

Food and Drug Administration Report on Good Guidance Practices

Improving Efficiency and Transparency

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INTRODUCTION

On January 21, 2009, President Obama issued a memorandum urging the heads of executive departments and agencies to create an “unprecedented level of openness” to “strengthen our democracy and promote efficiency and effectiveness.”¹ In response, the following June, the Commissioner of Food and Drugs, Dr. Margaret A. Hamburg, launched the Food and Drug Administration (FDA or the Agency) Transparency Initiative, noting that “increasing our openness will help us more effectively implement our mission to promote and protect the public health.” As part of this initiative, the Commissioner formed an internal task force (the Task Force) to develop recommendations for enhancing the transparency of FDA’s operations and decision-making processes.

The Task Force is proceeding with the Transparency Initiative² in three phases:³

- Phase I: *FDA Basics*⁴ – In January 2010, FDA launched a web-based resource called *FDA Basics*, which provides the public with basic information about FDA.
- Phase II: Public Disclosure⁵ – In May 2010, the Task Force released a report with draft proposals to increase FDA transparency, while protecting confidential information.
- Phase III: Transparency to Regulated Industry⁶ – In January 2011, the Task Force released a report (Phase III Report) with 19 action items and 5 draft proposals to make FDA more transparent and to foster a more efficient and cost-effective regulatory process.

In action item 11 of the Phase III Report, the Commissioner called for a cross-Agency Working Group (Working Group) to prepare a report identifying FDA’s “best practices” and making recommendations to: (1) streamline the development of guidance documents, (2) reduce the time between issuing draft and final guidance documents, and (3) make it easier to find guidance documents on FDA’s website.⁷

¹ Memorandum <http://edocket.access.gpo.gov/2009/pdf/E9-1777.pdf> to Heads of Executive Departments and Agencies on Transparency and Open Government, Jan. 21, 2009, 74 Fed. Reg. 4685 (Jan. 26, 2009).

² See also FDA’s [Transparency Initiative Homepage](http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm2023681.htm) <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm2023681.htm>.

³ See generally, FDA Transparency Initiative: Improving Transparency to Regulated Industry, dated Jan. 2011 ([Phase III Report](http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/default.htm))

<http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/default.htm>, at 6-8, available on FDA’s Transparency Initiative webpage.

⁴ *FDA Basics* <http://www.fda.gov/AboutFDA/Transparency/Basics/default.htm>.

⁵ FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration ([Phase II Report](http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure/default.htm)) <http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure/default.htm>.

⁶ [Phase III Report](http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/default.htm) <http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/default.htm>

⁷ See *id.* at 32.

Guidance documents are documents prepared for FDA staff and/or Agency stakeholders that describe the Agency's interpretation of, or policy on, a regulatory issue.⁸ Guidance documents include documents that relate to: (1) the design, production, labeling, promotion, manufacturing, and testing of regulated products, (2) the processing, content, and evaluation or approval of submissions, and (3) inspection and enforcement policies.⁹ Unlike statutes and regulations, guidance documents themselves cannot generally create legally binding requirements.¹⁰

Section 701(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)¹¹ directs FDA to establish uniform procedures for issuing guidance documents. FDA's Good Guidance Practices (GGP) regulation¹² implements that provision and establishes two types of guidance documents, Level 1 and Level 2. Level 1 guidances are those that: (1) set forth initial interpretations of statutory or regulatory requirements, (2) set forth changes in interpretation or policy that are of more than a minor nature, (3) include complex scientific issues, or (4) cover highly controversial issues.¹³ Level 2 guidances, in contrast, "set forth existing practices or minor changes in interpretation or policy."¹⁴

Typically, FDA solicits input on Level 1 guidances prior to implementation, and in preparing the final guidance, it reviews and considers the comments that it has received.¹⁵ Both draft and final Level 1 guidances are posted on FDA's website, and notices of availability (NOAs) regarding the guidances are published in the *Federal Register*.

