OFFICE OF MANAGEMENT AND BUDGET

Final Bulletin for Agency Good Guidance Practices

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final bulletin.

SUMMARY: The Office of Management and Budget (OMB) is publishing a final Bulletin entitled, ''Agency Good Guidance Practices,'' which establishes policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies. This Bulletin is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them.

On November 23, 2005, OMB proposed a draft Bulletin for public comment. 70 FR 71866 (November 30, 2005). Upon request, OMB extended the public comment period from December 23, 2005 to January 9, 2006. 70 FR 76333 (December 23, 2005). OMB received 31 comments on the proposal from diverse public and private stakeholders (see *http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html*) and input from Federal agencies. The final Bulletin includes refinements developed through the public comment process and interagency deliberations.

DATES: The effective date of this Bulletin is 180 days after its publication in the **Federal Register**.

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SUPPLEMENTARY INFORMATION:

Introduction

As the scope and complexity of regulatory programs have grown, agencies increasingly have relied on guidance documents to inform the public and to provide direction to their staffs. As the impact of guidance documents on the public has grown, so too, has the need for good guidance practices—clear and consistent agency practices for developing, issuing, and using guidance documents.

OMB is responsible both for promoting good management practices and for overseeing and coordinating the Administration's regulatory policy. Since early in the Bush Administration, OMB has been concerned about the proper development and use of agency guidance documents. In its 2002 draft annual Report to Congress on the Costs and Benefits of Regulations, OMB discussed this issue and solicited public comments regarding problematic guidance practices and specific examples of guidance documents in need of reform.[1] OMB has been particularly concerned that agency guidance practices should be more transparent, consistent and accountable. Such concerns also have been raised by other authorities, including Congress and the courts.[2]

In its 2002 Report to Congress, OMB recognized the enormous value of agency guidance documents in general. Well-designed guidance documents serve many important or even critical functions in regulatory programs.[3] Agencies may provide helpful guidance to interpret existing law through an interpretive rule or to clarify how they tentatively will treat or enforce a governing legal norm through a policy statement. Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties.

Experience has shown, however, that guidance documents also may be poorly designed or improperly implemented. At the same time, guidance documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review.[4] These procedures include: (1) Internal agency review by a senior agency official; (2) public participation, including notice and comment under the Administrative Procedure Act (APA); (3) justification for the rule, including a statement of basis and purpose under the APA and various analyses under Executive Order 12866 (as further amended), the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act; (4) interagency review through OMB; (5) Congressional oversight; and (6) judicial review. Because it is procedurally easier to issue guidance documents, there also may be an incentive for regulators to issue guidance documents in lieu of regulations. As the D.C. Circuit observed in *Appalachian Power:*

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the **Federal Register** or the Code of Federal Regulations.[5]

[1] U.S. Office of Management and Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations,* 67 FR 15,014, 15,034–35 (March 28, 2002).

[2] *See, e.g.,* Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 371(h) (establishing FDA good guidance practices as law); ''Food and Drug Administration Modernization and Accountability Act of 1997,'' S. Rep. 105–43, at 26 (1997) (raising concerns about public knowledge of, and access to, FDA guidance documents, lack of a systematic process for adoption of guidance documents and for allowing public input, and inconsistency in the use of guidance documents); House Committee on Government Reform, ''Non-Binding Legal Effect of Agency Guidance Documents,'' H. Rep. 106–1009 (106th Cong., 2d Sess. 2000) (criticizing ''back-door'' regulation); the Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong., § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents); *Gen. Elec. Co.* v. *EPA,* 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as legislative rule requiring notice and comment); *Appalachian Power Co.* v. *EPA,* 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment); *Chamber of Commerce* v. *Dep't of Labor,* 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as legislative rule requiring notice and comment); Administrative Conference of the United States, Rec. 92–2, 1 C.F.R. 305.92–2 (1992) (agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); *American Bar Association, Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting,* August 10–11, 1993, Vol. 118, No. 2, at 57 (''the American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.''); 3 American Bar Association, ''Recommendation on Federal Agency Web Pages'' (August 2001) (agencies should maximize the availability and searchability of existing law and policy on their Web sites and include their governing statutes, rules and regulations, and all important policies, interpretations, and other like matters on which members of the public are likely to request).

[3] *See* U.S. Office of Management and Budget, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities,* 72–74 (2002) (hereinafter ''2002 Report to Congress'').

[4] *Id.,* at 72.

[5] *Appalachian Power,* 208 F.3d at 1019.

Concern about whether agencies are properly observing the notice-and-comment requirements of the APA has received significant attention. The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they initially are labeled.[6] More general concerns also have been raised that agency guidance practices should be better informed and more transparent, fair and accountable.[7] Poorly designed or misused guidance documents can impose significant costs or limit the freedom of the public. OMB has received comments raising these concerns and providing specific examples in response to its proposed Bulletin,[8] its 2002 request for comments on problematic guidance [9] and its other requests for regulatory reform nominations in 2001 [10] and 2004.[11] This Bulletin and recent amendments to Executive Order 12866 respond to these problems.[12]

This Bulletin on ''Agency Good Guidance Practices'' sets forth general policies and procedures for developing, issuing and using guidance documents. The purpose of Good Guidance Practices (GGP) is to ensure that guidance documents of Executive Branch departments and agencies are: Developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as legally binding requirements. Moreover, GGP clarify what does and does not constitute a guidance document to provide greater clarity to the public. All offices in an agency should follow these policies and procedures.

There is a strong foundation for establishing standards for the initiation, development, and issuance of guidance documents to raise their quality and transparency. The former Administrative Conference of the United States (ACUS), for example, developed recommendations for the development and use of agency guidance documents.[13] In 1997, the Food and Drug Administration (FDA) created a guidance document distilling its good guidance practices (GGP).[14] Congress then established certain aspects of the 1997 GGP document as the law in the Food and Drug Administration Modernization Act of 1997 (FDAMA; Public Law No. 105–115).[15] The FDAMA also directed FDA to evaluate the effectiveness of the 1997 GGP document and then to develop and issue regulations specifying FDA's policies and procedures for the development, issuance, and use of guidance documents. FDA conducted an internal evaluation soliciting FDA employees' views on the effectiveness of GGP and asking whether FDA employees had received complaints regarding the agency's development, issuance, and use of guidance documents since the development of GGP. FDA found that its GGP had been beneficial and effective in standardizing the agency's procedures for development, issuance, and use of guidance documents, and that FDA employees had generally been following GGP.[16] FDA then made some changes to its existing procedures to clarify its GGP.[17] The provisions of the FDAMA and FDA's implementing regulations, as well as the ACUS recommendations, informed the development of this government-wide Bulletin.

Legal Authority for This Bulletin

This Bulletin is issued under statutory authority, Executive Order, and OMB's general authorities to oversee and coordinate the rulemaking process. In what is commonly known as the Information Quality Act, Congress directed OMB to issue guidelines to ''provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, utility, objectivity and integrity of information disseminated by Federal agencies.[18] Moreover, Executive Order 13422, ''Further Amendment to Executive Order 12866 on Regulatory Planning and Review,'' recently clarified OMB's authority to oversee agency guidance documents. As further amended, Executive Order 12866 affirms that ''[c]oordinated review of agency rulemaking is necessary to ensure that regulations and guidance documents are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order,'' and the Order assigns that responsibility to OMB.[19] E.O. 12866 also establishes OMB's Office of Information and Regulatory Affairs as ''the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency.'' [20] Finally, OMB has additional authorities to oversee the agencies in the administration of their programs.

The Requirements of the Final Bulletin and Response to Public Comments

A. Overview

This Bulletin establishes: a definition of a significant guidance document; standard elements for significant guidance documents; practices for developing and using significant guidance documents; requirements for agencies to enable the public to comment on significant guidance documents or request that they be created, reconsidered, modified or rescinded; and ways for making guidance documents available to the public. These requirements should be interpreted and implemented in a manner that, consistent with the goals of improving the quality, accountability and transparency of agency guidance documents, provides sufficient flexibility for agencies to take those

[6] *See, e.g., Appalachian Power; Gen. Elec. Co.; Chamber of Commerce;* House Committee on Government Reform, ''Non-Binding Legal Effect of Agency Guidance Documents''; ACUS Rec. 92–2, *supra* note 2; Robert A. Anthony, ''Interpretive Rules, Policy Statements, Guidances, Manuals and the Like—Should Federal Agencies Use Them to Bind the Public?'' 41 Duke L.J. 1311 (1992).

[7] *See, e.g.,* note 2, *supra.*

[8] U.S. Office of Management and Budget, ''Proposed Bulletin for Good Guidance Practices,'' 70 FR 76333 (Dec. 23, 2005).

[9] *See* note 1, *supra.*

[10] U.S. Office of Management and Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations,* 66 FR 22041 (May 2, 2001).

[11] U.S. Office of Management and Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations,* 69 FR 7987 (Feb. 20, 2004); *see also* U.S. Office of Management and Budget, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local and Tribal Entities* 107–125 (2005).

[12] President Bush recently signed Executive Order 13422, ''Further Amendment to Executive Order 12866 on Regulatory Planning and Review.'' Among other things, E.O. 13422 addresses the potential need for interagency review of certain significant guidance documents by clarifying OMB's authority to have advance notice of, and to review, agency guidance documents.

[13] *See, e.g.,* note 2, *supra.*

[14] Notice, ''The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents,'' 62 FR 8961 (Feb. 27, 1997).

[15] 21 U.S.C. 371(h).

[16] *See* FDA, ''Administrative Practices and Procedures; Good Guidance Practices,'' 65 FR 7321, 7322–23 (proposed Feb. 14, 2000).

[17] 21 CFR 10.115; 65 FR 56468 (Sept. 19, 2000).

[18] Pub. L. 106–554, § 515(a) (2000). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, which requires OMB, among other things, to ''develop and oversee implementation of policies, principles, standards, and guidelines to—(1) Apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated; and (2) promote public access to public information and fulfill the purposes of this subchapter, including through the effective use of information technology.'' 44 U.S.C. 3504(d).

[19] Executive Order 12866, as further amended, § 2(b).

[20] *Id.*

actions necessary to accomplish their essential missions.

B. Definitions

Section I provides definitions for the purposes of this Bulletin. Several terms are identical to or based on those in FDA's GGP regulations, 21 CFR 10.115; the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.; Executive Order 12866, as further amended; and OMB's Government-wide Information Quality Guidelines, 67 FR 8452 (Feb. 22, 2002).

Section I(1) provides that the term ''Administrator'' means the Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.

Section I(2) provides that the term ''agency'' has the same meaning as it has under the Paperwork Reduction Act, 44 U.S.C. 3502(1), other than those entities considered to be independent agencies, as defined in 44 U.S.C. 3502(5).

Section I(3) defines the term ''guidance document'' as an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended), that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue. This definition is used to comport with definitions used in Executive Order 12866, as further amended. Nothing in this Bulletin is intended to indicate that a guidance document can impose a legally binding requirement.

