license application, or premarket approval application for a device is approved, the refuse to file/accept/receive letter and the correspondence informing the sponsor that the application cannot be approved in its current form are publicly available, with appropriate redactions. But additional information letters sent to the sponsor of device applications are not released once the device is cleared and NSE letters are not released, even if the sponsor re-submits a 510(k) for the same device that is later cleared by FDA.

There are limited exceptions to the general prohibition on release of information from or about a pending application. FDA may release summaries of selected portions of safety and effectiveness information in a pending application if the existence of the application has been publicly disclosed or acknowledged by the sponsor, if relevant for public consideration of a specific pending issue.⁷¹ This exception is most commonly invoked when an advisory committee meeting is held to consider an

⁶⁸ 21 C.F.R. §§ 314.430(b) (human drug application), 514.11(b) (animal drug application), 601.51(b) (biologics license applications); 814.9(b) (device premarket approval application).

⁶⁹ 21 C.F.R. § 807.95.

⁷⁰ See 21 C.F.R. §§ 314.430(c) & (d), 514.11(c) & (d), 601.51(c) & (d), 807.95(b) & (c), 814.9(c) & (d).

⁷¹ 21 C.F.R. §§ 314.430(d)(1), 514.11(d), 601.51(d)(1), 814.9(d)(1).

application prior to its approval or clearance.⁷² Also, under the Best Pharmaceuticals for Children Act (BPCA) (which applies to human drug applications) and the Pediatric Research Equity Act (PREA) (which applies to both human drugs and biological products), FDA must release clinical, clinical pharmacology, and statistical reviews of pediatric studies within a statutorily defined time frame regardless of whether the application has been approved.⁷³

Because FDA's regulations generally prohibit the release of information from or about unapproved applications, FDA generally does not disclose the fact that a sponsor has withdrawn or abandoned a drug or device application, or biologics license application before it is approved. FDA also does not disclose the fact that a sponsor has withdrawn or abandoned a 510(k) application before it is cleared. However, the FDCA and FDA regulations require FDA to disclose non-summary safety and efficacy information from certain NDAs, INDs, and ANDAs, as well as from certain NADAs, INADs files, NCIEs, and ANADAs, in certain limited circumstances, upon request, unless "extraordinary circumstances" exist.⁷⁴ In practice, these provisions have been difficult to implement.

Some companies disclose on company Web sites, in press releases, and in calls with investors when an application has been filed by FDA for review. Securities and Exchange Commission (SEC) filings that companies are required to submit also may include information about marketing applications submitted to FDA.

2. *Summary of Public Comments*

Comments from patient groups, consumer groups, healthcare practitioners and individuals supported additional disclosure of information about the status and contents of applications. Comments from patient groups, consumer groups, and individuals stated that disclosure of emerging safety data and information about the status of products in development increases the credibility of FDA decisions, promotes better public understanding of the rationale for regulatory decisions, helps patients track the progress of unapproved treatments for their diseases and make decisions about management of their diseases, and prevents wasted scientific resources and unnecessary human suffering. A patient group stated that transparency was important to avoid and to address public mistrust of regulatory decisions.

In general, industry comments stated that the protections set forth in current law represent the correct balance between disclosure of information and maintaining the confidentiality necessary to foster innovation. Comments from manufacturers and industry trade groups contended that early release of information about the status of, or safety and effectiveness information on, products in development could give competitors an advantage by providing access to previously unavailable insights into the development process and harm incentives for innovation. These comments stated that the FDA's current policies regarding information about product applications are

⁷² See 21 C.F.R. §§ 314.430(d)(1), 514.11(d), 601.51(d)(1), 814.9(d)(1).

⁷³ FDCA §§ 505A(k), 505B(h).

⁷⁴ See FDCA §§ 505(l)(1)(A), 512(p)(1); 21 C.F.R. §§ 314.430(f), 514.11(f).

necessary to encourage innovation and that FDA's current policies provide adequate transparency.

Investors stated, however, that disclosure of more information during FDA's product review process about the status of the application, along with the FDA's views about the strength of an application, will foster innovation by directing resources towards research for products that can meet the Agency's standards of approval. One industry commenter stated that:

Moreover, it is our view that the majority of applicants disclose to the public—usually via press releases and annual financial reports—when an application for a new product or significant new indication has been submitted, approved or withdrawn. This is especially common practice for products that are new molecular entities.

Comments argued that in order to protect patients in trials of related compounds, additional disclosure of information about investigational applications is particularly important when research is stopped due to safety reasons. Comments stated that product sponsors do not publish negative results from clinical trials conducted on investigational and marketed products, and thus, other companies may expose patients to closely-related products without knowledge that another study of a similar compound revealed significant harm.

One industry comment stated that additional disclosure of information about clinical trials is not needed to protect subjects participating in clinical trials that are testing similar medical products because FDA oversees clinical trials and will prevent any unnecessary risks to subjects. Another industry comment stated that “disseminating certain additional trial information may reduce duplicative studies which divert industry resources that could be used to undertake innovative research,” but transparency objectives must be balanced by the need to protect proprietary information. Other comments stated that greater disclosure may encourage rather than discourage medical breakthroughs by allowing scientists to avoid repeating past failures.

One comment from industry stated that FDA should await implementation of the clinical trial registry and results data bank before changing its disclosure policies. One comment stated that industry compliance with ClinicalTrials.gov has been “uneven.”

Comments stated that FDA should disclose letters sent to applicants when FDA does not approve an NDA, NADA, BLA, or PMA or clear a 510(k). One comment noted that disclosure of these letters would “make it more difficult, if not impossible, to promote the drug off-label” for indications that were included in the marketing application and were not approved by FDA. Industry comments stated, however, that information in these letters would provide competitors with information they can use to gain an unfair competitive advantage and decrease the incentive to invest in the development of new medicines.

Comments suggested that FDA make publicly available summaries of the data in the product application prior to approval or clearance; other comments urged that FDA make publicly available non-summary safety and efficacy data (or require companies to do so). Industry comments stated that providing information found in product applications, such as raw safety and effectiveness data, clinical study protocols, and proposed indications and warnings for the product may provide competitors with insights into the development process and hinder product innovation.

Comments stated that the information in product applications that are withdrawn, terminated, or abandoned before approval may provide valuable information to health care professionals, patients, researchers, and others and should be disclosed. Some industry comments stated that information in such applications may still have commercial value to the sponsor and should not be disclosed. An industry comment stated support for the disclosure of clinical trial results if studies for certain products were stopped for safety issues prior to approval or clearance. Industry comments generally requested consultation with the sponsor before any information is disclosed.

Comments stated that the European Medicines Agency (EMA) releases information about product applications but that same information is not disclosed by FDA. Comments also stated that companies publicly disclose information about product applications but that same information is not disclosed by FDA.

3. *Considerations*

The Task Force considered rationales articulated by FDA in the past about current Agency policies regarding disclosure of information about pending applications. We took into account the principles underlying FDA's product-specific disclosure regulations, 21 C.F.R. Part 20, and the statements of former FDA personnel, including former Commissioner Donald Kennedy and former Chief Counsel Peter Barton Hutt.