FDA does not solicit public input on Level 1 guidances for which "prior public participation is not feasible or appropriate"¹⁶ (i.e., Level 1 guidance "for immediate implementation"), nor does FDA solicit public input on Level 2 guidances prior to implementation. However, FDA posts Level 1 guidances "for immediate implementation" and Level 2 guidances on its website, and stakeholders may comment on them at any time *after* they have been issued. FDA reviews the comments and revises the guidances, as appropriate.¹⁷

FDA issues a significant number of guidances each year. In 2010, for example, FDA issued 103 Level 1 guidances. Because guidances are critical to support industry efforts to comply with the law and to develop new products that may benefit the public health, they must be relevant, timely, and easy for stakeholders to find. Accordingly, in response to the directive in the Phase III Report, this report identifies current "best practices" and recommends strategies that may make the Agency's guidance processes more efficient and transparent. The report focuses on the following stages of the guidance life-cycle:

⁸ See 21 C.F.R. § 10.115(b) (2011).

⁹ See *id.*

¹⁰ See *id.* § 10.115(d).

¹¹ 21 U.S.C. § 371(h) (Supp. 2011).

¹² See 21 C.F.R. § 10.115.

¹³ See *id.* § 10.115(c)(1).

¹⁴ *Id.* § 10.115(c)(2).

¹⁵ See generally, 21 C.F.R. § 10.115(g).

¹⁶ *Id.* § 10.115(g)(2).

¹⁷ See *id.* § 10.115(g)(3), (4).

(1) Initiating Guidance (*i.e.*, the decision to begin developing guidance), (2) Prioritizing/Work Planning/Tracking Guidance, (3) Developing Guidance, (4) Reviewing and Clearing Guidance, and (5) Issuing Guidance and Outreach. Notably, the recommendations included in this report incorporate a number of innovative strategies that have already been implemented by various Centers/Offices.

The cross-Agency Working Group that prepared this report, under the leadership of the Office of Policy (OP), included senior policy leaders from FDA's six product Centers and a number of individual offices that also participate in the issuance of guidance, as follows:

- Center for Biologics Evaluation and Research (CBER),
- Center for Drug Evaluation and Research (CDER),
- Center for Devices and Radiological Health (CDRH),
- Center for Food Safety and Applied Nutrition (CFSAN),
- Center for Tobacco Products (CTP),
- Center for Veterinary Medicine (CVM),
- Office of Regulatory Affairs (ORA),
- Office of Special Medical Programs (OSMP),
- Office of Counterterrorism and Emerging Threats (OCET),
- Office of Foods (OF),
- Office of Critical Path Programs (OCPP), and
- Office of Chief Counsel (OCC).

This report focuses on the guidance processes in the six Centers and in OF. The other Offices that issue guidance tend to be smaller, issue fewer guidances, and have less formal procedures or adopt procedures from the Centers. The recommendations in the report, however, should be considered by each Center/Office that issues guidance or participates in the process.

The Working Group notes that many of the report's recommendations involve establishing and implementing written processes and templates to make guidance development more efficient. Although documented processes in many circumstances will expedite the issuance of final guidance, the Working Group recognizes that the processes must be flexible enough to enable FDA to issue emergency guidance, as needed. The Working Group also notes that these recommendations focus on Agency "best practices." The Working Group recognizes, however, that other factors, such as limited resources, competing priorities, and interagency review, directly affect the speed at which guidance is issued. It is understood that such factors must also be taken into consideration when issuing guidance.

FDA is issuing this report to the public to make its decision-making processes regarding guidance more transparent. The Agency looks forward to engaging with its stakeholders as it continues to seek opportunities to improve the efficiency and transparency of the guidance life-cycle.

CHAPTER 1: INITIATING GUIDANCE

The first phase in the guidance life-cycle is guidance initiation, the process that FDA Centers/Offices use to decide whether to develop a guidance document. In reviewing the different guidance initiation processes at the Centers,¹⁸ the Working Group focused on improving efficiency and transparency.

I. Summary of Current Guidance Initiation Practices

A. Current Stakeholder Input Prior to Guidance Development

FDA's GGP regulation specifically provides that stakeholders can: (1) suggest guidance topics, and/or (2) submit drafts of proposed guidance.¹⁹ Stakeholders often informally identify issues that would benefit from guidance at advisory committee meetings, industry meetings, roundtables, and listening sessions. Stakeholders also submit citizen petitions to identify policy issues that the Agency may decide to address by issuing guidance.²⁰ Because of resource constraints, however, FDA is not always able to issue guidance in response to stakeholder suggestions, or to issue guidance as expeditiously as it would like.

Recently, several Centers/Offices have been encouraging stakeholders to submit *draft guidance* to the Center/Office, for consideration, at a variety of different industry events, such as trade association meetings and on the FDA website.²¹ Submitting *draft guidance*, rather than guidance topics, enables the Center/Office to approach a guidance topic with a better understanding of the issues that interest the stakeholder. This may expedite the guidance development process, particularly if the topic involves novel scientific issues.