Guidance documents often come in a variety of formats and names, including interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, advisories, and the like. Guidance documents include, but are not limited to, agency interpretations or policies that relate to: the design, production, manufacturing, control, remediation, testing, analysis or assessment of products and substances, and the processing, content, and evaluation/approval of submissions or applications, as well as compliance guides. Guidance documents do not include solely scientific research. Although a document that simply summarizes the protocol and conclusions of a specific research project (such as a clinical trial funded by the National Institutes of Health) would not qualify as a guidance document, such research may be the basis of a guidance document (such as the HHS/USDA ''Dietary Guidelines for Americans,'' which provides guidance to Americans on what constitutes a healthy diet).

Some commenters raised the concern that the term ''guidance document'' reflected too narrow a focus on written materials alone. While the final Bulletin adopts the commonly used term ''guidance document,'' the definition is not limited only to written guidance materials and should not be so construed. OMB recognizes that agencies are experimenting with offering guidance in new and innovative formats, such as video or audio tapes, or interactive web-based software. The definition of ''guidance document'' encompasses all guidance materials, regardless of format. It is not the intent of this Bulletin to discourage the development of promising alternative means to offer guidance to the public and regulated entities.

A number of commenters raised concerns that the definition of ''significant guidance document'' in the proposed Bulletin was too broad in some respects. In particular, the proposed definition included guidance that set forth initial interpretations of statutory and regulatory requirements and changes in interpretation or policy. The definition in the proposed Bulletin was adapted from the definition of ''Level 1 guidance documents'' in FDA's GGP regulations.

Upon consideration of the comments, the need for clarity, and the broad application of this Bulletin to diverse agencies, the definition of ''significant guidance document'' has been changed. Section I(4) defines the term ''significant guidance document'' as a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to: (i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; or (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; or (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended. Under the Bulletin, significant guidance documents include interpretive rules of general applicability and statements of general policy that have the effects described in Section I(4)(i)–(iv).

The general definition of ''significant guidance document'' in the final Bulletin adopts the definition in Executive Order 13422, which recently amended Executive Order 12866 to clarify OMB's role in overseeing and coordinating significant guidance documents. This definition, in turn, closely tracks the general definition of ''significant regulatory action'' in E.O. 12866, as further amended. One advantage of this definition is that agencies have years of experience in the regulatory context applying the parallel definition of ''significant regulatory action'' under E.O. 12866, as further amended. However, a few important changes were made to the definition used in E.O. 12866, as further amended, to make it better suited for guidance. For example, in recognition of the non-binding nature of guidance the words ''may reasonably be anticipated to'' preface all four prongs of the ''significant guidance document'' definition. This prefatory language makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules.

Section I(4) also clarifies what is not a ''significant guidance document'' under this Bulletin. For purposes of this Bulletin, documents that would not be considered significant guidance documents include: Legal advisory opinions for internal Executive Branch use and not for release (such as Department of Justice Office of Legal Counsel opinions); briefs and other positions taken by agencies in investigations, pre-litigation, litigation, or other enforcement proceedings; speeches; editorials; media interviews; press materials; Congressional correspondence; guidances that pertain to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidances that pertain to the use, operation or control of a government facility; and internal operational guidances directed solely to other Federal agencies (including Office of Personnel Management personnel issuances, General Services Administration Federal Travel Regulation bulletins, and most of the National Archives and Records Administration's records management bulletins). The Bulletin also exempts speeches of agency officials.

Information collections, discretionary grant application packages, and compliance monitoring reports also are not significant guidance documents. Though the Bulletin does not cover

guidance documents that pertain to the use, operation, or control of a Federal facility, it does cover generally applicable instructions to contractors. Section I(4) also provides that an agency head, in consultation and concurrence with the OIRA Administrator, may exempt one or more categories of significant guidance documents from the requirements of the Bulletin.

The definition of guidance document covers agency statements of ''general applicability'' and ''future effect,'' and accordingly, the Bulletin does not cover documents that result from an adjudicative decision. We construe ''future effects'' as intended (and likely beneficial) impacts due to voluntary compliance with a guidance document. Moreover, since a significant guidance document is an agency statement of ''general applicability,'' correspondence such as opinion letters or letters of interpretation prepared for or in response to an inquiry from an individual person or entity would not be considered a significant guidance document, unless the correspondence is reasonably anticipated to have precedential effect and a substantial impact on regulated entities or the public. Thus, this Bulletin should not inhibit the beneficial practice of agencies providing informal guidance to help specific parties. If the agency compiles and publishes informal determinations to provide guidance to, and with a substantial impact on, regulated industries, then this Bulletin would apply. Guidance documents are considered ''significant'' when they have a broad and substantial impact on regulated entities, the public or other Federal agencies. For example, a guidance document that had a substantial impact on another Federal agency, by interfering with its ability to carry out its mission or imposing substantial burdens, would be significant under Section I(4)(ii) and perhaps could trigger Section I(5) as well.

In general, guidance documents that concern routine matters would not be ''significant.'' Among an agency's internal guidance documents, there are many categories that would not constitute significant guidance documents. There is a broad category of documents that may describe the agency's day-to-day business. Though such documents might be of interest to the public, they do not fall within the definition of significant guidance documents for the purposes of this Bulletin. More generally, there are internal guidance documents that bind agency employees with respect to matters that do not directly or substantially impact regulated entities. For example, an agency may issue guidance to field offices directing them to maintain electronic data files of complaints regarding regulated entities.

Section I(5) states that the term ''economically significant guidance document'' means a significant guidance document that ''may reasonably be anticipated to lead to'' an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy. The relevant economic impacts include those that may be imposed by Federal agencies, State, or local governments, or foreign governments that affect the U.S. economy, as well as impacts that could arise from private sector conduct. The definition of economically significant guidance document tracks only the part of the definition of significant guidance document in Section I(4)(i) related to substantial economic impacts. This clarifies that the definition of ''economically significant guidance document'' includes only a relatively narrow category of significant guidance documents. This definition enables agencies to determine which interpretive rules of general applicability or statements of general policy might be so consequential as to merit advance notice-and-comment and a response-to-comments document—and which do not. Accordingly, the definition of economically significant guidance document includes economic impacts that rise to $100 million in any one year or adversely affect the economy or a sector of the economy.

The definition of economically significant guidance document also departs in other ways from the language describing an economically significant regulatory action in Section 3(f)(1) of E.O. 12866, as further amended. A number of commenters on the proposed Bulletin raised questions about how a guidance document—which is not legally binding—could have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy. As other commenters recognized, although guidance may not be legally binding, there are situations in which it may reasonably be anticipated that a guidance document could lead parties to alter their conduct in a manner that would have such an economically significant impact.

Guidance can have coercive effects or lead parties to alter their conduct. For example, under a statute or regulation that would allow a range of actions to be eligible for a permit or other desired agency action, a guidance document might specify fast track treatment for a particular narrow form of behavior but subject other behavior to a burdensome application process with an uncertain likelihood of success. Even if not legally binding, such guidance could affect behavior in a way that might lead to an economically significant impact. Similarly, an agency might make a pronouncement about the conditions under which it believes a particular substance or product is unsafe. While not legally binding, such a statement could reasonably be anticipated to lead to changes in behavior by the private sector or governmental authorities such that it would lead to a significant economic effect. Unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures of section IV.

In recognition of the non-binding nature of guidance documents, the Bulletin's definition of economically significant guidance document differs in key respects from the definition of an economically significant regulatory action in section 3(f)(1) of E.O. 12866, as further amended. First, as described above, the words ''may reasonably be anticipated to'' are included in the definition. Second, the definition of economically significant guidance document contemplates that the guidance document could ''lead to'' (as opposed to ''have'') an economically significant effect. This language makes clear that the impacts of guidance documents often will be more indirect and dependent on third-party decisions and conduct than is the case with binding legislative rules. This language also reflects a recognition that, as various commenters noted, guidance documents often will not be amenable to formal economic analysis of the kind that is prepared for an economically significant regulatory action. Accordingly, this Bulletin does not require agencies to conduct a formal regulatory impact analysis to guide their judgments about whether a guidance document is economically significant.

The definition of ''economically significant guidance document'' excludes guidance documents on Federal expenditures and receipts. Therefore, guidance documents on Federal budget expenditures (*e.g.,* entitlement programs) and taxes (the administration or collection of taxes, tax credits, or duties) are not subject to the requirements for notice and comment and a response to comments document in § IV. However, if such guidance documents are ''significant,'' then they are subject to the other requirements of

this Bulletin, including the transparency and approval provisions.

Section I(6) states that the term ''disseminated'' means prepared by the agency and distributed to the public or regulated entities. Dissemination does not include distribution limited to government employees; intra-or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law.[21]

Consistent with Executive Order 12866, as further amended, Section I(7) defines the term ''regulatory action'' as any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of inquiry and notices of proposed rulemaking.

Section I(8) defines the term ''regulation,'' consistent with Executive Order 12866, as further amended, as an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.

C. Basic Agency Standards

Section II describes basic agency standards for significant guidance documents.

1. Agency Approval Procedures

Section II(1)(a) directs each agency to develop or have written procedures for the internal clearance of significant guidance documents no later than the effective date of this Bulletin. Those procedures should ensure that issuance of significant guidance documents is approved by appropriate agency officials. Currently at FDA the Director in a Center or an Office of Regulatory Affairs equivalent or higher approves a significant guidance document before it is distributed to the public in draft or final form. Depending on the nature of specific agency guidance documents, these procedures may require approval or concurrence by other components within an agency. For example, if guidance is provided on compliance with an agency regulation, we would anticipate that the agency's approval procedures would ensure appropriate coordination with other agency components that have a stake in the regulation's implementation, such as the General Counsel's office and the component responsible for development and issuance of the regulation.

Section II(1)(b) states that agency employees should not depart from significant agency guidance documents without appropriate justification and supervisory concurrence. It is not the intent of this Bulletin to inhibit the flexibility needed by agency officials to depart appropriately from significant guidance documents by rigidly requiring concurrence only by very high-level officials. Section II(1)(a) also is not intended to bind an agency to exercise its discretion only in accordance with a general policy where the agency is within the range of discretion contemplated by the significant guidance document.

Agencies are to follow GGP when providing important policy direction on a broad scale. This includes when an agency communicates, informally or indirectly, new or different regulatory expectations to a broad public audience for the first time, including regulatory expectations different from guidance issued prior to this Bulletin.[22] This does not limit the agency's ability to respond to questions as to how an established policy applies to a specific situation or to answer questions about areas that may lack established policy (although such questions may signal the need to develop guidance in that area). This requirement also does not apply to positions taken by agencies in litigation, pre-litigation, or investigations, or in any way affect their authority to communicate their views in court or other enforcement proceedings. This requirement also is not intended to restrict the authority of agency General Counsels or the Department of Justice Office of Legal Counsel to provide legal interpretations of statutory and regulatory requirements.