The Task Force considered whether the FDA's current disclosure policy allows the public to understand the rationale behind FDA's decisions about the approval of medical products. In addition, the Task Force considered whether the FDA's current disclosure policy provided all segments of industry, not just an individual product sponsor, with sufficient information about FDA's application review process and expectations for product approval.

The Task Force considered whether additional disclosure would promote Agency accountability for its regulatory decisions. The Task Force took into account whether greater public scrutiny of medical product approval decisions would increase the credibility of those decisions. Additional disclosure of information will allow others the ability to independently assess information about a medical product and may allow for new perspectives about the safety and efficacy of medical products.

The Task Force considered whether additional disclosure about medical product applications may advance scientific knowledge about medical products and lead to potential treatments for more diseases. The Task Force took into account the interest

clinical trial participants have in not being exposed to unnecessary risks and the interest they may have in ensuring that the results of those clinical trials are available to advance science and help other patients. The Task Force recognizes that additional disclosure of clinical data may prevent the unnecessary duplication of clinical trials and improve the design of future clinical trials.

The Task Force considered the public interest in finding out information about the progress of treatments for diseases. The Task Force took into account FDA's experience with patients, family members, and patient groups that are awaiting the approval of a particular treatment. Individuals are often frustrated when they do not receive information about the status of an application, particularly one that has been withdrawn.

The Task Force considered the amount of information related to marketing applications that is available in the public domain, including the information that is proactively released by companies and the recent requirement for manufacturers to post information about clinical trials and the results of those trials.

The Task Force considered the potential impact of disclosure on incentives for innovation. The Task Force considered how the disclosure of certain information from pending applications would give competitors a significant competitive advantage. The Task Force considered the different development models for FDA-regulated medical products and the potential impact disclosure may have in those markets. The Task Force took into account industry's comments that additional disclosure may decrease the investment in product development. The Task Force also took into account comments by the investor community that information from FDA about its views about the strength of an application during the review process will better direct resources and may stimulate investment.

The Task Force took into account the disclosure policies of other federal agencies, such as the National Institutes for Health, as well as foreign regulators, since many FDA-regulated companies operate in countries other than the United States. The Task Force considered other protections that may be available to protect a company's proprietary information.

The Task Force recognizes that a balance needs to be struck between the benefits of additional disclosure and the impact on product innovation.

4. Draft Proposal(s) for Public Comment

a) Existence or Non-Existence of Investigational Applications

DRAFT PROPOSAL 8:

FDA should disclose the existence and, when asked, confirm the existence or non-existence of investigational applications. For investigational applications, the disclosure should include the name of the application

sponsor, the date the application was received, the proposed indication(s) or intended use(s) of the product, and the proposed proper and/or trade name of the product, if available.

Reasoning: There are important public benefits to disclosing the existence of investigational applications received by FDA. Investigational applications inform FDA that a company plans to start a clinical trial in humans or animals. FDA receives questions from the public about planned clinical trials. If FDA could disclose when an investigational application has been received, it may encourage patient enrollment in clinical trials that are underway or are likely to be started, particularly those trials that may not be posted on ClinicalTrials.gov. Public availability of this information may reduce the potential for public confusion about the development of a particular product.

Most clinical trials conducted in the United States that are used to support approval of a new drug or device, or a new use of an existing drug or device, are conducted pursuant to an investigational application submitted to and reviewed by FDA. The public is provided information about clinical trials that are underway to develop new medical products, in large part due to federal requirements requiring public registration and results reporting for certain clinical trials, guidelines set forth by other public entities encouraging disclosure of clinical trials and results, and proactive disclosures by companies themselves about new products in development. Disclosure of an ongoing clinical trial in the United States in many cases means that an investigational application has been submitted to FDA.

The public benefits of disclosure apply to all clinical investigations conducted with FDA-regulated products. Disclosing the fact that FDA has received an investigational application will not allow a competitor to copy the formulation of a product or reverse engineer a device. The potential availability of a new product on the market is not the only basis on which products compete; for example, improved effectiveness of the product, fewer side effects, and easier use by the patient are among factors that differentiate products on the market.

As a result, the right balance is for FDA to disclose the existence of investigational applications to the public and answer questions from the public about the existence of these applications.

b) Clinical Trials: Holds, Withdrawals, and Terminations

DRAFT PROPOSAL 9:

FDA should disclose: (1) whether an investigational new drug application (IND) has been placed on hold, terminated, or withdrawn, whether an investigational device exemption (IDE) has been terminated or withdrawn, or whether an investigational exemption for a new animal drug has been terminated and (2) if an IND has previously been placed on hold, whether

and when the hold is lifted. A statement should be included that such actions may be taken for various reasons, only some of which relate to safety or effectiveness.

Reasoning: The public has an interest in knowing the status of clinical trials, namely whether FDA has concluded that a clinical trial should not be started, or should not be continued and when a previously stopped human clinical trial is permitted to begin again. Although companies may disclose when a clinical hold has been “lifted” by the FDA, it is equally, if not more important, to inform the public when a clinical hold has been imposed or when FDA has decided to terminate an exemption which permits the use of unapproved new animal drugs in clinical investigations. That way, individuals that are interested in enrolling in the clinical trial, or already are enrolled, and owners of animals that may be participating in the clinical trial are aware of FDA’s action and can take steps to limit exposure to unnecessary risks.

Providing the status of the clinical trial does not disclose information that could be used by competitors to “free-ride” off of the sponsor’s innovative effort. In some cases, the existence of human clinical trials is already public.

Disclosing the status of an investigational application or exemption yields significant public benefits, mainly in the protection of human and animal subjects, while furthering the Administration’s goals of more transparent government. All disclosures should be accompanied with a clear disclaimer about the limits of the information.

c) Existence or Non-Existence of Marketing Applications

DRAFT PROPOSAL 10:

FDA should disclose the fact that an NDA, NADA, ANDA, ANADA, BLA, PMA, or 510(k) application or supplement was submitted (or resubmitted) to the Agency at the time the application is received by FDA. The disclosure should include the name of the application sponsor, the date the application was received, the proposed indications or intended use of the product, and the proposed proper and/or trade name of the product, if available.

Reasoning: There are strong public interests that favor Agency disclosure of whether a marketing application has been submitted to FDA for review.

FDA receives questions from interested members of the public, including patients suffering from a specific disease, or family members of those patients, about whether an application for a new product is being reviewed by the Agency. The majority of the questions FDA receives request information about new products or new uses for existing products. Oftentimes, the person asking is eagerly awaiting a treatment for a particular disease and wants to know when that treatment may be available. Disclosing whether, and when, a marketing

application has been submitted for a specific use will provide helpful information to these individuals, and ease some of the current frustration that stems from the FDA's restrictions on providing this type of information.

Not only will greater disclosure alleviate the frustration of individuals who call FDA now, and receive no response, but greater disclosure may also increase Agency accountability. Disclosing whether an application for a new product, or new use of an existing product, has been submitted, and when, may provide greater insight into the application review process, i.e., when FDA action is expected on a specific application.

