OFFICE OF MANAGEMENT AND BUDGET

Proposed Bulletin for Good Guidance Practices

SUMMARY: The Office of Management and Budget (OMB) is proposing policies and procedures for agencies to develop, issue and use guidance documents. This Bulletin is intended to increase the quality and transparency of agency guidance practices and the guidance documents produced through them.

DATES: Interested parties should submit comments to OMB's Office of Information and Regulatory Affairs on or before December 23, 2005.

ADDRESSES: Because of potential delays in OMB's receipt and processing of mail, respondents are strongly encouraged to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic comments may be submitted to: OMB_GGP@omb.eop.gov. Please put the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number and e-mail address in the text of the message. Comments also may be submitted via facsimile to (202) 395-7245.

FOR FURTHER INFORMATION CONTACT: Lisa Jones, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, N.W., New Executive Office Building, Room 9013, Washington, DC, 20503. Telephone (202) 395-5897.

SUPPLEMENTARY INFORMATION:

I. 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 (GGP) -- 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 have been raised by other authorities, including Congress and the courts.[2]

As OMB discussed in its 2002 Report to Congress, guidance documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review. These procedures include: (1) internal agency review by a senior agency official; (2) interagency review through OMB; (3) public and Congressional oversight; (4) a variety of procedural safeguards, such as the Administrative Procedure Act, the Paperwork Reduction Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, the Congressional Review Act, Executive Order 12866 (regulatory analysis and review), and Executive Order 13272 (minimizing burdens on small entities); and (5) 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.[3]

The absence of procedural review mechanisms can undermine the lawfulness, quality, fairness and accountability of agency policymaking. The misuse of agency guidance also can impose significant costs on or limit the freedom of the public without affording notice and an opportunity to participate.

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[1] OMB, "Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities," at pp. 72-74.

[2] See, e.g., Food and Drug Modernization Act of 1997, Pub. L. 105-115, Section 405 (establishing FDA GGP as law); 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); H.R. 3521 (106th Cong.), the "Congressional Accountability for Regulatory Information Act of 2000," Section 4; 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 a legislative rule requiring notice and comment); Administrative Conference of the United States, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992); Rec. 76-5, 1 C.F.R. § 305.76-5 (1992).

[3] 208 F.2d at 1019.

The purpose of GGP is to ensure that agency guidance documents are: developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as 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.[4] In the last Administration, the Food and Drug Administration (FDA) created a guidance document distilling its good guidance practices. Congress then codified those practices in the Food and Drug Administration Modernization Act of 1997 (FDAMA). The FDAMA directed FDA to evaluate the effectiveness of the 1997 GGP document and then produce 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 questioning 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 have 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. FDA then made changes to its existing regulations to clarify its GGP.[5] The provisions of the FDAMA and FDA's implementing regulations, as well as the ACUS recommendations, informed the development of this government-wide Bulletin.

II. Requirements of Proposed Bulletin

A. Overview

This Bulletin provides a definition of guidance; describes the legal effect of guidance documents; establishes practices for developing guidance documents and receiving public input; and establishes ways for making guidance documents available to the public.

B. Definitions

Section I provides definitions that are central to this Bulletin. Several terms are based on or identical to those in FDA's GGP regulations, 10 C.F.R. § 10.115, and the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq.

Proposed § I(1) provides that the term "agency" has the same meaning as the Paperwork Reduction Act, 44 U.S.C. § 3502(1), other than those considered to be independent agencies, as defined in 44 U.S.C. § 3502(5).

[4] See note 2, supra.

[5] See Proposed Rule, 65 FR 7321, 7322-23 (Feb. 14, 2000); 21 C.F.R. § 10.115.

Proposed § I(2) defines the term "guidance document" as documents, other than those issued pursuant to 5 U.S.C. § 553 or § 554, that are prepared by an agency and available to the public to describe the agency's interpretation of or policy on a regulatory or technical issue. For example, guidance documents include, but are not limited to, documents that relate to: the design, production, manufacturing, control, remediation, testing or assessment of products and substances; and the processing, content, and evaluation/approval of submissions or applications. Proposed § I(4) defines the phrase "available to the public" to clarify that the term "guidance document" covers documents that are made available to the public by the agency or that are required to be disclosed under the Freedom of Information Act, 5 U.S.C. § 552.