Agencies also should ensure consistent application of GGP. Employees involved in the development, issuance, or application of significant guidance documents should be trained regarding the agency's GGP, particularly the principles of Section II(2). In addition, agency offices should monitor the development, issuance and use of significant guidance documents to ensure that employees are following GGP.

2. Standard Elements

Section II(2) establishes basic requirements for significant guidance documents. They must: (i) Include the term ''guidance'' or its functional equivalent; (ii) Identify the agenc(ies) or office(s) issuing the document; (iii) Identify the activity to which and the persons to whom the document applies; (iv) Include the date of issuance; (v) Note if it is a revision to a previously issued guidance document and, if so, identify the guidance that it replaces; (vi) Provide the title of the guidance and any document identification number, if one exists; and (vii) include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets.

In implementing this Bulletin, particularly Section II(2)(e), agencies should be diligent to identify for the public whether there is previous guidance on an issue, and, if so, to clarify whether that guidance document is repealed by the new significant guidance document completely, and if not, to specify what provisions in the previous guidance document remain in effect. Superseded guidance documents that remain available for historical purposes should be stamped or otherwise prominently identified as superseded. Draft significant guidance documents that are being made available for pre-adoption notice and comment should include a prominent ''draft'' notation. As existing significant guidance documents are revised, they should be updated to comply with this Bulletin.

Finally, Section II(2)(h) clarifies that, given their legally nonbinding nature, significant guidance documents should not include mandatory language such as ''shall,'' ''must,'' ''required'' or ''requirement,'' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose consideration by the agency of positions advanced by affected private parties.[23] For example, a guidance document may explain how the agency believes a statute or

[21] *See* U.S. Office of Management and Budget's Government-wide Information Quality Guidelines, 67 FR 8452, 8454, 8460 (Feb. 22, 2002).

[22] *See* FDA's Good Guidance Practices, 21 CFR 10.115(e): ''Can FDA use means other than a guidance document to communicate new agency policy or a new regulatory approach to a broad public audience? The agency must not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGPs must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience.''

[23] As the courts have held, *see supra* note 2, agencies need to follow statutory rulemaking requirements, such as those of the APA, to issue documents with legally binding effect, i.e., legislative rules. One benefit of GGP for an agency is that the agency's review process will help to identify any draft guidance documents that instead should be promulgated through the rulemaking process.

regulation applies to certain regulated activities. Before a significant guidance document is issued or revised, it should be reviewed to ensure that improper mandatory language has not been used. As some commenters noted, while a guidance document cannot legally bind, agencies can appropriately bind their employees to abide by agency policy as a matter of their supervisory powers over such employees without undertaking pre-adoption notice and comment rulemaking. As a practical matter, agencies also may describe laws of nature, scientific principles, and technical requirements in mandatory terms so long as it is clear that the guidance document itself does not impose legally enforceable rights or obligations.

A significant guidance document should aim to communicate effectively to the public about the legal effect of the guidance and the consequences for the public of adopting an alternative approach. For example, a significant guidance document could be captioned with the following disclaimer under appropriate circumstances:

''This [draft] guidance, [when finalized, will] represent[s] the [Agency's] current thinking on this topic. It does not create or confer any rights for or on any person or operate to bind the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach (you are not required to do so), you may contact the [Agency] staff responsible for implementing this guidance. If you cannot identify the appropriate [Agency] staff, call the appropriate number listed on the title page of this guidance.''

When an agency determines it would be appropriate, the agency should use this or a similar disclaimer. Agency staff should similarly describe the legal effect of significant guidance documents when speaking to the public about them.

D. Public Access and Feedback

Section III describes public access procedures related to the development and issuance of significant guidance documents.

1. Internet Access

Section III directs agencies to ensure that information about the existence of significant guidance documents and the significant guidance documents themselves are made available to the public in electronic form. Section III(1) enables the public to obtain from an agency's Web site a list of all of an agency's significant guidance documents. Under section III(1)(a), agencies will maintain a current electronic list of all significant guidance documents on their Web sites in a manner consistent with OMB policies for agency public Web sites and information dissemination.[24] To assist the public in locating such electronic lists, they should be maintained on an agency's Web site—or as a link on an agency's Web site to the electronic list posted on a component or subagency's Web site—in a quickly and easily identifiable manner (e.g., as part of or in close visual proximity to the agency's list of regulations and proposed regulations). New documents will be added to this list within 30 days from the date of issuance. The agency list of significant guidance documents will include: the name of the significant guidance document, any docket number, and issuance and revision dates. As agencies develop or revise significant guidance documents, they should organize and catalogue their significant guidance documents to ensure users can easily browse, search for, and retrieve significant guidance documents on their Web sites.

The agency shall provide a link from the list to each significant guidance document (including any appendices or attachments) that currently is in effect. Many recently issued guidance documents have been made available on the Internet, but there are some documents that are not now available in this way. Agencies should begin posting those significant guidance documents on their Web sites with the goal of making all of their significant guidance documents currently in effect publicly available on their Web sites by the effective date of this Bulletin.[25] Other requirements of this Bulletin, such as section II(2) (Standard Elements), apply only to significant guidance documents issued or amended after the effective date of the Bulletin. For such significant guidance documents (including economically significant guidance documents), agencies should provide, to the extent appropriate and feasible, a Web site link from the significant guidance document to the public comments filed on it. This would enable interested stakeholders and the general public to understand the various viewpoints on the significant guidance documents.

Under section III(1)(b), the significant guidance list will identify those significant guidance documents that were issued, revised or withdrawn within the past year. Agencies are encouraged, to the extent appropriate and feasible, to offer a list serve or similar mechanism for members of the public who would like to be notified by e-mail each time an agency issues its annual update of significant guidance documents. To further assist users in better understanding agency guidance and its relationship to current or proposed Federal regulations, agencies also should link their significant guidance document lists to Regulations.gov.[26]

2. Public Feedback

Section III(2) requires each agency to have adequate procedures for public comments on significant guidance documents and to address complaints regarding the development and use of significant guidance documents. Not later than 180 days from the publication of this Bulletin, each agency shall establish and clearly advertise on its Web site a means for the public to submit electronically comments on significant guidance documents, and to request electronically that significant guidance documents be issued, reconsidered, modified or rescinded. The public may state their view that specific guidance documents are ''significant'' or ''economically significant'' and therefore are subject to the applicable requirements of this Bulletin. At any time, the public also may request that an agency modify or rescind an existing significant guidance document. Such requests should specify why and how the significant guidance document should be rescinded or revised.

Public comments submitted under these procedures on significant guidance documents are for the benefit of the agency, and this Bulletin does not require a formal response to comments (of course, agencies must comply with any applicable statutory requirements to respond, and this Bulletin does not alter those requirements). In some cases, the agency, in consultation with the Administrator of OMB's Office of Information and Regulatory Affairs, may in its discretion decide to address public comments by updating or altering the significant guidance document.

[24] U.S. Office of Management and Budget, Memorandum M–05–04, ''Policies for Federal Agency Public Web sites'' (Dec. 17, 2004), available at: *http://www.whitehouse.gov/omb/memoranda/fy2005/m05–04.pdf;* U.S. Office of Management and Budget, Memorandum M–06–02, ''Improving Public Access to and Dissemination of Government Information and Using the Federal Enterprise Architecture Data Reference Model'' (Dec. 16, 2005), available at: *http://www.whitehouse.gov/omb/memoranda/fy2006/m06–02.pdf.*

[25] In this regard, we note that under the Electronic Freedom of Information Act Amendments of 1996, agencies have been posting on their Web sites statements of general policy and interpretations of general applicability. *See* 5 U.S.C. 552(a)(2).

[26] Regulations.gov is available at *http://www.Regulations.gov/fdmspublic/component/main.*

Although this Bulletin does not require agencies to provide notice and an opportunity for public comment on all significant guidance documents before they are adopted, it is often beneficial for an agency to do so when they determine that it is practical. Pre-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial. Agencies also are encouraged to consider observing notice-and-comment procedures for interpretive significant guidance documents that effectively would extend the scope of the jurisdiction the agency will exercise, alter the obligations or liabilities of private parties, or modify the terms under which the agency will grant entitlements. As it does for legislative rules, providing pre-adoption opportunity for comment on significant guidance documents can increase the quality of the guidance and provide for greater public confidence in and acceptance of the ultimate agency judgments. For these reasons, agencies sometimes follow the notice-and-comment procedures of the APA even when doing so is not legally required.[27] Of course, where an agency provides for notice and comment before adoption, it need not do so again upon issuance of the significant guidance document.[28]

Many commenters expressed the desire for a better way to resolve concerns about agency guidance documents and adherence to good guidance practices. To help resolve public concerns over problematic guidance documents, section III(2)(b) requires each agency to designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a guidance document as a binding requirement. The public also could turn to this office to request that the agency classify a guidance as ''significant'' or ''economically significant'' for purposes of this Bulletin. The agency shall provide the name and contact information for the office(s) on its Web site.

E. Notice and Comment on Economically Significant Guidance Documents

Under section IV, after the agency prepares a draft of an economically significant guidance document, the agency must publish a notice in the **Federal Register** announcing that the draft guidance document is available for comment. In a manner consistent with OMB policies for agency public Web sites and information dissemination, the agency must post the draft on its Web site, make it publicly available in hard copy, and ensure that persons with disabilities can reasonably access and comment on the guidance development process.[29] If the guidance document is not in a format that permits such electronic posting with reasonable efforts, the agency should notify the public how they can review the guidance document. When inviting public comments on the draft guidance document, the agency will propose a period of time for the receipt of comments and make the comments available to the public for review. The agency also may hold public meetings or workshops on a draft guidance document, or present it for review to an advisory committee or, as required or appropriate, to a peer review committee.[30] In some cases, the agency may, in its discretion, seek early public input even before it prepares the draft of an economically significant guidance document. For example, the agency could convene or participate in meetings or workshops.

After reviewing comments on a draft, the agency should incorporate suggested changes, when appropriate, into the final version of the economically significant guidance document. The agency then should publish a notice in the **Federal Register** announcing that the significant guidance document is available. The agency must post the significant guidance document on the Internet and make it available in hard copy. The agency also must prepare a robust response-to-comments document and make it publicly available. Though these procedures are similar to APA notice-and-comment requirements, this Bulletin in no way alters (nor is it intended to interpret) the APA requirements for legislative rules under 5 U.S.C. 553.

Prior to or upon announcing the availability of the draft guidance document, the agency should establish a public docket. Public comments submitted on an economically significant guidance document should be sent to the agency's docket. The comments submitted should identify the docket number on the guidance document (if such a docket number exists), as well as the title of the document. Comments should be available to the public at the docket and, when feasible, on the Internet. Agencies should provide a link on their Web site from the guidance document to the public comments as well as the response to comments document.