Further, the public is at times currently provided information about whether an application has been submitted to FDA for review. Often, this information is proactively provided by sponsors themselves, or provided pursuant to other legal requirements.

FDA should disclose whether marketing applications seeking approval of a new product, or a new use for an existing product, have been submitted to FDA, and if so, when. The public health benefits associated with disclosing the existence of marketing applications are strongest in the case of such marketing applications. While members of the public may be interested in other applications, such as labeling changes, the public health interests does not warrant the significant resources entailed in proactive disclosure of this information.

d) Withdrawn or Abandoned Unapproved Applications

DRAFT PROPOSAL 11:

FDA should disclose that an unapproved NDA, ANDA, NADA, ANADA, BLA, or PMA, or uncleared 510(k) has been withdrawn or, if FDA determines that the application was abandoned, abandoned by the sponsor. If the drug, biological product, or device is associated with a significant safety concern, FDA should provide a brief description of the product, the use for which approval was sought or obtained, and the identified safety concern.

Reasoning: Information in a withdrawn or abandoned application may still have competitive value to the sponsor. But the European Medicines Agency (EMA) currently discloses that a marketing authorization application (i.e., marketing application) has been withdrawn and information about its evaluation of the product at issue.⁷⁵ Given the global nature of the pharmaceutical and medical device industries, we believe that most of the industries regulated by FDA are subject to the EMA's disclosure policy. As a result, there are situations where competitive harm can be mitigated to the point it is not significant, while

⁷⁵ EMA, Publication Of Withdrawals Of Marketing Authorisation Applications For Human Medicinal Products, Oct. 5, 2006, Doc. Ref. EMA/239350/2005 Rev. 1.

providing the public with important information FDA knows and believes can help promote and protect public health.

There are significant interests that favor disclosing the fact that a pending application has been voluntarily withdrawn or abandoned by the sponsor. Disclosure of the fact that an application has been voluntarily withdrawn or abandoned by the sponsor allows interested individuals and the investor community to provide funding or to seek other opportunities that will allow for continued development of the product, if that community believes the treatment is worthwhile. Additionally, if the public is aware that an application has been submitted to FDA (as disclosed by the company and/or FDA), disclosure of when the application was withdrawn is likely equally important to patients who may be awaiting new treatments for their diseases.

Further, it is important for FDA to inform the public when it is aware that an application has been withdrawn or abandoned by the sponsor due to a significant safety concern. Under current law, FDA has authority to withdraw approval of an application in certain circumstances.⁷⁶ In those cases, FDA can disclose when approval has been withdrawn,⁷⁷ and in the case of NDAs and ANDAs, FDA can explain to the public if the drug was withdrawn due to a safety concern, or was shown not to be effective for its intended use.⁷⁸ FDA also makes available a detailed summary of information about the safety and effectiveness of the device that is the subject of a PMA withdrawn by FDA.⁷⁹

But when a sponsor withdraws or abandons an application before approval (in other words, requests that FDA stop its review of the application) for a safety or efficacy reason, that information is not conveyed to the public. Disclosure of when and why an application is withdrawn or abandoned by the sponsor for a significant safety reason should allow researchers studying the same molecule or device, or a closely related molecule or device, to use that information to protect patients from the identified and potential risks. If the information concerns an unapproved (off-label) use of a marketed product, health care professionals and patients would have access to information that could influence decisions about whether to use the products for that off-label use, if such use is not otherwise prohibited.

The right balance is to allow FDA to disclose when a marketing application has been withdrawn or abandoned by the sponsor and to allow FDA to communicate additional information about the application when there is a significant safety concern. Continuing FDA's current practice of not disclosing the fact that an application has been withdrawn or abandoned by the sponsor means that information that is prohibited from disclosure in the United States is disclosed in

⁷⁶ FDCA §§ 505(e), 512(e); 21 C.F.R. §§ 314.150(a), 514.115, 814.46(a).

⁷⁷ 21 C.F.R. §§ 314.152, 514.116.

⁷⁸ 21 C.F.R. § 314.152.

⁷⁹ 21 C.F.R. § 814.46(e).

Europe. This disparate treatment is not merited, given the global nature of the regulated industry, and does not further the Administration's goal for more open government.

e) **Withdrawn or Abandoned Application for a Designated but Unapproved Orphan Drug or Designated Minor Use/Minor Species Animal Drug, Not Due to Safety Concerns**

DRAFT PROPOSAL 12:

When an application for a designated orphan drug or a designated minor use/minor species animal drug has been withdrawn, terminated, or abandoned, FDA should disclose, if it determines, based on its review, that the application *was not* withdrawn, terminated, or abandoned for safety reasons and the product, if approved, could represent a significant therapeutic advance for a rare disease or for a minor animal species. A disclaimer that provides that FDA's expressed views about the product do not reflect whether a subsequent application involving the product will be accepted for filing or will be approved by FDA should accompany the disclosure of this information.

Reasoning: Applications for products for rare diseases and minor animal species are sometimes abandoned before approval, solely for business reasons. In those circumstances, disclosure of FDA's view that a certain product may represent a significant therapeutic advance for a rare disease or for a small population of animals may foster development of promising products for that disease. Disclosure of FDA's view that a product holds promise may provide encouragement to the private sector to continue development of a promising product. Disclosure may also allow the community affected by this disease to seek funding, or other opportunities that will allow for continued development of the product.

Disclosure of FDA's views about the product does not equate to disclosure of the information in the actual application. FDA's announcement should not negatively impact companies planning to continue development of the product once it is economically feasible to do so. Indeed, FDA's announcement may help such companies obtain funding to continue development of the product, or may support efforts to find another company that is interested in doing so.

FDA should disclose its determination that a certain product may represent a significant therapeutic advance for a rare disease or a minor animal species if the application is withdrawn, terminated, or abandoned for other than a safety reason. Any such announcement by FDA must make clear that the Agency's view about the product is no indication that a subsequent marketing application submitted to FDA would be accepted for filing or approved by FDA.

f) Letters Issued When FDA Does Not Accept a Marketing Application or Approve or Clear a Marketing Application

DRAFT PROPOSAL 13:

FDA should disclose the fact that the Agency has issued a refuse-to-file or complete response letter in response to an original NDA, BLA, or an efficacy supplement for an NDA or BLA at the time the refuse-to-file or complete response letter is issued, and should, at the same time, disclose the refuse-to-file or complete response letter, which contains the reasons for issuing the letter.

DRAFT PROPOSAL 14:

FDA should disclose the fact that the Agency has issued a refuse to approve letter in response to a NADA, or a supplemental NADA to add a new species or indication, at the time the refuse to approve letter is issued, and should, at the same time, disclose the refuse to approve letter, which contains the reasons for issuing the letter.

DRAFT PROPOSAL 15:

FDA should disclose the fact that the Agency has issued a “not approvable” letter in response to a PMA for a medical device and the fact that FDA has issued an “additional information (AI)” letter in response to a 510(k) submission, and should, at the same time, disclose the reasons for issuing the “not approvable” letter or “additional information (AI)” letter, which contains the reasons for issuing the letter.