To generate additional stakeholder input and inform the stakeholder community about FDA's plans for guidance development, FDA's GGP regulation also requires FDA to publish an annual guidance agenda, listing "possible topics for *future* guidance document development or revision during the next year,"²² in the *Federal Register* and on the Internet. During its review, the Working Group observed that each of the Centers/Offices has different standards for determining which guidances to list on the annual agenda. For example, some Centers list guidances that they plan to publish in the calendar year while others list guidances that they are considering developing, as well as those that they expect to publish in the calendar year. The Centers/Offices unanimously agreed that establishing uniform criteria for the guidance agendas and making those criteria public would better inform stakeholders about FDA's plans to develop or revise guidance.

¹⁸ OF does not have practices to determine whether a guidance should be initiated because the guidances it is developing are required by the Food Safety Modernization Act of 2011 (FSMA).

¹⁹ See 21 C.F.R. § 10.115(f)(2)-(3).

²⁰ See *id.* § 10.30 (governing Citizen Petitions).

²¹ See Documents the Center for Devices and Radiological Health is Considering for Development (FY11), listed on the [Device Advice](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm) webpage. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm>

²² 21 C.F.R. § 10.115(f)(5); see Fiscal Year 2011 Guidance Agenda, 75 Fed. Reg. 76011 (Dec. 7, 2010).

The Working Group also noted that the requirement to publish a comprehensive guidance agenda annually in the *Federal Register* is administratively burdensome and that because priorities shift, the list is often outdated by the time it is published. Moreover, the *Federal Register* requirement is redundant because each Center/Office already is required to post a guidance agenda on the Internet. Internet posting permits Centers/Offices to update their guidance agendas more frequently, making the agendas more useful to stakeholders.

B. Current Decision-Making Processes For Initiating Guidance

To determine whether a particular guidance should be developed, most of the Centers use high-level documents, such as guidance initiation forms (GIFs). CDER's form, for example, provides: (1) guidance initiator information, (2) author information, (3) the guidance topic, (4) the guidance objective, (5) working group requirements, (6) resource requirements, and (7) the projected date of issuance.²³ Other Centers use "concept papers" to determine whether to develop guidance. "Concept papers" are generally longer than GIFs and may include additional information that the Centers find helpful in their decision-making process, as well as in the guidance development process.

In some Centers, the decision to develop guidance is made by an individual, generally by the director of the lead office or the director of the Center's regulations staff. In others, the decision is made by a lead office leadership team, the entire senior staff at the Center, or a management council. In still others, circumstances dictate whether an individual or a management council makes the decision. During the review, a number of Centers/Offices noted that either an individual or a management council may make decisions efficiently, as long as there is a process to help the guidance initiator quickly identify the decision-maker(s).

The Centers/Offices also observed that some low priority guidances that are approved for development are never completed, or are outdated by the time of completion. The Centers/Offices suggested that it may be helpful for guidance initiators to better communicate with decision-makers during the guidance initiation process about the guidance objective and how they believe it fits within the larger Office, Center, and Agency programs and priorities. This information would help inform management prioritization decisions (see discussion in Chapter 2), if the guidance is approved for development.

II. Recommendations

²³ See CDER's Guidance Initiation Sheet in Manual for Policies and Procedures, "Developing and Issuing Guidance," [MAPP 4000.2](http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm073004.pdf), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm073004.pdf>

Recognizing that each Center/Office that issues guidance documents has different demands and resource constraints, the Working Group recommends the following strategies to make the guidance initiation process more efficient:

- (1) Centers/Offices should encourage stakeholders to submit draft guidance to Centers/Offices for consideration, in addition to guidance topics, if such drafts would help advance the Center/Office's understanding of a particular issue and expedite the guidance issuance process;
- (2) FDA should revise the GGP regulation to require the Agency to publish the annual guidance agenda on the Internet only. Eliminating the *Federal Register* publication requirement would reduce the Agency's burden and increase efficiency. Moreover, it would prevent stakeholders from being confused by the outdated information in the notices, which would also advance transparency (see Recommendation 5, bullet 2, below); and
- (3) Each Center/Office should develop a written guidance initiation process to ensure that: (1) guidance initiators understand how to get guidance development approved expeditiously, and (2) decision-makers better understand the objective of the guidance, how it fits with other Office, Center, and Agency programs and priorities, and/or other requirements necessary to issue the document. The written process should achieve the following:
 - Identify decision-maker(s) and
 - Require guidance initiators to, among other things:
 - Disclose guidance initiator/author contact information,
 - Identify affected Centers/Offices to ensure that appropriate individuals are included in the development process,
 - Clarify guidance objectives and/or concepts,
 - Address the potential burden on the lead Center/Office and affected Centers/Offices,
 - Address how the guidance relates to the Center/Office programs and priorities to better inform management prioritization decisions if the guidance is approved for development (see Chapter 2, Recommendation 1), and
 - Address the potential effect of the guidance on stakeholders and potential stakeholder response.