After providing an opportunity for comment, an agency may decide, in its discretion, that it is appropriate to issue another draft of the significant guidance document. The agency may again solicit comment by publishing a notice in the **Federal Register**, posting a draft on the Internet and making the draft available in hard copy. The agency then would proceed to issue a final version of the guidance document in the manner described above. Copies of the **Federal Register** notices of availability should be available on the agency's Web site. In addition, the response-to-comments document should address the additional comments received on the revised draft.

An agency head, in consultation and concurrence with the OIRA Administrator, may identify a particular significant guidance document or class of guidance documents for which the procedures of this Section are not feasible and appropriate. Under § IV, the agency is not required to seek public comment before it implements an economically significant guidance document if prior public participation is not feasible or appropriate. It may not be feasible or appropriate for an agency to seek public comment before issuing an economically significant guidance document if there is a public health, safety, environmental or other emergency requiring immediate issuance of the guidance document, or there is a statutory requirement or court order that requires immediate issuance. Another type of situation is presented by guidance documents that, while important, are issued in a routine and frequent manner. For example, one commenter raised concerns that the National Weather Service not only frequently reports on weather and air conditions but also gives consumers guidance, such as heat advisories, on the best course of action to take in

[27] For example, in developing its guidelines for self-evaluation of compensation practices regarding systemic compensation discrimination, the Department of Labor provided for pre-adoption notice and opportunity for comment. *See* Office of Federal Contract Compliance Programs, ''Guidelines for Self-Evaluation of Compensation Practices for Compliance with Nondiscrimination Requirements of Executive Order 11246 with Respect to Systemic Compensation Discrimination,'' 69 FR 67,252 (Nov. 16, 2004).

[28] *See, e.g.,* Office of Federal Procurement Policy Act, 41 U.S.C. 418(b) (providing for pre-adoption notice and comment for procurement policies with a significant effect or cost).

[29] Federal agency public Web sites must be designed to make information and services fully available to individuals with disabilities. For additional information, see: *http://www.access-board.gov/index.htm*; *see also* Rehabilitation Act, 29 U.S.C. 701, 794, 794d.

[30] *See* U.S. Office of Management and Budget, ''Final Information Quality Bulletin For Peer Review,'' 70 FR 2664 (Jan. 14, 2005).

severe weather conditions. Even if such notices or advisories had an economically significant impact, subjecting them to the notice-and-comment procedures of Section IV would not be feasible or appropriate. An agency may discuss with OMB other exceptions that are consistent with section IV(2).

Though economically significant guidance documents that fall under the exemption in section IV(2) are not required to undergo the full notice-and-comment procedures, the agency should: (a) Publish a notice in the **Federal Register** announcing that the guidance document is available; (b) post the guidance document on the Internet and make it available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts); and (c) seek public comment when it issues or publishes the guidance document. If the agency receives comments on an excepted guidance document, the agency should review those comments and revise the guidance document when appropriate. However, the agency is not required to provide post-promulgation notice-and-comment if such procedures are not feasible or appropriate.

F. Emergencies

In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with this Bulletin. For those significant guidance documents that are governed by a statutory or court-imposed deadlines, the agency shall, to the extent practicable, schedule its proceedings so as to permit sufficient time to comply with this Bulletin.

G. Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.[31]

H. Effective Date

The requirements of this Bulletin shall take effect 180 days after publication in the **Federal Register** except that agencies will have 210 days to comply with requirements for significant guidance documents promulgated on or before the date of publication of this Bulletin.

Bulletin for Agency Good Guidance Practices

I. Definitions

For purposes of this Bulletin—

1. The term ''Administrator'' means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

2. The term ''agency'' has the same meaning it has under the Paperwork Reduction Act, 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5).

3. The term ''guidance document'' means an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended, section 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue.

4. The term ''significant guidance document''—

a. Means (as defined in Executive Order 12866, as further amended, section 3(h)) a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

(i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.

b. Does not include legal advisory opinions for internal Executive Branch use and not for release (such as Department of Justice Office of Legal Counsel opinions); briefs and other positions taken by agencies in investigations, pre-litigation, litigation, or other enforcement proceedings (nor does this Bulletin in any other way affect an agency's authority to communicate its views in court or in other enforcement proceedings); speeches; editorials; media interviews; press materials; Congressional correspondence; guidance documents that pertain to a military or foreign affairs function of the United States (other than guidance on procurement or the import or export of non-defense articles and services); grant solicitations; warning letters; case or investigatory letters responding to complaints involving fact-specific determinations; purely internal agency policies; guidance documents that pertain to the use, operation or control of a government facility; internal guidance documents directed solely to other Federal agencies; and any other category of significant guidance documents exempted by an agency head in consultation with the OIRA Administrator.

5. The term ''economically significant guidance document'' means a significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant guidance documents do not include guidance documents on Federal expenditures and receipts.

6. The term ''disseminated'' means prepared by the agency and distributed to the public or regulated entities. Dissemination does not include distribution limited to government employees; intra- or interagency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar laws.

7. The term ''regulatory action'' means any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of inquiry and notices of proposed rulemaking (see Executive Order 12866, as further amended, section 3).

8. The term ''regulation'' means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency (see Executive Order 12866, as further amended, section 3).

II. Basic Agency Standards for Significant Guidance Documents

1. *Approval Procedures:*

[31] The provisions of this Bulletin, and an agency's compliance or noncompliance with the Bulletin's requirements, are not intended to, and should not, alter the deference that agency interpretations of laws and regulations should appropriately be given.

a. Each agency shall develop or have written procedures for the approval of significant guidance documents. Those procedures shall ensure that the issuance of significant guidance documents is approved by appropriate senior agency officials.

b. Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence.

2. *Standard Elements:* Each significant guidance document shall:

a. Include the term ''guidance'' or its functional equivalent;

b. Identify the agenc(ies) or office(s) issuing the document;

c. Identify the activity to which and the persons to whom the significant guidance document applies;

d. Include the date of issuance;

e. Note if it is a revision to a previously issued guidance document and, if so, identify the document that it replaces;

f. Provide the title of the document, and any document identification number, if one exists;

g. Include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets; and

h. Not include mandatory language such as ''shall,'' ''must,'' ''required'' or ''requirement,'' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties.

III. Public Access and Feedback for Significant Guidance Documents

1. *Internet Access:*

a. Each agency shall maintain on its Web site—or as a link on an agency's Web site to the electronic list posted on a component or subagency's Web site—a current list of its significant guidance documents in effect. The list shall include the name of each significant guidance document, any document identification number, and issuance and revision dates. The agency shall provide a link from the current list to each significant guidance document that is in effect. New significant guidance documents and their Web site links shall be added promptly to this list, no later than 30 days from the date of issuance.

b. The list shall identify significant guidance documents that have been added, revised or withdrawn in the past year.

2. *Public Feedback:*

a. Each agency shall establish and clearly advertise on its Web site a means for the public to submit comments electronically on significant guidance documents, and to submit a request electronically for issuance, reconsideration, modification, or rescission of significant guidance documents. Public comments under these procedures are for the benefit of the agency, and no formal response to comments by the agency is required by this Bulletin.

b. Each agency shall designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a significant guidance document as a binding requirement. The agency shall provide, on its Web site, the name and contact information for the office(s).

IV. Notice and Public Comment for Economically Significant Guidance Documents

1. *In General:* Except as provided in Section IV(2), when an agency prepares a draft of an economically significant guidance document, the agency shall:

a. Publish a notice in the **Federal Register** announcing that the draft document is available;

b. Post the draft document on the Internet and make it publicly available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts);

c. Invite public comment on the draft document; and

d. Prepare and post on the agency's Web site a response-to-comments document.

2. *Exemptions:* An agency head, in consultation with the OIRA Administrator, may identify a particular economically significant guidance document or category of such documents for which the procedures of this Section are not feasible or appropriate.

V. Emergencies

In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with this Bulletin. For those significant guidance documents that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule its proceedings so as to permit sufficient time to comply with this Bulletin.

VI. Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

VII. Effective Date

The requirements of this Bulletin shall take effect 180 days after its publication in the **Federal Register** except that agencies will have 210 days to comply with requirements for significant guidance documents promulgated on or before the date of publication of this Bulletin.

Dated: January 18, 2007.

Steven D. Aitken,

Acting Administrator, Office of Information and Regulatory Affairs.

[FR Doc. E7–1066 Filed 1–24–07; 8:45 am]

BILLING CODE 3110–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 27668; 812–13201]

Hercules Technology Growth Capital, Inc.; Notice of Application

January 19, 2007.

AGENCY: Securities and Exchange Commission (the ''Commission'').

ACTION: Notice of an application for an order under section 61(a)(3)(B) of the Investment Company Act of 1940 (the ''Act'').

SUMMARY OF APPLICATION: Applicant, Hercules Technology Growth Capital, Inc. (''HTGC''), requests an order approving a proposal to issue options to purchase HTGC's common stock (''Common Stock'') to directors who are not officers or employees of HTGC (''Eligible Directors'') pursuant to HTGC's 2006 Non-employee Director Plan (the ''Plan'').

FILING DATES: The application was filed on June 21, 2005 and amended on December 12, 2006.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 13, 2007, and

subject matter involved. When more than one FDA representative is in attendance, only the presiding or head representative will report the meeting on the public calendar. If a large number of persons is involved, the name of each need not be specified. Meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in FDA) will not be reported.

(3) The following FDA representatives and their deputies are subject to the requirements of paragraphs (b)(1) and (2) of this section:

(i) Commissioner of Food and Drugs.

(ii) Deputy Commissioner.

(iii) Associate Commissioners.

(iv) Executive and Special Assistants to the Commissioner.

(v) [Reserved]

(vi) Director, National Center for Toxicological Research.

(vii) Center Directors.

(viii) Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel.

(4) A copy of the public calendar will be placed on public display in the following places:

(i) Dockets Management Branch.

(ii) Office of the Associate Commissioner for Public Affairs.

(iii) A central place in each center.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

[66 FR 12849, Mar. 1, 2001]

EFFECTIVE DATE NOTE: At 66 FR 12849, Mar. 1, 2001, § 10.100a was added, effective Jan. 22, 2001, to Apr. 22, 2001.

§ 10.105 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in an administrative proceeding subject to this part.

(b) A petition, comment, objection, or other representation by an organization will not abridge the right of a member to take individual action of a similar type, in the member's own name.

(c) It is requested that each organization participating in FDA administrative proceedings file annually with the Dockets Management Branch a current list of all of the members of the organization.

(d) The filing by an organization of an objection or request for hearing under §§ 12.20 through 12.22 does not provide a member a legal right with respect to the objection or request for hearing that the member may individually exercise. A member of an organization wishing to file an objection or request for hearing must do so individually.

(e) In a court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name. Regardless of whether the case is brought or considered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and a member of the organization that the issues are precluded from further litigation by the member under the doctrines of collateral estoppel or res judicata.