Reasoning: There are significant public benefits associated with disclosing information about letters FDA issues when the Agency does not accept a marketing application or approve or clear a marketing application for a medical product. Disclosing that FDA has sent the sponsor one of these letters would inform the public about the current status of an application and the fact that FDA cannot approve or clear the application in its current form. Disclosing the letter would provide the public with FDA’s reasons for its actions. Disclosing that the letter has been sent, and the letter itself, may be valuable to patients and health care providers who want to know whether, and when, new medical treatments will become available. If the application at issue seeks approval of a new indication for a product that is currently used off-label for that indication (i.e., for an indication that has not been approved by FDA), health care professionals and patients would have access to information that could influence decisions about whether to use the products for that off-label use, if such use is not otherwise prohibited. Investors may also be provided with information that may allow for the most efficient use of limited research dollars.

Companies sometimes disclose the receipt of these letters from FDA to the public. But even when it is publicly reported that FDA has not approved or cleared an application, or has not filed or accepted the application for review, FDA's reasons for its action may not be presented. FDA does not say anything to the public about the basis for its decision. And in cases where a sponsor provides an explanation to the public about FDA's determination, the information provided may not give the public a complete picture of FDA's rationale for its decision.

FDA should publicly explain its rationale for not filing or receiving an application to market a product, not approving a medical product, or not clearing a medical device. Disclosure of the letter sent to sponsors, which sets forth those reasons, enhances the credibility of FDA's decisions by revealing the basis for the Agency's decisions not to permit the marketing of a product and furthers the goal of more transparent and open government called for by the Administration. FDA will also be able to explain its concerns about an application to the public in more detail, even in cases where the company provides information to the public about FDA's action. And by allowing FDA to explain its decision-making process to the public, the public may get a better understanding of FDA's application review process. Disclosing the letters FDA issues when the Agency does not accept a marketing application, or approve or clear a marketing application for a medical product will provide the public with reasons for FDA's decision about the application.

The EMA currently makes available online the reasons for denying initial marketing authorization applications (i.e., marketing applications), denying applications for new indications, or denying applications for an extension of a marketing authorization (e.g., changes to the active substance or a new route of administration).⁸⁰ As noted above, given the global nature of the industry, some companies operating in the U.S. are currently subject to the EMA's disclosure policy.

The Task Force concluded that when FDA issues letters to sponsors in response to ANDAs, ANADAs, chemistry, manufacturing, and controls (CMC) supplements, or labeling supplements FDA's rationale for not approving the application primarily relates to how the drug was made, or to labeling negotiations between the sponsor and FDA. Additionally, CMC information contains a great deal of trade secret information, which the Task Force supports redacting. Disclosing these letters would provide little insight about the rationale underlying FDA's drug review process.

⁸⁰ European Medicines Agency, Committee for Medical Products for Human Use, Publication of CHMP Negative Opinion and Refusal of Marketing Authorisation Applications for Human Medicinal Products, Doc. Ref. EMA/311355/2005, adopted Jan. 24, 2007; European Medicines Agency, Committee for Medicinal Products for Veterinary Use, Reflections Paper on the Publication of the CHMP's Negative Opinion and Refusal to Recommend the Granting of a Marketing Authorisation for Veterinary Medicinal Products, Doc. Ref. EMA/CVMP/459912/2006, adopted Jul. 12, 2007.

The public health interests set forth above strongly favor disclosure when FDA has made a decision not to accept a marketing application or to approve or clear a marketing application for a new medical product, or for a new use for an existing product. In most cases, those letters will include deficiencies relating to the safety and efficacy of the product. The Task Force is not proposing disclosure of letters issued to sponsors in response to ANDAs, ANADAs, chemistry, manufacturing, and controls (CMC) supplements, or labeling supplements because those letters will yield little public benefit, particularly in light of the need to protect trade secret information and maintain incentives for innovation.

g) Safety and Effectiveness Data

DRAFT PROPOSAL 16:

FDA should disclose relevant summary safety and effectiveness information from an investigational application, or from a pending marketing application, if the Agency concludes that disclosure is in the interest of the public health, which includes when FDA believes it is necessary to correct misleading information about the product that is the subject of the application.

Reasoning: Many stakeholders have an interest in whether safety and effectiveness data is made available to the public. Sponsors and developers of that data have an interest in recouping the significant investment of resources that was required to develop the data before it becomes available to competitors. Medical researchers have an interest in accessing this information to develop significant medical treatments more quickly. Health care providers may use the information to inform prescribing decisions. And investors may be better able to direct resources towards promising treatments based on an assessment of that data.

A balance must be struck between these competing interests in a manner that advances the public interest while maintaining the incentive for companies to develop new products for life-saving diseases.

The disclosure of all data from ongoing trials or from pending marketing applications, before the company has had an opportunity to use those data to obtain approval of the product, may negatively affect product development. Disclosure of certain information, at the wrong time, may have the unintended consequence of slowing, or even stifling, product development.

Blanket protection of all information in pending product applications, however, has not been shown by industry to be economically necessary, in light of other legal protections provided for innovative research (e.g., patent and unfair competition laws, exclusivity periods provided innovator drugs). Further, the impact on a company's competitive position may cut both ways—disadvantages to one product line may be more than compensated for by the overall benefits to a

company. And there are public benefits to be gained by the disclosure of safety and effectiveness information, including in the advancement of science, protection of patients that may use these products, and the efficient use of limited resources available for research.

After considering the competing interests in disclosing safety and effectiveness information from investigational and pending applications, the Task Force proposes that limited additional disclosure is warranted. The correct balance is to allow FDA to disclose a *summary* of safety and efficacy information, when it determines the information is necessary to protect the public health. Selective publication of clinical trials results has, in the past, created a misleading picture of the safety and efficacy of a product, with negative implications for the public health. This is particularly pronounced when the product is used off-label (i.e., for indications that have not been approved by FDA).

A blanket policy against disclosure of summary safety and effectiveness information from an investigational application or notice, or pending marketing application does not adequately account for the public health benefits that could result from disclosure. Further, industry has not demonstrated that blanket protection of aggregate information is warranted to maintain incentives for innovation.

DRAFT PROPOSAL 17:

FDA should convene a group of internal and external stakeholders to discuss the possible uses of non-summary safety and effectiveness data from product applications, the circumstances under which it would be appropriate for sponsors to disclose non-summary safety and effectiveness data from applications submitted to FDA, and if appropriate, the format and the method by which disclosure should occur.

Reasoning: A different balance may be struck with respect to the disclosure of non-summary safety and effectiveness information. A blanket policy against disclosure of this type of information may not be justified because there are significant public health benefits associated with the disclosure of this information, including reducing the costs and increasing the efficiency of research.

But given the nature of the information, other factors may weigh more strongly here. For example, the timing of any disclosure, the potential uses for this information, the means by which disclosure would occur, and the impact disclosure may have on innovation, may lead to a different balance regarding the disclosure of non-summary safety and effectiveness data.

For these reasons, the issue would benefit from a broader discussion with relevant stakeholders to decide upon the right balance to strike.