The Working Group also recommends the following strategies to make the guidance initiation process more transparent:

- (4) Each Center/Office should use the same standard for listing developing guidance on its annual guidance agenda, namely, whether the Center/Office expects to publish the guidance within the next year. Using this uniform standard will align

- stakeholder expectations as to when guidance will issue and increase predictability;
- (5) FDA, as a whole, as well as the individual Centers/Offices, should implement strategies to improve the dialogue with stakeholders regarding the guidance agenda and potential topics for guidance development. For example, strategies could include:
- Describing on *FDA Basics for Industry*²⁴ ways in which interested individuals can provide input to the Agency about guidance development,
 - Providing links to each Center/Office's annual guidance agenda on *FDA Basics for Industry*²⁵ and updating the guidance agenda, and/or
 - Posting on *FDA Basics for Industry*²⁶ lists of guidance topics under consideration.

CHAPTER 2. PRIORITIZING/WORK PLANNING/TRACKING GUIDANCE

The second phase in the guidance life-cycle involves prioritizing, work planning, and tracking guidance. During this review, the Centers/Offices suggested that these tools could be better used to allocate resources and to make the guidance development and review/clearance processes more efficient.

I. Summary of Center/Office Prioritizing/Work Planning/Tracking Processes

Each of the Centers/Offices considers roughly the same factors in determining how to prioritize guidance documents. For example, among other factors, Centers/Offices generally consider whether the guidance involves a significant public health issue, whether the guidance must be issued by a specific statutory deadline, and whether the guidance would save FDA or industry resources. During the review, the Working Group observed that systematic prioritization processes better enable the lead Center/Office to allocate resources for guidance documents based on priorities relative to other guidances and on resources available to devote to guidance development.

In addition, each of the Centers and OF engages in work planning prior to drafting guidance. However, some Centers/Offices have formal templates and others do not. Of the formal templates, only CDER's has recommended time-frames for each individual milestone, although CDRH has suggested time-frames for each phase of review. Other Centers/Offices develop time-frames on a guidance-by-guidance basis.

Finally, with regard to tracking, most of the Centers/Offices that we interviewed begin tracking guidance immediately after the decision is made to develop it. The

²⁴ *FDA Basics for Industry*, <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm>

²⁵ *Id.*

²⁶ *Id.*

Centers/Offices employ a number of different tracking methods, such as cover sheets and internal databases that use e-rooms, commercial software, and/or web-platforms.

In the Office of the Commissioner, OP's Regulations Policy and Management Staff (RPMS) also employs an Agency-wide tracking system for all documents that are published in the *Federal Register*, including NOAs, which accompany all Level 1 guidances and may accompany certain Level 2 guidances, such as Small Entity Compliance Guides. The tracking system is web-based, and FDA staff in all affected Centers/Offices can sign into the system to check on a document's progress. Centers are asked to create a record in the system as soon as they determine that a Level 1 guidance and accompanying NOA will be developed. In practice, however, records often are not created until later in the process. The Agency is in the process of updating and enhancing this tracking system.

II. Recommendations

Recognizing that each Center/Office that issues guidance documents has different demands and resource constraints, the Working Group recommends the following strategies to help Centers/Offices better allocate resources and to make the guidance development and review/clearance processes more efficient:

- (1) Each Center/Office should establish a systematic prioritization process. The process should be dynamic and permit the Center/Office to adjust priorities as needed, so that they are consistent with Center and Agency priorities. Resources should be assigned to guidances based on priority relative to other guidances and on resources available to devote to guidance development; and
- (2) Each Center/Office should implement work planning and tracking strategies to ensure that affected staff are fully aware of established time-frames. These strategies may include:
 - Better, more integrated tracking systems (*e.g.*, the Agency-wide tracking system that RPMS is enhancing and updating), and
 - Developing work plans with target milestones and managing guidance development against those milestones.²⁷

²⁷ Milestones may need to be adjusted to account for changes in available resources and shifts in priorities.