Proposed § I(3) defines the term "significant guidance document" as a guidance document that may: (i) Reasonably be anticipated to lead to an annual effect of $100 million or more or adversely affect in a material way the economy or a sector of the economy; (ii) Raise highly controversial issues related to interagency concerns or important Administration priorities; (iii) Set forth initial interpretations of statutory or regulatory requirements, or changes in interpretation or policy; or (iv) Concern novel or complex scientific or technical issues.

Section I(3) also clarifies what is not a significant guidance document under this Bulletin. For purposes of this Bulletin, documents that would fall into the non-significant guidance category include: contractor instructions, legal advisory opinions for internal Executive Branch deliberations (such as Department of Justice Office of Legal Counsel opinions), briefs and other litigation positions, speeches, journal articles, editorials, media interviews, press materials, memoranda of understanding or warning letters. Memoranda of understanding would not be considered guidance documents because memoranda of understanding are agreements that agencies make with other Federal or State government organizations to determine who will enforce certain laws. These documents do not articulate agency policy, and therefore they fall outside the definition of a guidance document.

Among an agency's internal documents, there is a category of documents that may describe its day-to-day business. Though such documents might be of interest to the public, they do not fall within the definition of guidance documents for the purposes of this Bulletin. Examples of such documents could include staff guides regarding personnel information or leave policies or directives on how to route documents for review within the agency.

Section I(5) states that the term "economically significant guidance document" has the same meaning given in Section I(3)(i) of the Bulletin, except that economically significant guidance documents do not include documents on Federal expenditures and receipts. Accordingly, significant guidance documents on Federal budget expenditures and taxes are not subject to Section IV, but they are covered by the other requirements of this Bulletin.

C. Basic Agency Standards

Proposed § II describes basic agency standards for significant guidance documents.

1. Agency Approval Procedures

Guidance documents represent the agency's current position. Accordingly, § II(1)(a) states that agency employees may depart from significant guidance documents only with appropriate justification and supervisory concurrence. To implement § II(1)(a), proposed § II(1)(b) directs each agency to develop or have written procedures for the internal clearance of significant guidance documents. Those procedures should ensure that issuance of significant guidance documents is approved by appropriate senior agency officials. Currently at FDA, for example, the Director in a Center or an Office of Regulatory Affairs equivalent or higher approves a significant guidance document before it goes out to the public in draft or final form. The Chief Counsel approves a draft or final guidance document that describes new legal interpretations. The Director of the Office of Policy approves the release of a draft or final guidance document that describes significant changes in agency policy. Other agencies should consider adopting FDA's approval procedures.

Agencies should follow GGP when providing important policy direction on a broad scale. Accordingly, § II(1)(c) states that each agency should not use documents or other means of communication that are excluded from the definition of significant guidance document to informally or indirectly communicate new or different regulatory expectations to a broad public audience for the first time. This requirement does not apply to positions taken by agencies in litigation, or in any way affect their authority to communicate their views in court or other enforcement proceedings.

Agencies also should ensure consistent application of GGP. Current and new employees involved in the development, issuance or application of significant guidance documents should be trained regarding the agency's GGP. In addition, agency Offices should regularly monitor the development, issuance and use of guidance documents to ensure that employees are following good guidance practices.

2. Standard Elements

Section II(2) establishes basic requirements for significant guidance documents. They should: (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 people 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 identify the document that it replaces; and (vi) Provide the title of the guidance, and any docket number, if one exists. Finally, § II(2)(vii) clarifies that, given their nonbinding nature, 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. Agencies should educate the public about the legal effect of guidance and explain the legal effect when speaking to the public about guidance documents.

D. Public Access and Feedback

Proposed § 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 guidance documents and guidance documents themselves are made available to the public in electronic form. Proposed § III(1) enables the public to obtain a list of all of an agency's significant guidance documents. Under proposed § III(1)(a), agencies will maintain a current list of all significant guidance documents on their Web site. New documents will be added to this list within 30 days of issuance. The agency shall provide a link from the list to each guidance document that has been made public.

Under § III(1)(b), the agencies annually will post on their Web sites a comprehensive update of significant guidance documents added to the list, revised or withdrawn. Agencies are encouraged to offer a listserve or similar mechanism for members of the public who would like to be notified by email each time an agency issues its annual update of guidance documents. Agencies will link their guidance document lists to the U.S. Government's official Web portal: firstgov at *http://www.FirstGov.gov*. Under § III(1)(c), the agency guidance document lists will include: (1) The name of the guidance document, any docket number, and issuance and revision dates; and (2) information on how to obtain copies of the document. Many recently issued guidance documents have been made available through the Internet, but there are some documents that are not available in an electronic version that easily can be included on the Internet.