G. Recalls

1. Background

When an FDA-regulated product is defective, potentially harmful, or mislabeled, recalling that product—removing it from the market or correcting the problem—is often the most effective means for protecting the public from products that violate the laws administered by FDA.

Generally, FDA does not have mandatory recall authority (i.e., the authority to order a manufacturer and/or distributor to recall a product), except under limited circumstances related to certain devices, biological products, human tissue intended for transplantation, and infant formula.⁸¹

A firm may initiate a recall at any time. With the exception of recalls ordered under FDA's mandatory recall authority or pursuant to a court order, a recall is a voluntary action that takes place because manufacturers and/or distributors carry out their responsibility to protect the public from products that present a risk of injury or gross deception, or are otherwise defective. A recall may also follow notification of a problem by FDA or a state agency. In certain urgent situations, FDA may formally request a recall.⁸² If a manufacturer does not recall a violative product, or if a firm-initiated recall proves inadequate, FDA can seek relief in court that requires the company to correct the violations and/or destroy the violative product.

FDA has issued guidance on recalls in 21 C.F.R. Part 7 which provides FDA's policy and procedures and industry responsibilities.⁸³ An additional document titled "Guidance for Industry: Product Recalls, Including Removals and Corrections" is also available on FDA's Web site.⁸⁴ It provides guidance both in the conduct of recalls and in the information needed by FDA to classify, monitor, and assess the effectiveness of a recall.

FDA requests that if a firm is removing or correcting a distributed product because the firm believes the product to be in violation of the statutes or regulations administered by FDA, that the recalling firm provide certain information to the agency. This requested information includes the identity of the product that is the subject of the recall, the reason for the recall, an evaluation of the risk, the volume of the product, the distribution of the product, and the firm's strategy for the recall.

⁸¹ FDCA § 518(e), 21 C.F.R. Part 810 (mandatory recalls of devices where Agency finds that there is a reasonable probability that device intended for human use would cause serious adverse consequences or death); 42 U.S.C. § 262 (biological products); 42 U.S.C. § 264, 21 C.F.R. § 1271.440 (certain human cell, tissue, and cellular and tissue-based product intended for human transplantation); 21 C.F.R. Part 107, Subpart E (infant formula).

⁸² 21 C.F.R. § 7.45.

⁸³ In addition, FDA-ordered recalls generally have timelines and procedures, including information that must be provided to FDA, specified in the applicable regulations.

⁸⁴ Guidance for Industry: Product Recalls, Including Removals and Corrections (Nov. 2003), available at <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

As specified in FDA's Regulatory Procedures Manual,⁸⁵ FDA reviews the information provided, assesses the health hazard presented by the product that is the subject of the recall, and classifies the recall as a Class I, Class II, or Class III recall. Recalls are classified according to the level of health hazard involved:

- **Class I** is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause adverse health consequences or death. Examples could include: food found to contain botulinum toxin, food with undeclared allergens, a label mix-up on a lifesaving drug, or a defective artificial heart valve.
- **Class II** is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. An example could include drugs that are under-strength but not used to treat life-threatening conditions.
- **Class III** is a situation in which use of, or exposure to, a violative product is not likely to cause any adverse health consequences, but the product violates FDA labeling or manufacturing laws. Examples could include a minor container defect, or a lack of English labeling on a retail food.

After classifying a recall, FDA includes information about the recall in the *FDA Enforcement Report*, which is available on FDA's Web site. The time that it takes for FDA to classify a recall upon receipt of information from a recalling firm impacts the timing of FDA's communications to the public about the recall.

In addition, FDA immediately posts on its Web site press releases related to recalls. Most often these press releases are issued by recalling firms. FDA also posts on its Web site press releases issued by state agencies. FDA may also issue a press release and post that on its Web site if the Agency believes that there is a recall of a product likely to have a serious public health consequence and the recalling firm has not issued a press release or other public statement.

FDA monitors the firm's implementation of the recall to ensure that it has been effective and determines when the recall action should be terminated. A recall is considered terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy and when it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed. FDA issues a written notification that a recall is terminated to the recalling firm, but does not notify the public when a recall has been terminated.

⁸⁵ Regulatory Procedures Manual, Chapter 7, Recall Procedures (Mar. 2009), available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>.

2. *Summary of Public Comments*

When making suggestions about FDA’s recall procedures, comments from industry, consumer groups, and individuals acknowledged the importance of protecting the public. An industry group stated that “I want to stress again that we all have the same priority—protecting the public health.”

Industry comments stated that FDA should disclose more information about the basis for recalls, including risk assessments and the underlying scientific basis for the recall, without revealing a company’s proprietary information. Consumer groups and individuals requested notifications from FDA about more recalls, including recalls for products with undeclared food allergens, as well as those classified as Class II or Class III recalls by FDA.

In addition, an individual requested that when FDA requests a recall of a food product and has the capability to check whether the product has been taken off the market, FDA should also release the names and addresses of retail outlets where that food product was sold. A consumer group stated that FDA could provide a sign on its Web site that notifies the public that a product has been recalled, which can be downloaded by retailers and placed in establishments.

Comments from industry stated that when a safety issue arises with an FDA-regulated product, FDA should communicate when it is safe to use a product or eat the food. Both industry and consumer groups stated that the FDA should disclose when a recall has been completed. For example, one industry comment requested that FDA develop “an ‘all clear’ procedure that will alert the public that they can resume eating a particular food when it is again safe to do so.”

3. *Considerations*

The Task Force considered FDA’s limited authority with respect to recalls of FDA-regulated products and the extent to which that has hampered FDA’s ability to quickly analyze and address potential risks posed by a defective or otherwise violative product. Except in limited circumstances (which affect a limited number of FDA-regulated products), FDA generally does not have the authority to require manufacturers and/or distributors to recall products or to provide FDA with information about recalls of products. Additional disclosure of information by industry about defective or otherwise violative products that are being recalled may improve FDA’s ability to assess the risk associated with a recall more rapidly.

The Task Force considered how FDA could most effectively communicate the risk associated with the defective product. The Task Force considered the amount of control FDA has over the message that is communicated to the public about the recall. The Task Force took into account the importance of communicating to the public that the risk has passed following an effective recall.

The Task Force also considered whether the information associated with FDA’s recall classification decision—e.g., Class I, Class II, or Class III recall—would provide useful, understandable, actionable information to the public.

4. *Draft Proposal(s) for Public Comment*

DRAFT PROPOSAL 18:

When a system is set up that provides FDA with authority to require companies to submit certain information to the Agency when they initiate an action to recover or correct a product that is in the chain of distribution, FDA should disclose this information as soon as practicable after receiving this information from the firm.

Reasoning: Where a recall is being conducted voluntarily, FDA cannot require recalling firms to submit to the Agency specific information about a defective or otherwise violative product on the market, and therefore, FDA may not be able to provide the public with information it may deem important for the public to know about a recalled product.

Due to the current limitations of the Agency's authority and its implications for FDA's ability to protect the public health, FDA should seek authority that would require manufacturers and distributors to inform the Agency when they initiate an action to recover or correct a product that is in the chain of distribution due to a defect with the product, or is believed to be in violation of FDA laws and regulations.