CHAPTER 3. DEVELOPING GUIDANCE

The next phase in the guidance life-cycle is guidance development. This phase often involves: (1) establishing working groups, and (2) developing concepts and drafting the guidance. A summary of these processes and recommendations to make them more efficient follow.

I. Summary of Guidance Development Processes

A. Establishing Working Groups

FDA Centers/Offices that issue guidance tend to treat guidance development as a group project, although there are circumstances when a guidance is developed by a single author. When working groups are used, their size, make-up, and structure tend to vary from project to project, although there are many common elements. Generally, the lead office determines the structure and make-up of a working group. Working groups typically include a chair (often from the lead office), subject matter experts (SMEs) from the lead Center/Office, SMEs from other affected Centers/Offices, and individuals from some other affected Centers/Offices who are required to review and clear the document (*e.g.*, OCC).

During the Working Group's review, the Centers/Offices identified a number of inefficiencies that can arise in working groups: (1) failure to include staff from OCC and other affected offices early in the process, which can lead to the need to revisit policy decisions late in the development process and cause delay, (2) over-inclusive working groups, the reverse of the first inefficiency, which can lead to inefficient development of deliverables and/or strain resources from less affected Centers/Offices, (3) failure to clearly define roles and responsibilities, which can lead to duplicative efforts, (4) failure of working group members to keep management informed about policy issues discussed and resolved in the working group, which can lead to revisiting issues during the review and clearance process, and (5) a preference for reaching consensus within the working group, which can lead to protracted discussions, delay in decision-making, and/or the revisiting of contentious issues at the management level during the review and clearance process.

B. Developing Concepts and Drafting the Guidance

Some Centers consider drafting the guidance to be the most challenging aspect of guidance development, and it is often the most time-consuming step in the guidance development process. During this review, the Centers/Offices observed that the writing process can stagnate if: (1) the working group does not thoroughly identify and resolve major policy issues, (2) the technical SME (or other writer) who has been assigned to the project is not a strong writer, or (3) the SME has competing priorities, such as review responsibilities.

Most Centers/Offices often rely on GIFs, outlines, concept papers, or a combination of these to clarify concepts before drafting the guidance. CVM takes this a step further, creating a detailed story board even after preparing a GIF and a concept paper. This process is intended to refine the concepts to the point that drafting the guidance simply involves converting the story board concepts into plain language. The Centers/Offices observed that outlines, concept papers, and story boards can expedite drafting in certain circumstances, but noted that they may not be necessary for every guidance.

During this review, a number of Centers/Offices suggested that employing editors or professional writers to translate detailed story boards or concept papers into guidances could also expedite the drafting process. Currently, however, the Centers that use editors tend to use them in other ways. CDER, for example, sometimes consults with an editor early in the drafting process to discuss how a guidance should be organized, and the Center always has an editor review a draft of the guidance to put technical jargon into plain language, to the extent possible, and ensure that the guidance complies with the GGP regulation. Similarly, CVM, at times, uses editors in the drafting process. Although using editors in these ways may not make the drafting process faster, it significantly improves the quality of the documents, which expedites the review and clearance processes later in the guidance life-cycle.

In addition, most Centers have templates for guidance, and all of the Centers have templates for NOAs. These templates can expedite drafting the non-substantive components of those documents and ensure that the documents meet Center and/or Agency formatting requirements. OP's RPMS also has NOA templates that can be used by each Center.

II. Recommendations

Recognizing that each Center/Office that issues guidance documents has different demands and resource constraints, the Working Group recommends the following strategies to make the guidance development processes more efficient:

- (1) For training purposes, Centers/Offices should develop “best practices” for working groups to ensure that they operate efficiently. These “best practices” should recognize that each guidance has different needs, and they should direct the guidance leads to consider strategically the following:
 - Whether a working group is necessary,
 - Whether the issues in the guidance are cross-cutting, such that the lead should reach out to other Centers/Offices,
 - How to include staff from non-lead Centers/Offices in the working group during the early stages of, and throughout, the guidance development process so that they have the opportunity to help shape the guidance,
 - Whether smaller core working groups could more efficiently develop specific deliverables,