§ 10.110 Settlement proposals.

At any time in the course of a proceeding subject to this part, a person may propose settlement of the issues involved. A participant in a proceeding will have an opportunity to consider a proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, will not be admissible in evidence in an FDA administrative proceeding. FDA will oppose the admission in evidence of settlement information in a court proceeding or in another administrative proceeding.

§ 10.115 Good guidance practices.

(a) *What are good guidance practices?* Good guidance practices (GGP's) are FDA's policies and procedures for developing, issuing, and using guidance documents.

(b) *What is a guidance document?*

(1) Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.

(2) Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.

(3) Guidance documents do not include: Documents relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms.

(c) *What other terms have a special meaning?*

(1) "Level 1 guidance documents" include guidance documents that:

(i) Set forth initial interpretations of statutory or regulatory requirements;

(ii) Set forth changes in interpretation or policy that are of more than a minor nature;

(iii) Include complex scientific issues; or

(iv) Cover highly controversial issues.

(2) "Level 2 guidance documents" are guidance documents that set forth existing practices or minor changes in interpretation or policy. Level 2 guidance documents include all guidance documents that are not classified as Level 1.

(3) "You" refers to all affected parties outside of FDA.

(d) *Are you or FDA required to follow a guidance document?*

(1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.

(2) You may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations.

(3) Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.

(e) *Can FDA use means other than a guidance document to communicate new agency policy or a new regulatory approach to a broad public audience?* The agency may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGP's must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience.

(f) *How can you participate in the development and issuance of guidance documents?*

(1) You can provide input on guidance documents that FDA is developing under the procedures described in paragraph (g) of this section.

(2) You can suggest areas for guidance document development. Your suggestions should address why a guidance document is necessary.

(3) You can submit drafts of proposed guidance documents for FDA to consider. When you do so, you should mark the document "Guidance Document Submission" and submit it to Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(4) You can, at any time, suggest that FDA revise or withdraw an already existing guidance document. Your suggestion should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.

(5) Once a year, FDA will publish, both in the FEDERAL REGISTER and on the Internet, a list of possible topics for future guidance document development or revision during the next year. You can comment on this list (e.g., by

suggesting alternatives or making recommendations on the topics that FDA is considering).

(6) To participate in the development and issuance of guidance documents through one of the mechanisms described in paragraphs (f)(1), (f)(2), or (f)(4) of this section, you should contact the center or office that is responsible for the regulatory activity covered by the guidance document.

(7) If FDA agrees to draft or revise a guidance document, under a suggestion made under paragraphs (f)(1), (f)(2), (f)(3) or (f)(4) of this section, you can participate in the development of that guidance document under the procedures described in paragraph (g) of this section.

(g) *What are FDA's procedures for developing and issuing guidance documents?*

(1) FDA's procedures for the development and issuance of Level 1 guidance documents are as follows:

(i) Before FDA prepares a draft of a Level 1 guidance document, FDA can seek or accept early input from individuals or groups outside the agency. For example, FDA can do this by participating in or holding public meetings and workshops.

(ii) After FDA prepares a draft of a Level 1 guidance document, FDA will:

(A) Publish a notice in the FEDERAL REGISTER announcing that the draft guidance document is available;

(B) Post the draft guidance document on the Internet and make it available in hard copy; and

(C) Invite your comment on the draft guidance document. Paragraph (h) of this section tells you how to submit your comments.

(iii) After FDA prepares a draft of a Level 1 guidance document, FDA also can:

(A) Hold public meetings or workshops; or

(B) Present the draft guidance document to an advisory committee for review.

(iv) After providing an opportunity for public comment on a Level 1 guidance document, FDA will:

(A) Review any comments received and prepare the final version of the guidance document that incorporates suggested changes, when appropriate;

(B) Publish a notice in the FEDERAL REGISTER announcing that the guidance document is available;

(C) Post the guidance document on the Internet and make it available in hard copy; and

(D) Implement the guidance document.

(v) After providing an opportunity for comment, FDA may decide that it should issue another draft of the guidance document. In this case, FDA will follow the steps in paragraphs (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of this section.

(2) FDA will not seek your comment before it implements a Level 1 guidance document if the agency determines that prior public participation is not feasible or appropriate.

(3) FDA will use the following procedures for developing and issuing Level 1 guidance documents under the circumstances described in paragraph (g)(2) of this section:

(i) After FDA prepares a guidance document, FDA will:

(A) Publish a notice in the FEDERAL REGISTER announcing that the guidance document is available;

(B) Post the guidance document on the Internet and make it available in hard copy;

(C) Immediately implement the guidance document; and

(D) Invite your comment when it issues or publishes the guidance document. Paragraph (h) of this section tells you how to submit your comments.

(ii) If FDA receives comments on the guidance document, FDA will review those comments and revise the guidance document when appropriate.

(4) FDA will use the following procedures for developing and issuing Level 2 guidance documents:

(i) After it prepares a guidance document, FDA will:

(A) Post the guidance document on the Internet and make it available in hard copy;

(B) Immediately implement the guidance document, unless FDA indicates otherwise when the document is made available; and

(C) Invite your comment on the Level 2 guidance document. Paragraph (h) of this section tells you how to submit your comments.

(ii) If FDA receives comments on the guidance document, FDA will review those comments and revise the document when appropriate. If a version is revised, the new version will be placed on the Internet.

(5) You can comment on any guidance document at any time. Paragraph (h) of this section tells you how to submit your comments. FDA will revise guidance documents in response to your comments when appropriate.

(h) *How should you submit comments on a guidance document?*

(1) If you choose to submit comments on any guidance document under paragraph (g) of this section, you must send them to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(2) Comments should identify the docket number on the guidance document, if such a docket number exists. For documents without a docket number, the title of the guidance document should be included.

(3) Comments will be available to the public in accordance with FDA's regulations on submission of documents to the Dockets Management Branch specified in § 10.20(j).

(i) *What standard elements must FDA include in a guidance document?*

(1) A guidance document must:

(i) Include the term "guidance,"

(ii) Identify the center(s) or office(s) issuing the document,

(iii) Identify the activity to which and the people to whom the document applies,

(iv) Prominently display a statement of the document's nonbinding effect,

(v) Include the date of issuance,

(vi) Note if it is a revision to a previously issued guidance and identify the document that it replaces, and

(vii) Contain the word "draft" if the document is a draft guidance.

(2) Guidance documents must not include mandatory language such as "shall," "must," "required," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

(3) When issuing draft guidance documents that are the product of international negotiations (e.g., guidances resulting from the International Conference on Harmonisation), FDA need not apply paragraphs (i)(1) and (i)(2) of this section. However, any final guidance document issued according to this provision must contain the elements in paragraphs (i)(1) and (i)(2) of this section.

(j) *Who, within FDA, can approve issuance of guidance documents?* Each center and office must have written procedures for the approval of guidance documents. Those procedures must ensure that issuance of all documents is approved by appropriate senior FDA officials.

(k) *How will FDA review and revise existing guidance documents?*

(1) The agency will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

(2) When significant changes are made to the statute or regulations, the agency will review and, if appropriate, revise guidance documents relating to that changed statute or regulation.

(3) As discussed in paragraph (f)(3) of this section, you may at any time suggest that FDA revise a guidance document.

(l) *How will FDA ensure that FDA staff are following GGP's?*

(1) All current and new FDA employees involved in the development, issuance, or application of guidance documents will be trained regarding the agency's GGP's.

(2) FDA centers and offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed.

(m) *How can you get copies of FDA's guidance documents?* FDA will make copies available in hard copy and, as feasible, through the Internet.

(n) *How will FDA keep you informed of the guidance documents that are available?*

(1) FDA will maintain on the Internet a current list of all guidance documents. New documents will be added to this list within 30 days of issuance.

(2) Once a year, FDA will publish in the FEDERAL REGISTER its comprehensive list of guidance documents. The comprehensive list will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list.

(3) FDA's guidance document lists will include the name of the guidance document, issuance and revision dates, and information on how to obtain copies of the document.

(o) What can you do if you believe that someone at FDA is not following these GGP's? If you believe that someone at FDA did not follow the procedures in this section or that someone at FDA treated a guidance document as a binding requirement, you should contact that person's supervisor in the center or office that issued the guidance document. If the issue cannot be resolved, you should contact the next highest supervisor. You can also contact the center or office ombudsman for assistance in resolving the issue. If you are unable to resolve the issue at the center or office level or if you feel that you are not making progress by going through the chain of command, you may ask the Office of the Chief Mediator and Ombudsman to become involved.

[65 FR 56477, Sept. 19, 2000]

Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

SOURCE: 49 FR 14726, Apr. 13, 1984, unless otherwise noted.

§ 10.200 Scope.

This guideline describes FDA's policy and procedures applicable to electronic media coverage of agency public administrative proceedings. It is a guideline intended to clarify and explain FDA's policy on the presence and operation of electronic recording equipment at such proceedings and to assure uniform and consistent application of practices and procedures throughout the agency.

§ 10.203 Definitions.

(a) *Public administrative proceeding* as used in this guideline means any FDA proceeding which the public has a right to attend. This includes a formal evidentiary public hearing as set forth in part 12, a public hearing before a Public Board of Inquiry as set forth in part 13, a public hearing before a Public Advisory Committee as set forth in part 14, a public hearing before the Commissioner as set forth in part 15, a regulatory hearing before FDA as set forth in part 16, consumer exchange meetings, and Commissioner's public meetings with health professionals.

(b) *Advance notice* as used in this guideline means written or telephone notification to FDA's Office of Public Affairs (Press Relations Staff) of intent to electronically record an agency public administrative proceeding.

(c) *Electronic recording* as used in this guideline means any visual or audio recording made by videotape recording equipment or moving film camera, and/or other electronic recording equipment.