If recalling firms are required to provide FDA with basic information about every recall, including: the identity of the product that is being recovered or corrected, the estimated number of medical products (e.g., number of tablets or devices) or food items that are subject to recovery or correction, the reason for the action to recover or correct the product, and the geographic distribution of the product, FDA quickly could provide that information to the public, enhancing the Agency's ability to protect the public health. In addition, FDA could provide the public with consistent messages whenever an FDA-regulated product was recalled.

FDA is in the best position to ensure that useful, actionable information is provided to the public about a problem with an FDA-regulated product so that consumers can make informed decisions in response to a recall announcement. In addition, with ready access to key information about a recalled product, health care providers can better evaluate a patient's condition and provide appropriate care.

DRAFT PROPOSAL 19:

If FDA is aware of confusion in the marketplace about products that may be implicated in a food outbreak, and information gathered by industry or other sources may serve to alleviate that confusion, FDA should support efforts by industry and others to communicate information to the public about products that are not subject to the recall when sufficiently reliable information about products not connected with the recall exist, if FDA concludes that disclosure of this information is in the interest of public health.

Reasoning: During a recall of a food product, not only is it important to alert the public when there may be a risk associated with a specific product, it is important for the public to have an understanding about the products that are not implicated in the recall. In situations where the public appears confused about the products implicated in the recall, FDA should, when appropriate, and when sufficiently reliable information about products not connected with the recall exist, support efforts by industry and others to alleviate this confusion.

DRAFT PROPOSAL 20:

If FDA determines that a recall is terminated, that information should be disclosed to the public. A recall is considered terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy and when it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.

Reasoning: Not only is it important to communicate quickly and effectively to the public when there is a risk associated with a FDA-regulated food, but when possible, it is also important to alert the public when the risk has passed and there is no longer a hazard posed by a specific product. FDA should inform the public when a recall has been completed, which will support public health and further the Administration's goal of more transparent government. As a result, FDA should disclose the written notification sent to a recalling firm notifying the firm that FDA considers the recall terminated.

H. Warning and Untitled Letters

1. Background

In the event of a violation of the Federal Food, Drug, and Cosmetic Act, depending on its nature, FDA may give individuals and firms an opportunity to take voluntary and prompt action to correct the violation before FDA initiates an enforcement action.⁸⁶ FDA will issue either a warning letter or an untitled letter to individuals or firms notifying them of such violations to allow them to voluntarily comply with the law.

Warning letters are used for violations that may lead to enforcement action if not promptly and adequately corrected. Untitled letters are used for violations that do not meet the threshold of regulatory significance for a warning letter and request correction of the violations. Unlike a warning letter, an untitled letter does not include a statement that warns the individual or firm that failure to promptly correct the violation may result in enforcement action.

FDA generally is under no legal obligation to warn individuals or firms about violations before taking enforcement action.

⁸⁶ FDA Regulatory Procedures Manual, Chapter 4: Advisory Actions (Mar. 2009).

FDA currently posts warning letters on the FDA Web site and if FDA can determine that a firm has fully corrected violations raised in a warning letter, FDA will issue an official “close-out” notice that also will be posted online. If requested by a recipient of a warning letter, FDA will post the company or individual’s response to the warning letter on the FDA Web site. Some Centers proactively post untitled letters, for example, the Center for Biologics Evaluation and Research (CBER) and the Division of Drug Marketing, Advertising, and Communications (DDMAC) in the Center for Drug Evaluation and Research (CDER).

2. *Summary of Public Comments*

Individuals and consumer groups suggested that FDA disclose all warning letters and untitled letters issued by the Agency. They argued that the public should be informed about firms FDA has determined are in violation of the law and the rationale underlying FDA’s determination, so that members of the public can make more informed decisions about FDA-regulated products.

3. *Considerations*

The Task Force considered the utility of educating the public about violative practices or conditions at firms that market and/or distribute FDA-regulated products and alerting the public to these practices or conditions. Disclosure of violative practices or conditions may increase public accountability of firms, which may deter future violations and increase compliance with the law.

The Task Force took into account the fact that in some circumstances, untitled letters include information about violations that may affect the safety or efficacy of medical products or the safety of the food supply. Additional disclosure of these letters would provide the public with information that can be used to make more informed health decisions. The Task Force also took into account that in other circumstances, an untitled letter is sent for relatively minor violations of the law.

The Task Force considered the potential volume of this information, and whether the volume of the information would diminish the value of disclosing all untitled letters. The Task Force considered that some Centers already disclose untitled letters on the FDA Web site, and the potential benefits of a consistent Agency practice in this area.

4. *Draft Proposal(s) for Public Comment*

DRAFT PROPOSAL 21:

FDA should post untitled letters on the FDA Web site, and, if requested by the recipient of the letter, the response to the untitled letter, as appropriate.

Reasoning: Information in untitled letters reflects problematic practices of regulated firms and individuals and potential public health risks associated with FDA-regulated products. The public has an interest in learning about firms and individuals that violate the FDCA because that information may inform decisions about whether, or from whom, to purchase a product. Further, similarly situated regulated entities can

use this information to determine what activities and practices FDA finds violative, and use the information to modify behavior.

Not all of the information provided in untitled letters reflects problems with FDA-regulated products that may pose a direct risk to the public health. But the public may benefit from improved compliance with the law by regulated firms due to the accountability generated by public disclosure of this information. Transparency about these violative practices and conditions will allow the public to make more informed decisions about the use of FDA-regulated products and further the goals of the Administration for more openness in government.

VI. OTHER AREAS OF PUBLIC COMMENT

A. Advisory Committee Meetings

Several comments from both industry and consumer groups requested that FDA explain the role of an advisory committee recommendation when FDA is making a decision about whether to approve a product application. These comments noted that this explanation is particularly important when FDA does not follow the advisory committee's advice. A consumer group noted that "such transparency will facilitate acceptance and understanding of consumers."

Comments also suggested substantive changes to FDA's advisory committee process, including: the selection of the advisory committee members, the conflict of interest policy and training of advisory committee members.

FDA's advisory committees provide independent expert advice to the Agency on a range of complex scientific, technical, and policy issues. An advisory committee meeting also provides a forum for a public airing of important matters concerning FDA policies and FDA-regulated medical products. Although advisory committees provide recommendations to FDA, FDA makes the final decision. After seeking the views of an advisory committee, FDA does not now always explain how the advisory committee's advice was considered in the Agency's final determination.

The procedures governing advisory committees are set forth in general terms in FDA regulations.⁸⁷ FDA has published several guidance documents about the advisory committee process.⁸⁸

It is FDA's practice to request the curricula vitae of all individuals serving on advisory committees and post them on FDA's Web site where allowed by law. All advisory committee members are trained on the advisory committee process and applicable laws and regulations before participating in their first advisory committee meeting. Information that will be considered by the advisory committee (i.e., the briefing package) is posted online prior to the meeting, with appropriate redaction of non-public information.