- How to clearly delineate roles and responsibilities for each working group member to prevent duplicative efforts,
 - How to keep management informed about policy issues discussed and resolved in the working group so that those issues are not revisited during the review and clearance process, and
 - Whether it may be helpful to develop procedures to elevate and resolve key issues that the working group cannot resolve expeditiously;
- (2) Centers/Offices also should implement additional strategies to expedite the guidance drafting process. These strategies may include the following:
- Choosing authors carefully to ensure that they have the requisite scientific and drafting expertise, or appropriate support (e.g., technical writers or professional editors) to draft quality guidance documents expeditiously,
 - Developing Center/Office-specific guidance templates to expedite the drafting process and ensure that the guidance meets Center and/or Agency formatting requirements, and
 - Placing deliverables related to guidance development in the performance plans of SMEs and others with key roles in the guidance drafting process.

CHAPTER 4. REVIEWING AND CLEARING GUIDANCE

The next phase in the guidance document life-cycle is Agency-wide review and clearance.²⁸ A summary of these processes and recommendations to improve efficiency follow.

I. Summary of the Review and Clearance Processes

Each of the Centers require guidance documents to be reviewed internally, at the office level and Center level, and externally by other affected Centers/Offices, prior to formal clearance. At most of the Centers, the lead office, the working group, or the regulations and policy staff will identify reviewers within the Center, and if appropriate, other parts of the Agency, on a case-by-case basis.

Typically, clearance for Level 2 guidance only requires clearance within the Center from certain principals, such as the director of the lead office, directors of other offices affected by the guidance, the director/associate director of the policy office, and at times, the Center Director.

Level 1 guidance requires the same Center-level formal clearance as Level 2 guidance, and in some circumstances, it also requires formal clearance from OCC, Paperwork

²⁸ After formal clearance at the Agency level, the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB) have the opportunity to review certain Level 1 guidance documents, which they have designated previously.

Reduction Act of 1995 (PRA) specialists, OP, the Office of Policy and Planning (OPP), and/or other affected Centers/Offices.

In preparing this report, the Working Group identified two primary inefficiencies in the review and clearance processes: (1) failure to meet review/clearance time-frames (or inappropriately long time-frames), and (2) multiple review/clearance cycles. During the interviews, the Centers/Offices noted that these inefficiencies often arise when the review/clearance phase is the point at which policy decisions are made. If reviewers and managers have not been informed about contentious issues during the development process, the review process may trigger a series of meetings, significant revisions, and multiple review cycles. Many of the Centers/Offices interviewed already have implemented strategies to minimize these issues, and these strategies have been incorporated into the recommendations below.

II. Recommendations

Recognizing that each Center/Office has different demands and resource constraints, each Center/Office should consider implementing strategies to encourage compliance with review/clearance time-frames, and prevent multiple review/clearance cycles, both within their own organizations and when reviewing documents from other parts of FDA. The strategies, for example, may include the following:

- (1) Identifying cross-cutting issues early, so that affected Centers/Offices are brought into the process prior to the review/clearance phase,
- (2) Resolving policy issues before the review/clearance phase so that the formal review/clearance processes are not used to address or revisit contentious issues,
- (3) Streamlining the review/clearance processes in a number of ways:
 - Improving communication between staff and management in multi-tiered review processes, so that each level of review is less iterative and the final review is more ministerial,
 - Identifying the appropriate reviewers prior to initiating clearance to avoid requesting clearance unnecessarily from certain individuals or offices,
 - Delegating authority to clear documents to additional senior staff, and
 - Limiting multi-level reviews within the same office to controversial or otherwise difficult documents.
- (4) Entering into inter-Center/Office agreements that establish goals for review/clearance time-frames. Even though the goals may not always be met, these documents can align expectations and promote collaboration and respect among the various groups. The time-frames should be flexible and take into consideration Center and Agency priorities, the complexity of the subject matter, and the length of the document, among other things.

- (5) Encouraging compliance with review/clearance time-frames by:
 - Clearly communicating expectations that established time-frames be met,
 - Clearly communicating any obstacles to meeting established time-frames, as they arise, and working to resolve those obstacles,
 - Improving tracking/project management systems, and
 - Establishing internal review/clearance targets to establish clear expectations.
- (6) Enhancing processes to expedite and facilitate the review/clearance processes. Strategies may include the following:
 - Facilitating clearance by the use of voting buttons that permit reviewers to: (a) concur, (b) concur with comments, (c) non-concur with comments, and (d) acknowledge receipt without comments,
 - Highlighting issues relevant to individual reviewers, and
 - Facilitating reviewer briefings and/or targeted dialogues between the reviewer and the author, SME, or other lead on the guidance.
- (7) Establishing clear expectations with regard to limited review cycles, the appropriate scope of review for each reviewer, and deference to author writing styles. This may be accomplished with the following:
 - Training sessions,
 - Established standard operating procedures (SOPs),
 - Better two-way communication between reviewers and working groups, and
 - Center/Office-specific documents regarding “best practices” for review/clearance.