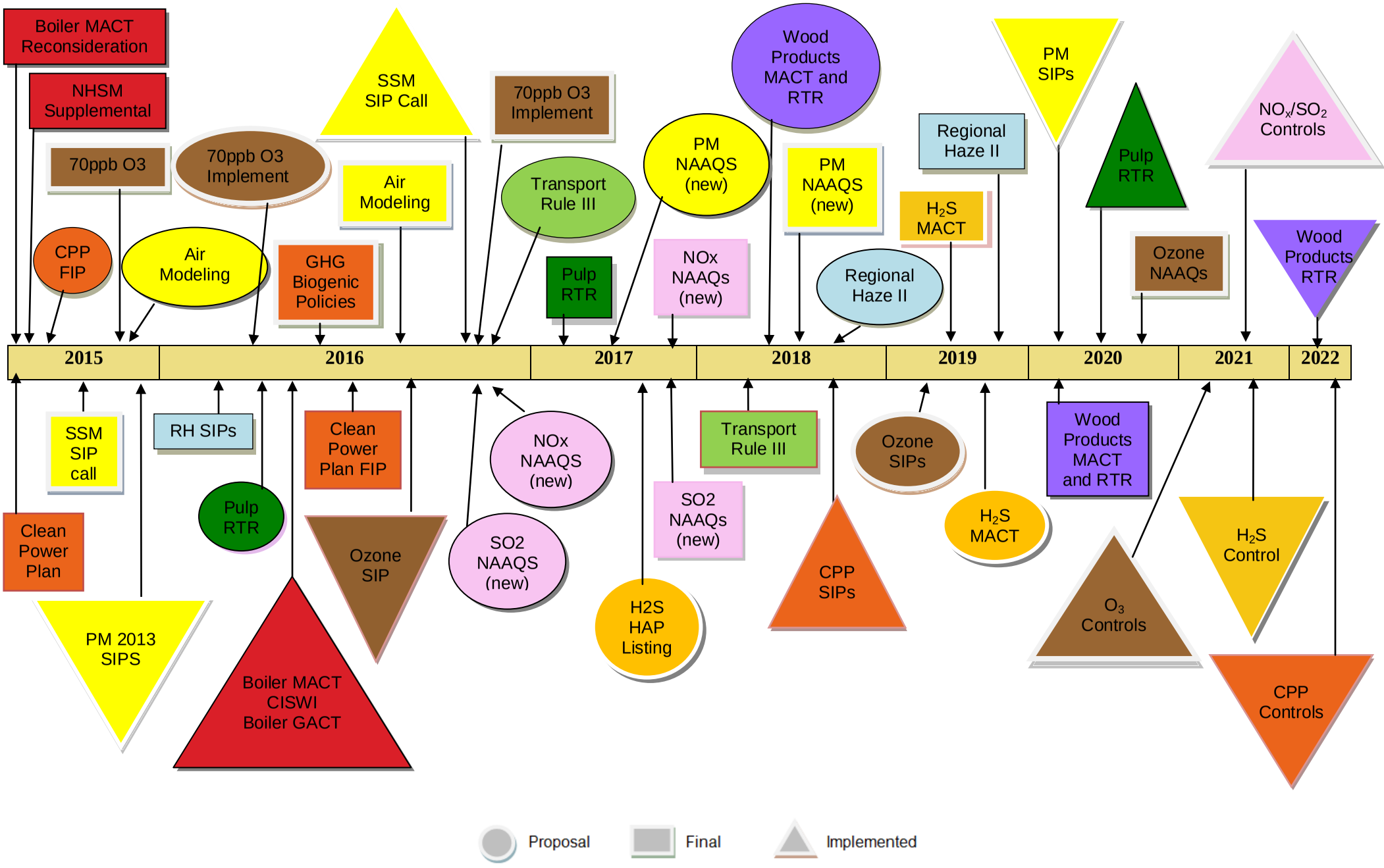
[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

§ 10.204 General.

(a) FDA has for many years willingly committed itself to a policy of openness. In many instances FDA has sought to make the open portions of agency public administrative proceedings more accessible to public participation. Similarly, FDA has sought, wherever possible, to allow full written media access to its proceedings, so that members of the press would have the opportunity to provide first-hand reports. However, because electronic media coverage presents certain difficulties that are easier to resolve with advance notice to the agency and all participants, FDA believes that codification of its policy will facilitate and further increase media access to its public administrative proceedings. The agency intends to refer to this guideline when notices of hearing, or individual advisory committee meetings, are published in the FEDERAL REGISTER. Thus, all parties to a proceeding will be on notice that the proceeding may be recorded electronically and any person interested in videotaping or otherwise recording the proceeding will be notified that there are established procedures to be followed.

(b) The designated presiding officer of a public administrative proceeding retains the existing discretionary authority set forth in specific regulations pertaining to each type of administrative proceeding to regulate the conduct

Potential Air Regulations Affecting Forest Products (2015-2022)



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Symposium: Due Process and Management for Guidance Documents: Good Governance Long Overdue

25 YALE J. ON REG. 103

Due Process and Management for Guidance Documents: Good Governance Long Overdue

Paul R. Noe

John D. Graham[†]

On January 18, 2007, President Bush signed amendments to clarify and strengthen Executive Order (E.O.) 12,866, which President Clinton had issued to update principles for inter-agency planning and review of regulations. The most important provisions of President Bush's E.O. 13,422 clearly extend inter-agency review to guidance documents. E.O. 13,422 was reinforced by a Bulletin for Agency Good Guidance Practices issued by the Office of Management and Budget (OMB).[1] Together, E.O. 13,422 and the OMB Bulletin establish the first government-wide "rules of the road" to manage the development and use of guidance documents.

OMB now has clear authority to review significant agency guidance documents, just as OMB reviews significant agency regulations. The agencies, in turn, are required to give OMB advance notice of their upcoming significant guidance documents. OMB will be responsible for ensuring that other interested agencies occasionally have notice and an opportunity to provide input into the most important guidance documents.

In the view of the authors, the outcry that followed the issuance of the Order and Bulletin was remarkable and unwarranted.[2] On one hand, the two most controversial provisions in E.O. 13,422 (which are irrelevant to guidance documents) were edits to authorities already provided by the Clinton Order—edits that were unnecessary and unlikely to practically affect regulatory policy de-

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1 Under the OMB Bulletin, agencies first must implement procedures for the approval and use of significant guidance documents by appropriate senior officials. Second, significant guidance documents must have standard elements. Agencies are directed to avoid inappropriate mandatory language in guidance documents. Finally, the Bulletin establishes public access and feedback procedures. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007). For the Order, see Exec. Order No. 13,422, 72 Fed. Reg. 2763, 2765 (Jan. 23, 2007).

2 *See, e.g.*, Paul Krugman, *The Green-Zoning of America*, N.Y TIMES, Feb. 5, 2007, at A21; Robert Pear, *Bush Directive Increases Sway on Regulation*, N.Y. TIMES, Jan. 30, 2007, at A1; Cindy Skryzcki, *Bush Order Limits Agencies' "Guidance,"* WASH. POST, Jan. 30, 2007, at D1.

velopment.[3] On the other hand, extending the existing regulatory review process to significant guidance documents is a beneficial and essential change—the most important change to the regulatory review process since President Reagan formalized it in 1981. This Essay briefly reviews the evolution of E.O. 13,422 and the OMB Bulletin and argues that their good guidance provisions were firmly supported by precedent and long overdue.

I. Background

President Reagan's Executive Order 12,291, which firmly established OMB regulatory review, covered virtually all rules.[4] E.O. 12,291 defined its scope by incorporating most of the definition of "rule" from the Administrative Procedure Act, which includes not only legally binding legislative rules ("regulations"), but also interpretive rules and policy statements ("guidance documents").[5] In theory, OMB's authority under the Reagan Order was strikingly broad on two levels: First, it did not establish a "significance" threshold for OMB review. Second, the Order did not limit OMB review of guidance documents.

In practice, too, the breadth of OMB's authority was unwieldy. Each year, agencies issue on the order of 4000 regulations,[6] and the number of guidance documents is orders of magnitude larger.[7] With several dozen staff, OMB's Office of Information and Regulatory Affairs (OIRA) cannot hope to review more

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3 The most-criticized features of E.O. 13,422, a provision on Regulatory Policy Officers and a provision on market failure analysis, were actually established by President Clinton's E.O. 12,866. E.O. 13,422 only made minor modifications to those provisions, and those modifications have little practical significance. *See Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I: Hearing Before the Subcomm. on Commerce & Admin. Law, of the H. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Paul R. Noe, Partner, C&M Capitolink LLC), *available at* http://judiciary.house.gov/media/pdfs/Noe070213.pdf. Others have staunchly disagreed, and some have gone so far as to claim that the provision on Regulatory Policy Officers is unconstitutional. *Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I: Hearing Before the Subcomm. on Commerce & Admin. Law of the H. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Peter L. Strauss, Professor, Columbia University School of Law), *available at* http://judiciary.house.gov/media/pdfs/Strauss070213.pdf.

4 *See* Administrative Procedure Act, 5 U.S.C. § 551(4) (2000).

5 *See* Exec. Order No. 12,291, 3 C.F.R. 127, 127 (1981) ("'Regulation' or 'rule' means an agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the procedure or practice requirements of an agency . . . .").

6 *See, e.g.*, Office of Mgmt. & Budget, Office of Info. & Regulatory Affairs, Report to Congress on the Costs and Benefits of Federal Regulations (1997), http://www.whitehouse.gov/omb/inforeg/rcongress.html (last visited Dec. 14, 2007).

7 *See, e.g.*, Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1469 (1992) (noting that the formally adopted rules of the Federal Aviation Administration are two inches thick, but the corresponding guidance materials, over forty feet; Part 50 of the Nuclear Regulatory Commission's regulations on nuclear plant safety, in loose-leaf edition, is 3/16 of an inch, but the supplemental technical guidance is 9 3/4 inches; and the formally adopted regulations of the IRS occupy one foot of shelf space, but Revenue rulings and similar publications, about twenty feet); *see also* H. COMM. ON GOV'T. REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009 (2000) (noting that between March 1996 through 1999, NHTSA had issued 1225 guidance documents, EPA 2653, and OSHA 1641).

than a small fraction of these rules. Our understanding is that during the Reagan and G.H.W. Bush years, OMB rarely called in guidance documents for review and did not have an established practice for doing so. However, OIRA did routinely review large numbers of legislative rules in its early years.[8]

In 1993, President Clinton replaced the Reagan Order with E.O. 12,866, which limited OIRA review to "regulatory actions" that were "significant." This was both wise and unwise. Given the vastness of federal regulatory activity and the limited resources of OIRA, it was eminently sensible to try to sort the significant agency activity from the insignificant. The problem is that while the Clinton Order applied to significant legally binding regulations, it neglected guidance documents. Indeed, while the Clinton Order is less than pellucid, it evidently curtailed the previous OMB authority over guidance documents.[9] Former OIRA Administrator Sally Katzen has stated that "Executive Order 12,866 was written to apply *only* where agencies undertook regulatory actions that had the force and effect of law"[10] and that she never reviewed a guidance document during her tenure in the Clinton administration. If that is the case, we believe that the Clinton Order was not only unclear but also fundamentally flawed.[11]

II. The Foundation for Good Guidance Practices

There is a strong foundation for the good guidance practices reflected in the OMB Bulletin and E.O. 13,422. First and foremost, the Administrative

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8 A cursory review of the record shows that OIRA reviewed a much greater number of rules under E.O. 12,291 during the Reagan and Bush-41 years than under E.O. 12,866 during the Clinton and Bush-43 years. For example, under E.O. 12,291, OIRA reviewed 2637 rules in 1982 (79 were economically significant) and in 1990 reviewed 2137 (82 were economically significant). By contrast, under E.O. 12,866, OIRA reviewed 831 rules in 1994 (134 were economically significant) and in 2002 reviewed 669 rules (100 were economically significant). *See* Office of Mgmt & Budget, Review Counts, http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init (last visited Dec. 14, 2007).