The Task Force believes that the basis for FDA's action to approve or not approve a product application should be understood by the public. Explaining how the advice of the advisory committee was relevant to the decision, especially where FDA does not follow that advice, will help the public better understand FDA's decision about whether an application should be approved. Disclosing this information leads to a better

⁸⁷ See 21 C.F.R. Part 14.

⁸⁸ See, e.g., Final Guidance, Guidance for FDA Advisory Committee Members and FDA: Voting Procedures for Advisory Committee Meetings, available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125641.pdf>; Final Guidance, Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees, available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf>.

understanding of the basis for FDA’s decision, increasing Agency accountability and credibility in FDA’s decision-making, and furthering the goals of the Administration for a more transparent and accountable government.

FDA will explain the Agency’s reasons for not following the recommendation of an advisory committee in review documents, and those reasons will be disclosed when those documents are disclosed. In addition, FDA will provide basic explanations to the public about the advisory committee process through the web-based resource, *FDA Basics*.

B. Citizen Petition Process

Comments stated that FDA should disclose the materials reviewed by FDA to respond to a citizen’s petition. Comments stated that disclosure of this information would explain to the public why certain citizen petitions were denied or granted, especially when those determinations “appear to be counter to consumers’ interests.”

When FDA receives a citizen petition, the Division of Dockets Management assigns the petition a docket number and establishes a docket for the citizen petition. Interested parties can submit information relating to the petition to the public docket and these submissions are accessible to the public. The public can submit comments about any pending citizen petition. That information is also added to the docket for that petition and made available to the public.

The information and materials that serve as the basis for FDA’s decision on the citizen petition are explained in the response to the citizen petition. FDA’s response to a petition usually involves an in-depth analysis of the issues raised in the petition and an extensive explanation of the Agency’s rationale for its determination. At the time the response is issued, FDA places in the public docket any published literature that is referenced in the response but has not been placed in the public docket by the petitioner or by commenters.

The Task Force concluded that FDA’s current practice sufficiently explains to the public the reason for its decision on any particular citizen petition. FDA provides the public with a detailed rationale in the response to the citizen petition and provides the public with access to the documents that serve as the basis for FDA’s determination. To the extent a member of the public disagrees with FDA’s decisions, there is a procedure for requesting that FDA reconsider its decision. The Task Force is not recommending changes to current practice.

C. Communicating About Safety Concerns and Emerging Safety Issues

Consumers and industry acknowledged the challenges inherent in risk communication about emerging safety issues with FDA-regulated products. Some comments noted that when the health or safety of the public is at risk, FDA should notify the public about the safety issue. Other comments stated that when FDA does not have usable information to communicate to the public about the safety issue, i.e., “news you can use,” FDA should not issue an official communication to the public. Some industry comments also stated that FDA should make every effort to communicate and coordinate with affected

manufacturer(s) before notifying the public about a safety issue with a FDA-regulated product.

Many comments encouraged FDA to establish principles and criteria for communicating about emerging food safety issues; others noted favorably FDA's development of the *Strategic Plan for Risk Communication* and urged FDA to implement the principles set forth in that document.

FDA determines whether, when, and how to communicate safety information to the public, but FDA does not currently disclose the rationale for its conclusions that a safety issue does or does not merit disclosure. Although some individual Centers have procedures for communicating about safety issues, FDA does not have an Agency-wide set of principles about when and how to communicate this information.⁸⁹

The Task Force believes that it is important to provide the public with a better understanding of FDA's basis for issuing communications about safety concerns with FDA-regulated products. And to the extent possible, the Task Force believes that FDA should communicate risk information to the public in a consistent way. Disclosing the criteria FDA uses to determine whether to communicate about a potential safety problem with a FDA-regulated product will enhance FDA's process for communicating important information to the public that can be used to make healthcare decisions, and further the Administration's goal for more transparency in government operations.

Last fall, FDA announced the *Strategic Plan for Risk Communication* (Strategic Plan), which describes FDA's strategy for improving how it communicates about FDA-regulated products.⁹⁰ As part of FDA's *Strategic Plan*, FDA has committed to identifying consistent criteria for when and how to communicate emerging risk information.

The Task Force concluded that FDA should tell the public the criteria FDA uses to decide whether to communicate about a potential safety problem with an FDA-regulated product, when to communicate that information, and how to effectively communicate that information to target audiences. FDA's implementation of the *Strategic Plan for Risk Communication* will address these issues.

D. Freedom of Information Act

In general, comments stated that FDA should improve the efficiency of the process for requesting and receiving documents via a Freedom of Information (FOIA) request. Many of these comments stated that it took too long to receive a response and some of these

⁸⁹ For example, the Center for Drug Evaluation and Research (CDER) has issued a final guidance for industry that discusses when FDA communicates about an important drug safety issue and when CDER discloses emerging drug safety information. Final Guidance for Industry, Drug Safety Information – FDA's Communication to the Public, *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072281.pdf>.

⁹⁰ FDA, *Strategic Plan for Risk Communication*, *available here* <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm183673.htm>.

comments stated that FDA should implement a fast track process. Some comments stated that FDA should make better use of technology to accept and respond to FOIA requests. A comment stated that FDA should implement a process to ensure that responsive documents were redacted in a consistent manner.

While the Transparency Initiative was not intended to be a review of the FOIA process, the draft proposals for public comment in this report have direct implications on the process FDA uses to implement FOIA. As outlined in Section V, the Task Force believes that the public interest weighs in favor of allowing the public ready access to certain important information and proposes that FDA proactively provide this information to the public. The implementation of any of these draft proposals for public comment will make that information available to the public without the need to submit a FOIA request for the information.

HHS has made reform of the FOIA process a key component of the Department's efforts in support of the Administration's Open Government Directive. The Department is taking steps to improve the FOIA process, including creating a new staff position within the Office of the Assistant Secretary of Public Affairs dedicated to FOIA reform. This person will identify, develop and help implement key FOIA reforms across the Department. FDA is participating in the Department-wide process. FDA also plans to track and disclose measures of performance related to FOIA on a monthly basis. The public will be able to follow FDA's progress on key FOIA-related performance measures online.

E. Inspection Results from Food Facilities

Several comments requested that FDA make inspection results available to the public online, in a timely fashion. Many of these comments identified inspection results from food facilities in particular.

Disclosing observations regarding significant violations found during an inspection of a food establishment, or the knowledge that these may be disclosed, may encourage FDA-regulated food facilities to comply with the law. Further, individuals and companies that purchase products from these entities have an interest in knowing what FDA observed during an inspection of an establishment. Disclosure of the inspectional observations provides companies, federal agencies, and others who may want to contract with, or purchase food products from, these entities with information they can use to make informed decisions.

The Task Force believes that inspection reports contain information that if disclosed, would be helpful in protecting the food supply. But not all of the information in inspection reports is needed to promote the public health. The Task Force believes that some information should be withheld from public disclosure and must be redacted, for example, information about a firm's manufacturing processes. This type of information is usually found in inspection reports.

The Task Force concluded that FDA should explore the feasibility of making inspectional observations from food facilities available to the public quickly. Additional information is needed to determine whether useful information about inspection results can be provided to the public in a manner that does not unduly hamper the ability of investigators to conduct inspections of facilities in a timely manner.