CHAPTER 5. ISSUING GUIDANCE AND OUTREACH

The final phase in guidance development involves issuing final guidance, and after the guidance is issued, making internal and external stakeholders aware of the guidance. A summary of the processes involved in this phase and recommendations to make the processes more efficient and transparent follow.

I. Summary of Guidance Issuance and Outreach Processes

The GGP regulation prescribes FDA’s guidance issuance processes. As mentioned, FDA generally solicits public input on a Level 1 guidance prior to implementation, and in preparing the final guidance, the Agency reviews and considers the comments that it has received.²⁹ Both draft and final Level 1 guidances (including Level 1 guidance “for

²⁹ See generally, 21 C.F.R. § 10.115(g).

immediate implementation”) are posted on FDA’s website, and NOAs regarding the guidances are published in the *Federal Register*.

FDA does not solicit public input on Level 2 guidances, which in most cases are issued without NOAs, nor on Level 1 guidances “for immediate implementation”³⁰ prior to implementation. However, FDA posts Level 2 guidances and Level 1 guidances “for immediate implementation” on its website, and stakeholders may comment on them at any time *after* they have been issued. FDA reviews the comments and revises the guidances, as appropriate.³¹

During this review, the Working Group focused on identifying Agency-wide and Center/Office-specific “best practices” to: (1) make the finalization of guidance more efficient and expeditious, and (2) increase transparency by increasing awareness of recently issued and withdrawn guidances.

A. Processes for Finalizing Guidance

During this review, the Working Group identified the following “best practices” for issuing final guidances more expeditiously:

- Many work plans only include the milestones that occur between developing and issuing the *draft* guidance and do not address the milestones that occur between issuing the *draft* guidance and the *final* guidance, such as reviewing comments on Level 1 guidance, revising the guidance, and clearing and issuing the *final* guidance. A number of Centers and individual offices, including CDER and CVM’s Office of New Animal Drug Evaluation (ONADE), reported that they have reduced delay in finalizing guidance by including these additional milestones;
- CDER encourages working groups to resolve issues raised by the comments on draft guidance within six months after the comment period closes, and CDER is developing recommended target milestones for completing final guidances after the draft guidance comment period closes;
- CDRH has responded to the difficulty of issuing guidance rapidly enough to keep pace with emerging scientific information³² by issuing an SOP outlining the use of Notice to Industry letters. These letters will be used to notify affected manufacturers of changes in data submission expectations in response to scientific advances.³³ The Center plans to issue the letters that are considered guidance as Level 1 guidance “for immediate implementation.” Level 1 guidance may be issued “for immediate implementation” if “prior public participation is not feasible or appropriate.”³⁴

³⁰ See *id.* § 10.115(g)(2).

³¹ See *id.* § 10.115(g)(3), (4).

³² See [CDRH Preliminary Internal Evaluations](http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM220783.pdf)

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM220783.pdf> - Volume II: Task Force on the Utilization of Science in Regulatory Decision Making, Preliminary Report and Recommendations, Aug. 2010, at 4-5.

³³ See 76 Fed. Reg. 43693 (July 21, 2011).

³⁴ 21 C.F.R. § 10.115(g)(2).

CDRH's SOP for these letters also includes an abbreviated initiation and development process and uniform templates to expedite development and review; and

- On occasion, several Centers/Offices have finalized draft guidance that does not receive any substantive comments expeditiously, after the comment period closes, by streamlining review and moving to formal clearance more quickly.

In addition, a number of Centers/Offices observed that the “best practices” for working groups, identified in Chapter 3 (*e.g.*, delineating working group member roles, ensuring appropriate staffing, keeping management informed, and quickly elevating contentious issues for resolution) are also relevant to expeditiously finalizing guidance documents.