9 E.O. 12,866 applied to an "agency statement of general applicability and future effect, *which the agency intends to have the force and effect of law*, that is designed to implement, interpret or prescribe law or policy or to describe the procedure or practice requirements of an agency." *See* Exec. Order No. 12,866, 3 C.F.R. 638, 641 (1993), *reprinted in* 5 U.S.C. § 601 (2000) (emphasis added).

10 *Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I: Hearing Before the Subcomm. on Investigation & Oversight of the H. Comm. on Sci. & Tech.*, 110th Cong. 9 (2007) (statement of Sally Katzen, Adjunct Professor, University of Michigan Law School), *available at* http://democrats.science.house.gov/Media//File/Commdocs/hearings/2007/oversight/13feb/katzentestimony.pdf.

11 The growth in so-called "spurious rule" court cases in the 1990s may not be a coincidence. *See, e.g.*, Gen. Elec. Co. v. EPA, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as a spurious rule requiring notice and comment); Appalachian Power Co. v. EPA, 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as spurious rule requiring notice and comment); U.S. Chamber of Commerce v. Dep't of Labor, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as a spurious rule requiring notice and comment). An interesting research project would be to compare the growth in "spurious rule" court cases with the abstention of OMB review of guidance documents. *See also* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3435 (Jan. 25, 2007); Office of Mgmt. & Budget, Key to Public Comments, http://www.whitehouse.gov/omb/inforeg/keycomments.html (last visited Dec. 14, 2007).

Conference of the United States (ACUS)[12] issued recommendations for the development and use of agency guidance documents.[13] As far back as the mid-1970s, for example, ACUS recognized the importance of ensuring a notice and comment process for the most significant guidance documents.

ACUS Recommendation 76-5 states:

> Before an agency issues, amends or repeals an interpretive rule of general applicability or statement of general policy which is likely to have a substantial impact on the public, the agency normally should utilize the procedures set forth in the Administrative Procedure Act subsections 553(b) and (c) .... Where there has been no prepromulgation notice and opportunity for comment, the publication of an interpretive rule of general applicability or a statement of general policy ... should include ... an invitation to interested persons to submit written comments.[14]

ACUS Recommendation 92-2 later added:

> Agencies should not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures .... Policy statements of general applicability should make clear that they are not binding.... Agencies that issue policy statements should examine, and where necessary, change their ... procedures ... to allow as an additional subject requests for modification or reconsideration of such statements.[15]

In 1993, the American Bar Association (ABA) reaffirmed the ACUS recommendations on the use of informal notice and comment procedure for significant guidance documents.[16] In 2001, the ABA further recommended that agencies "explore means to maximize the availability and searchability of existing law and policy on their websites" and include "their governing statutes, all

12 ACUS was a federal advisory agency charged with providing recommendations on administrative procedure issues. During its existence from 1986 to 1995, ACUS made over 300 recommendations on administrative procedure issues, and over 200 were adopted by agencies or by Congress. *See* Florida State University College of Law, ABA Administrative Procedure Database, www.law.fsu.edu/library/admin/acus/acustoc.html (last visited Dec. 14, 2007).

13 *See* Recommendations of the Administrative Conference of the United States, Agency Policy Statements, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305922.html; AM. BAR ASS'N, ANNUAL REPORT INCLUDING PROCEEDINGS OF THE FIFTY-EIGHTH ANNUAL MEETING 57 (1993) ("[T]he American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.").

14 Recommendations of the Administrative Conference of the United States, Interpretive Rules of General Applicability and Statements of General Policy, Rec. 76-5, 1 C.F.R. § 305.76-5 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305765.html.

15 Agency Policy Statements, Rec. 92-2, 1 C.F.R. § 305.92-2.

16 AM. BAR ASS'N, *supra* note 13.

agency rules and regulations, and all important policies, interpretations, and other like matters which members of the public are likely to request."[17]

In 1997, the Food and Drug Administration (FDA) created a guidance document distilling its good guidance practices (GGP).[18] Following the FDA's publication of its original GGP, Congress then mandated by law certain aspects of the 1997 GGP document in the Food and Drug Administration Modernization Act of 1997 (FDAMA).[19] In FDAMA, Congress detailed basic elements of good guidance practices and required the FDA to issue new GGP as regulations.[20]

In the legislative history of FDAMA, Congress expressed particular concern about public knowledge of, and access to, FDA guidance documents; the lack of a systematic process for adopting guidance documents and for allowing public input; and inconsistency in the use of guidance documents.[21] Recognizing that those same concerns apply to other agencies as well, OMB used the FDA regulations mandated by Congress as a model for its government-wide Good Guidance Practices.[22]

Finally, though ACUS and the ABA do not have formal positions specifically addressing OMB review of guidance documents, they produced longstanding recommendations supporting presidential oversight of rulemaking as an essential element of good government.[23]

In sum, the good guidance provisions of E.O. 13,422 and the OMB Bulletin are firmly rooted in the recommendations of leading authorities that have stood for decades. If anything, the Order and Bulletin modestly implement

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17 AM. BAR ASS'N, RECOMMENDATION ON FEDERAL AGENCY WEB PAGES 1 (2001), http://www.abanet.org/adminlaw/federal02.pdf.

18 The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997).

19 21 U.S.C. § 371(h) (2000).

20 *Id.* (establishing FDA good guidance practices as law). The FDAMA also directed the FDA to evaluate the effectiveness of the 1997 GGP document and then to develop and issue the regulations specifying the FDA's policies and procedures for the development, issuance and use of guidance documents. The FDA conducted an internal evaluation soliciting FDA employees' views on the effectiveness of GGP and asking whether FDA employees had received complaints regarding the agency's development, issuance and use of guidance documents since the development of GGP. FDA found that its GGP had been beneficial and effective in standardizing the agency's procedures for development, issuance and use of guidance documents, and that FDA employees had generally been following GGP. The FDA then made some changes to its existing procedures to clarify its GGP. *See* Administrative Practices and Procedures: Good Guidance Practices, 21 C.F.R. § 10.115 (2007).

21 FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997, S. REP. NO. 105-43, at 26 (1997).

22 *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3432 (Jan. 25, 2007).

23 *See* Recommendations of the Administrative Conference of the United States, Presidential Review of Agency Rulemaking, Rec. 88-9, 1 C.F.R. § 305.88-9 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305889.html ("Presidential review should apply generally to federal rulemaking."); AM. BAR ASS'N, SECTION OF ADMIN. LAW & REGULATORY PRACTICE, REPORT TO THE HOUSE OF DELEGATES, RECOMMENDATION ON PRESIDENTIAL REVIEW OF RULEMAKING 1 (1990) (same); AM. BAR ASS'N, SECTION OF ADMIN. LAW, REPORT TO THE HOUSE OF DELEGATES, EXECUTIVE OVERSIGHT 1 (1986) (same).

those recommendations. For example, E.O. 13,422 established a more streamlined review process for guidance documents than used for regulations. Likewise, the OMB Bulletin requires pre-adoption notice and comment only for potentially "economically significant" guidance, whereas the FDA, as well as ACUS and the ABA, would do so for all significant guidance.[24]

III. The Need for Good Guidance Practices

We support prioritizing regulatory review based on significance as President Clinton's E.O. 12,866 did, but we have no doubt that guidance documents can be quite significant and have been neglected.

Although guidance documents may not properly carry the force of law, they are a key component of regulatory programs. As the breadth and complexity of regulatory programs has grown, agencies increasingly have relied on guidance documents to provide direction to their staff and to the public. That direction is essential to operating regulatory programs.

Nonetheless, concerns have persisted over the years about agency guidance practices. On one level, there are basic concerns about due process and fairness—the need for greater transparency, opportunity for comment, and accountability in issuing guidance. There also have been concerns about the need for coordination and management of guidance documents so they are coherent within and across agency programs and do not conflict with the priorities of the President. Finally, there is growing concern that guidance documents often are being used in lieu of regulations—without observing the procedural safeguards for regulations. As the D.C. Circuit observed:

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. . . . Law is made, without

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24 *See* FDA Good Guidance Practices, 21 C.F.R § 10.115(g) (2007) (pre-adoption notice and comment for "Level 1" guidance documents); Recommendations of the Administrative Conference of the United States, Interpretive Rules of General Applicability and Statements of General Policy, Rec. 76-5, 1 C.F.R. § 305.76 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305765.html (pre-adoption notice and comment for nonlegislative rules "likely to have a substantial impact"); AM. BAR ASS'N, ANNUAL REPORT INCLUDING PROCEEDINGS OF THE FIFTY-EIGHTH ANNUAL MEETING 57 (1993) (same). While the OMB did not go so far as to mandate pre-adoption notice and comment for all significant guidance, the OMB encouraged it. As it stated in the preamble to its Bulletin:

> Although this Bulletin does not require agencies to provide notice and an opportunity for public comment on all significant guidance documents before they are adopted, it is often beneficial for an agency to do so when they determine that it is practical. Pre-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial.

72 Fed. Reg. at 3438. Perhaps in the future after the Bulletin has been successfully implemented, its scope could be expanded consistent with this precedent.

> notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.[25]

It should be noted that whether or not guidance documents are "spurious rules"[26] subject to legal challenge, as a practical matter guidance can have coercive effects or lead parties to alter their conduct. As OMB explained in the preamble to the Bulletin:

> For example, under a statute or regulation that would allow a range of actions to be eligible for a permit or other desired agency action, a guidance document might specify fast track treatment for a particular narrow form of behavior but subject other behavior to a burdensome application process with an uncertain likelihood of success. Even if not legally binding, such guidance could affect behavior in a way that might lead to an economically significant impact. Similarly, an agency might make a pronouncement about the conditions under which it believes a particular substance or product is unsafe. While not legally binding, such a statement could be reasonably anticipated to lead to changes in behavior by the private sector or governmental authorities such that it would lead to a significant economic effect.[27]

Because such impacts—while perhaps more remote and attenuated—can be as significant as the impacts of regulations, it is reasonable that the Bulletin establishes a presumption of pre-adoption notice and comment for "economically significant" guidance and that E.O. 13,422 facilitates interagency review of significant guidance.

Prior to the issuance of E.O. 13,422 and the Bulletin on Good Guidance Practices, OMB had received scores of examples of problematic guidance and agency practices in response to its 2002 request for comments on problematic guidance,[28] other requests for regulatory reform nominations,[29] and the public comments on the proposed Bulletin.[30] The supporters of good guidance practices were as diverse as the Ornithological Council, homebuilders, funeral directors, the farming community, large and small business, educational organizations, and state and local government.

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25 Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (striking down emissions monitoring guidance as requiring notice and comment through legislative rulemaking procedures).

26 *See supra* note 11.

27 *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. at 3435.

28 Office of Mgmt. & Budget, Key to Public Comments, http://www.whitehouse.gov/omb/inforeg/key_comments.html (last visited Dec. 14, 2007).