The Office of Foods will convene a workgroup to explore the feasibility of making information about inspectional observations of food facilities more available to the public in a timely fashion, including by re-designing inspection reports to provide a separate summary page of significant inspection results. The Task Force was informed that other jurisdictions have figured out a way to make useful information about inspection results from food facilities available to the public quickly and the workgroup can look to some of those experiences as possible models.

F. Media Policy

Comments from some members of the media stated that FDA's current procedures for dealing with the media restricted the flow of information between the public and FDA personnel. These comments stated that public affairs officials can play an important role answering questions and facilitating interviews, "[b]ut when they forbid, delay or monitor contact between reporters and employees, they interfere with the public's right to know and can delay access to timely information necessary to protect and advance public health." Comments stated that prior administrations allowed more communication between FDA employees and the media and that FDA's practice is not universal among federal agencies.

A conference call was held on April 12, 2010 with representatives from the Association of Health Care Journalists and the Society of Environmental Journalists to follow-up on the comments they submitted to the Task Force. During the call, representatives provided suggestions on ways FDA can facilitate contacts with the press, including holding regular conference calls about activities at the agency, providing the press with a list of agency experts by topic area, and committing to return calls from the press within two hours. Participants stated that FDA would benefit from a written media policy. One participant noted that implementing a media policy is "harder at regulatory agencies," such as FDA.

Given FDA's regulatory authority and responsibility, it is very important that FDA provide information to the news media as promptly and accurately as possible. Like many other public agencies, FDA has a public affairs office to facilitate and coordinate requests from the media. On average, the public affairs office fields between 50 and 100 inquiries from journalists every day. FDA personnel may establish a record of what is discussed to improve their own understanding of issues and to identify additional information of relevance that can be shared with the journalists.

FDA plans to track and disclose measures of performance related to its interactions with the media and will start by tracking the number of press inquiries received each month. FDA will also draft a policy outlining FDA's media process and post this policy on its

Web site. FDA will continue to explore additional ways to make the Agency's system as effective as possible.

In addition, the Department of Health and Human Services, as part of the President's Open Government Initiative, is reviewing the media policies of various HHS agencies. FDA will participate in this process.

G. Meetings with Stakeholders

Comments stated that FDA should post a calendar that lists meetings with certain members of the public. One comment stated that "any important official meetings" between FDA and industry representatives should be disclosed while other comments stated that FDA should disclose meetings with external stakeholders as well as industry. One comment stated that the name and affiliation of attendees as well as the date, time, location, and subject of the meeting should be disclosed.

FDA staff interact with the public frequently, from scheduled in-person meetings, to unscheduled phone calls and emails about the status of a matter. Many meetings with industry are about product applications under review, thus proprietary information is discussed at such meetings and may be apparent if FDA discloses details about the subject of the meeting. Meetings with patients and patient groups may concern specific FDA-regulated products for certain diseases, thus personal information may be discussed at the meeting, in which case it would not be appropriate to disclose both the subject of the meeting and the names of the patients participating. Capturing an increased level of detailed information regarding all those interactions would consume significant Agency resources but provide little insight about the functioning of the Agency.

Under FDA's current regulations significant meetings with persons outside the executive branch involving FDA leadership are disclosed. On a weekly basis, FDA posts to a public calendar significant meetings, conferences, seminars, speeches, and social events sponsored by regulated industry that are attended by the FDA Commissioner, Principal Deputy Commissioner, the Deputy Commissioners, the Associate Commissioner for Regulatory Affairs, Center Directors, or the Chief Counsel.⁹¹ The calendar provides the date and subject matter of the meeting.

The Task Force concluded that listing all meetings held by all Agency personnel would not provide the public with a corresponding level of understanding about FDA and how it does its work. Information about significant meetings held by the key policy makers at FDA, however, is publicly available and easily accessible on the FDA Web site. The Task Force recommends that FDA continue its current practice.

⁹¹ Food and Drug Administration, Past Meetings With FDA Officials, *available at* <http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/PastMeetingsWithFDAOfficials/default.htm>. *See also* 21 C.F.R. § 10.100.

VII. NEXT STEPS

A. Phase II

The Task Force will solicit comments on the draft proposals for public comment set forth in this report for 60 days. Comments will be solicited via www.regulations.gov as well as the FDA Web site, www.fda.gov/transparency. As part of the comments, FDA is seeking public input on which draft proposals should be given priority and the tools, techniques, and processes the Agency can use to improve transparency and efficiency, while reducing costs.

Based on this input, the 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. Some of the draft proposals may require extensive resources to implement, and some may require changes to regulations and possibly even legislation. As a result, the Task Force may ultimately recommend some, but not all, of the draft proposals for implementation.

For proposals that are implemented, FDA will assess whether implementation is allowing the Agency to more effectively achieve its mission of protecting and promoting the public health.

B. Phase III

The final phase of the Transparency Initiative will address FDA's transparency to regulated industry. The Task Force published a notice soliciting comments until April 12, 2010. Comments were also solicited via the FDA Transparency Blog. These comments will be used to inform draft proposals the Task Force will put forward this summer on ways FDA may improve transparency to regulated industry and foster a more efficient and cost-effective regulatory process.

VIII. APPENDIX: GLOSSARY OF ACRONYMS AND ABBREVIATIONS

AERS: Adverse Event Reporting System

AI: Additional Information Letter

ANADA: Abbreviated New Animal Drug Application

ANDA: Abbreviated New Drug⁹² Application

BLA: Biologics Licensing Application

BPCA: Best Pharmaceuticals for Children Act

CBP: United States Customs and Border Protection

CBER: Center for Biologics Evaluation and Research

CDER: Center for Drug Evaluation and Research

CMC: Chemistry, Manufacturing, and Controls

DDMAC: Division of Drug Marketing, Advertising, and Communications

DOJ: Department of Justice

EIR: Establishment Inspection Report

EMA: European Medicines Agency

FDA: Food and Drug Administration

FDAAA: Food and Drug Administration Amendments Act

FDCA: Federal Food, Drug, and Cosmetic Act

FOIA: Freedom of Information Act

HHS: Department of Health and Human Services

ICMJE: International Committee of Medical Journal Editors

ICSR: Individual Case Study Report

IDE: Investigational Device Exemption

INAD: Investigational New Animal Drug

IND: Investigational New Drug Application

IRB: Institutional Review Board

JAMA: Journal of the American Medical Association

MAUDE: Manufacturer and User Facility Device Experience

MDR: Mandatory Medical Device Reporting

NADA: New Animal Drug Application

NAI: No Action Indicated

NDA: New Drug Application

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

NEJM: New England Journal of Medicine

NIH: National Institutes of Health

NLM: National Library of Medicine

NSE: Not substantially equivalent

OAI: Office Action Indicated

ORA: Office of Regulatory Affairs

OTC: Over-the-counter

PhRMA: Pharmaceutical Research and Manufacturers of America

PMA: Premarket Approval Application

PREA: Pediatric Research Equity Act

SEC: Securities and Exchange Commission

VAERS: Vaccine Adverse Event Reporting System

VAI: Voluntary Action Indicated