Similarly, in the finalization phase, as with the guidance initiation phase and the work planning, prioritization, and tracking phase, it is critical to have clear communication between the reviewers and the working group regarding how the document fits with other Office, Center, and Agency programs and priorities, and it is critical to have appropriate resources. Some have questioned how the Agency should balance the need to publish new draft guidance against the desire to complete final guidances that are already out in draft, given limited Agency resources for guidance development.

B. Making Stakeholders Aware of Draft and Final Guidances

The GGP regulation requires FDA to annually provide stakeholders with a list of existing guidances and to identify guidance documents that have been withdrawn from the list in the past year.³⁵ In addition, all the Centers/Offices conduct outreach on significant guidance, which may include, among other things, press releases, workshops, and social media.

One office in the Office of the Commissioner, OCPP, is considering the routine use of webinars to increase awareness of recently issued significant guidance. OCPP is considering hosting webinars on certain guidances, shortly after they are issued, to increase transparency, and in the case of draft guidances, to create a more robust dialogue with industry that could inform and improve the final guidance. OCPP is planning to launch its webinar series in late 2011. The webinars will be recorded and posted on the *FDA Basics for Industry* website.³⁶

Notably, as part of *FDA Basics*,³⁷ the Agency also hosts high-level, 30 minute, on-line webinars each month, where FDA officials give overviews of certain topics, some of which may involve recent guidance documents. These monthly on-line sessions provide the public with an opportunity to ask questions in real time. The presentations and any accompanying slides are posted on the *FDA Basics* website for future reference.³⁸ In addition, other Centers/Offices have successfully incorporated new tools to better reach

³⁵ See *id.* § 10.115(n).

³⁶ *FDA Basics for Industry* <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm>.

³⁷ *FDA Basics* <http://www.fda.gov/AboutFDA/Transparency/Basics/default.htm>.

³⁸ See *id.* (Ask Us: *FDA Basics* Webinar Series).

affected stakeholders, such as giving stakeholders the opportunity to register for automatic e-mail notifications when new guidances are issued and highlighting newly issued guidance on the Internet guidance lists.

Finally, as mentioned, the GGP regulation requires FDA to provide stakeholders with a guidance list and to identify guidances that have been withdrawn from the list in the past year.³⁹ To make existing guidance and withdrawn guidance easier to access, or more transparent, FDA has developed a centralized webpage on *FDA Basics for Industry*,⁴⁰ which links to each Center/Office's guidance lists.⁴¹ The Agency, as part of the Transparency Initiative, also is in the process of providing centralized access to Center/Office guidance that has been withdrawn in the past year.

II. Recommendations

As a general matter, to make the issuance of final guidance more efficient and expeditious, the Centers/Offices should refer to the “best practices” for working groups established in Chapter 3 (*e.g.*, delineating working group member roles, ensuring appropriate staffing, keeping management informed, and quickly elevating contentious issues for resolution) and ensure that there is clear communication among reviewers regarding how the document fits with other Office, Center, and Agency programs and priorities so that appropriate resources can be allocated. Recognizing that each Center/Office has different demands and resource constraints, each Center/Office may implement the following strategies:

- (1) Establishing milestones in work planning documents for reviewing comments, revising the guidance, as needed, and issuing the final guidance, but also allowing the flexibility to revise the milestones based on competing priorities and available resources,
- (2) Using innovative forms of guidance that comply with GGP requirements, such as issuing Notice to Industry letters as Level 1 guidance “for immediate implementation,” to communicate more quickly with industry,
- (3) Periodically evaluating draft guidance to determine whether any guidance that has been in draft for more than three years should be withdrawn, finalized, or issued as a revised draft, taking into account resources and competing priorities,
- (4) Establishing expectations that working groups resolve issues raised by comments received on a draft guidance within a certain time-frame after the comment period closes, and
- (5) Establishing goals to finalize draft guidance that receives no comments, expeditiously, after the comment period closes.

³⁹ See 21 C.F.R. § 10.115(n).

⁴⁰ See *FDA Basics for Industry* <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm>.

⁴¹ See *id.* (Guidances Section).

To increase transparency, or awareness, of recently issued and withdrawn guidance:

(6) Centers/Offices should consider using social media tools to increase outreach for recently issued significant guidance, including:

- Webinars and
- Automatic e-mail alerts; and

(7) FDA should continue to:

- Provide a centralized webpage that links to each Center/Office's guidance list on *FDA Basics for Industry*, and update it as needed, and
- Build a centralized webpage that links to a list of guidances that have been withdrawn by the Centers/Offices, and once it has been completed, update it as needed.