29 Office of Mgmt & Budget, Peer Review and Public Comments on the 2005 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, http://www.whitehouse.gov/omb/inforeg/2005_cb/toc.html (last visited Dec. 14, 2007); Office of Mgmt & Budget, Public Comments on 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, http://www.whitehouse.gov/omb/inforeg/2004cb/list_2004cb.html (last visited Dec. 14, 2007).

30 Office of Mgmt & Budget, Comments on Proposed Bulletin on Good Guidance Practices, http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html (last visited Dec. 14, 2007).

As OMB detailed in the preamble to the Bulletin, such concerns have been raised for years by many authorities, including Congress,[31] the courts,[32] the Executive Branch,[33] the ABA,[34] scholars,[35] and the regulated community.[36]

In July 2007, after a rider to block funding for implementation of E.O. 13,422 was attached to a House appropriations bill, the regulated community swiftly reacted to oppose a similar Senate provision. Sixty-four trade associations representing most of the American economy opposed the rider, including big and small business, agriculture, education and other interests.[37] The primary motivation evidently was to preserve the good guidance practices reflected in the Order and Bulletin.[38] In addition, the Director of OMB sent a let-

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31 *See, e.g.*, Congressional Review Act of 1996, 5 U.S.C. §§ 801-808 (2000) (providing fast-track procedures for Congressional resolutions of disapproval of rules and incorporating the APA definition of "rule"); Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 371(h) (2000) (establishing FDA good guidance practices as law); Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong. § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents); H. COMM. ON GOVERNMENT REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009 (2000) (criticizing "back-door" regulation); FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997, S. REP. NO. 105-43, at 26 (1997) (raising concerns about the lack of transparency and consistency in the use of guidance documents).

32 *See supra* note 11.

33 Recommendations of the Administrative Conference of the United States, Agency Policy Statements, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305922.html (stating that agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); Recommendations of the Administrative Conference of the United States, Interpretive Rules of General Applicability and Statements of General Policy, Rec. 76-5, 1 C.F.R. § 305.76 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305765.html (stating that agencies should utilize APA notice and comment procedures for interpretive rules of general applicability or statements of general policy likely to have a substantial impact on the public); The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997) (notice) (establishing FDA's original good guidance practices); Draft Report to Congress on the Costs and Benefits of Federal Regulations, 67 Fed. Reg. 15,014, 15,034-35 (Office of Mgmt. & Budget Mar. 28, 2002) (detailing concerns over soliciting public comments on problematic agency guidance practices and specific examples of guidance documents in need of reform).

34 AM. BAR ASS'N, ANNUAL REPORT INCLUDING PROCEEDINGS OF THE FIFTY-EIGHTH ANNUAL MEETING 57 (1993) (recommending notice and comment for guidance documents likely to have a significant impact on the public); AM. BAR ASS'N, *supra* note 17 (recommending that agencies post on their Websites, *inter alia*, all important policies and interpretations).

35 *See, e.g.*, Robert A. Anthony, *"Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 ADMIN. L.J. 1 (1994); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like—Should Federal Agencies Use Them to Bind the Public?* 41 DUKE L.J. 1311 (1992).

36 One of the more notorious examples of problematic agency guidance during the Clinton administration was an OSHA advisory letter instructing a company stating that employers were liable for ensuring that the home offices of their employees were in compliance with OSHA workplace regulations. *See OSHA Policy Concerning Employees Working at Home: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Educ. & the Workforce*, 106th Cong. (2000), *available at* http://commdocs.house.gov/committees/edu/hedo&i6-81.000/hedo&i6-81.htm.

37 Letter from sixty-four trade associations to The Honorable Robert C. Byrd, Chairman, Comm. on Appropriations, and The Honorable Thad Cochran, Ranking Member, Comm. on Appropriations (July 12, 2007) (on file with the author).

38 *See* Cindy Skryzcki, *Congress Balks at White House Rulemaking Order*, WASH. POST, July 17, 2007, at D2.

ter to the appropriators threatening a veto recommendation for any provision that would prohibit funding or restrict implementation of E.O. 13,422.[39]

The rider was dropped before the Senate appropriations committee markup, but the rider still had strong support.[40] Following a debate on the Order and Bulletin at the annual meeting of the ABA Section of Administrative Law and Regulatory Practice, the Section sent letters to Congress opposing defunding of the Bulletin and the good guidance provisions of the Order.[41] Ultimately, the House rider was chopped from the final consolidated appropriations act.[42]

In the day-to-day operations of the Executive Branch, there is a need for ground rules to address ignorance and confusion about what agencies are doing on important guidance documents. Likewise, there is a need to demarcate the authority and responsibilities of OMB and the agencies. E.O. 13,422 clarifies while streamlining the traditional review process. For guidance documents, the agencies need only provide OMB with an advance list of upcoming significant guidance (not the guidance itself, nor an economic analysis). OMB can call in for review only the small share of guidance documents that merit consideration by its limited staff and the other interested agencies. This avoids needless burdens on the agencies and OMB.

Finally, clear OMB authority over guidance documents is necessary to preserve OMB's authority over regulations. Otherwise, the dysfunction diagnosed by the D.C. Circuit in *Appalachian Power* could occur in the regulatory review process. An agency could issue "regulations containing broad language, open-ended phrases, ambiguous standards and the like."[43] Such skeletal regulation might pass through interagency review without raising concerns. However, the agency could then follow with guidance "expanding the commands in the regulations"[44] and so forth to a degree that would have raised concerns in the interagency review process—or in Congress—had the details appeared in the regulations from the start. Indeed, the dearth of clear OMB authority could explain how *Appalachian Power* occurred.

From that perspective, E.O. 13,422 can be viewed as part of a larger movement by the three constitutional branches of government—the Legisla-

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39 Letter from Rob Portman, Director, Office of Mgmt. & Budget, to the Honorable Robert C. Byrd, Chairman, Comm. on Appropriations (July 12, 2007) (on file with the author).

40 *See Durbin Vows to Block Funds for White House Regulatory Review Order*, INSIDE EPA, Aug. 22, 2007 (on file with the Yale Journal on Regulation).

41 *See* Letter from Michael Asimow, Chair of the ABA Section of Administrative Law and Regulatory Practice, to Senators Richard Durbin and Sam Brownback (Nov. 8, 2007) (on file with the author). The letter does not take a position with respect to the controversial provisions of E.O. 13,422. *See also supra* note 3.

42 JOINT EXPLANATORY STATEMENT TO ACCOMPANY CONSOLIDATED APPROPRIATIONS AMENDMENT, FINANCIAL SERVICES AND GENERAL GOVERNMENT APPROPRIATIONS ACT, 2008, at 78, available at http://www.rules.house.gov/110/text/omni/jes/jesdivd.pdf.

43 Appalachian Power Co. v. EPA, 208 F.3d 1015, 1019 (D.C. Cir. 2000).

44 *Id.*

tive,[45] the Judicial,[46] and the Executive—to assert authority over the so-called "Fourth Branch of Government."

IV. Conclusion

Controversy has been with us since the inception of centralized review of rules, and doubtless it will continue. Nonetheless, it is our hope that a close consideration of the relevant language and practical significance of E.O. 13,422 and the OMB Bulletin will mitigate those concerns. Formally extending the regulatory review process to guidance documents was much needed and long overdue.

45 Congress asserted direct supervisory power and "veto" authority over agency rules—both regulations and guidance documents—in the Congressional Review Act of 1996. *See* 5 U.S.C. § 804(3) (2000) (incorporating the APA's definition of "rule"). As discussed above, in FDAMA Congress legislatively mandated FDA's pre-existing good guidance practices. *See supra* notes 18-21 and accompanying text.

46 *See supra* notes 11 & 25 and accompanying text.

Recommendations of the Administrative Conference of the United States

CODE OF FEDERAL REGULATIONS

TITLE 1--GENERAL PROVISIONS

CHAPTER III--ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

PART 305--RECOMMENDATIONS OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

1 C.F.R. s 305.76-5

s 305.76-5 Interpretive Rules of General Applicability and Statements of General Policy (Recommendation 76-5).

(a) Agencies often explain their view of the meaning of statutes or rules by issuing interpretive rules of general applicability, and agencies indicate how they will exercise discretion by announcing statements of general policy. The Administrative Procedure Act requires that these interpretive rules and policy statements be published in the Federal Register. But the Act does not require that interested persons be given advance notice and opportunity to comment upon interpretive rules and policy declarations. Courts, however, have occasionally imposed that requirement.

(b) At times policy statements and interpretive rules are barely distinguishable from substantive rules for which notice and comment is required. For that and other reasons many agencies have often utilized the notice-and-comment procedures set forth in section 553 of the Act, without regard to whether their pronouncements fall into one category or another. This is, in general, beneficial to both the agencies and potentially affected elements of the public. Providing opportunity for comment upon interpretive rules and policy statements of general applicability, sometimes before and sometimes after their adoption, makes for greater confidence in and broader acceptance of the ultimate

agency judgments. The following recommendations look toward wider voluntary adoption of such procedures by the agencies. Nothing here proposed would in any event alter the existing provisions of Administrative Procedure Act section 553(e), allowing any person to petition at any time for the amendment or repeal of a rule, including an interpretive rule or a statement of general policy. Moreover, the recommended procedures are not intended to apply to interpretations or policies set forth in opinions in formal or informal adjudications.

Recommendation

1. Before an agency issues, amends, or repeals an interpretive rule of general applicability or a statement of general policy which is likely to have substantial impact on the public, the agency normally should utilize the procedures set forth in Administrative Procedure Act subsections 553(b) and (c), by publishing the proposed interpretive rule or policy statement in the Federal Register, with a concise statement of its basis and purpose and an invitation to interested persons to submit written comments, with or without opportunity for oral presentation. If it is impracticable, unnecessary, or contrary to the public interest to use such procedures the agency should so state in the interpretive rule or policy statement, with a brief statement of the reasons therefor.

2. Where there has been no prepromulgation notice and opportunity for comment, the publication of an interpretive rule of general applicability or a statement of general policy, even one made effective immediately, should include a statement of its basis and purpose and an invitation to interested persons to submit written comments, with or without opportunity for oral presentation, within a following period of not less than thirty days. The agency should evaluate the rule or statement in the light of comments received. Not later than sixty days after the close of the comment period, the agency should indicate in the Federal Register its adherence to or alteration of its previous action, responding as may be appropriate to significant comments received. An agency may omit these post-adoption comment procedures when it incorporates in the interpretive rule or policy statement a declaration, with a brief statement of reasons, that such procedures would serve no public interest or would be so burdensome as to outweigh any foreseeable gain.

[41 FR 56769, Dec. 30, 1976]

Authority: 5 U.S.C. 591-596.

SOURCE: 38 FR 19782, July 23, 1973; 57 FR 61760, 61768, Dec. 29, 1992, unless otherwise noted.