2. Public Feedback

Each agency should have adequate procedures to address complaints regarding the development and use of guidance documents. Not later than 90 days from the issuance of this Bulletin in final form, each agency shall establish and clearly advertise on its Web site a means for the public to electronically submit comments on significant guidance documents, and to electronically request that significant guidance documents be created, reconsidered or modified. Public comments submitted under these procedures on significant guidance documents are for the benefit of the agency, and no formal response to comments by the agency is required. 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 guidance document.

E. Notice and Comment on Economically Significant Guidance Documents

Under § IV, after the agency prepares a draft economically significant guidance document, the agency should publish a notice in the **Federal Register** announcing that

the draft guidance document is available. The agency should post the draft on the Internet and make it publicly available in hard copy. The agency should invite public comments on the draft guidance document. The agency at its discretion also may hold public meetings or workshops on a draft guidance document, or present it to a peer review committee or an advisory committee for review. 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 guidance document. The agency then should publish a notice in the **Federal Register** announcing that the guidance document is available. The agency should post the guidance document on the Internet and make it available in hard copy. The agency also should prepare a 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 guidance document. The agency will 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 Website.

Under Section 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. For example, it may not be feasible or appropriate for an agency to seek public comment before implementing a significant guidance document if there are public health, safety, environmental or other emergencies requiring immediate implementation of the guidance document, or there is a statutory requirement, Executive order, or court order that requires immediate implementation. An agency may discuss with OMB other exceptions that are consistent with § IV(2), if the need arises. Agencies may, in consultation with OMB, identify particular guidance documents or classes of guidance documents for which the procedures of this Section are not feasible and appropriate.

Though economically significant guidance documents that fall under the exemption in § IV(2) are not required to undergo the full notice and comment procedures, to the extent practical, the agency should: (1) Publish a notice in the **Federal Register** announcing that the guidance document is available; (2) Post the guidance document on the Internet and make it available in hard copy; and (3) Seek public comment when it issues or publishes the guidance document. If the agency receives comments on one of the excepted guidance documents, the agency should review those comments and revise the guidance document, when appropriate.

The public should know when a significant guidance document has been issued because it will be posted on the Internet. In addition, the agency's electronic current list will be updated within 30 days of issuance, and the agency's annual Web site list will

identify all guidance documents that have been issued since the previous list was published.

The agency's guidance document development process should be as open as possible. The agency should review the comments that it receives and revise guidance documents in response to the comments, when appropriate. When a draft economically significant guidance document is issued, the agency should propose a period of time for the receipt of comments. Comments received after the closing date of the specified comment period should be reviewed to the extent practicable, and issues raised in those comments may be addressed in a future revision of the document, as the agency deems appropriate.

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. Once comments have been received, the agency should establish a docket for the guidance document, and all additional comments will be routed to that docket. Comments should be available to the public at the docket, and when feasible, on the Internet.

F. 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.

G. Effective Date

Unless otherwise specified, the requirements of this Bulletin shall take effect 90 days after issuance in final form.

Proposed OMB Bulletin for Good Guidance Practices

I. Definitions.

For purposes of this Bulletin—

1. The term "agency" has the same meaning as 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).

2. The term "guidance document" means a document, other than a document issued pursuant to 5 U.S.C. § 553 or § 554, prepared by an agency and available to the public to describe the agency's interpretation of or policy on a regulatory or technical issue.

3. The term "significant guidance document" means a guidance document that may:

(i) Reasonably be anticipated to lead to an annual effect of $100 million or more or adversely affect in a material way the economy or a sector of the economy;

(ii) Raise highly controversial issues related to interagency concerns or important Administration priorities;

(iii) Set forth initial interpretations of statutory or regulatory requirements, or changes in interpretation or policy; or

(iv) Concern novel or complex scientific or technical issues.

Significant guidance documents do not include contractor instructions, legal advisory opinions for internal Executive Branch deliberations, briefs and other litigation positions, speeches, journal articles, editorials, media interviews, press materials, memoranda of understanding, or warning letters.

4. The term "available to the public" means made available to the public by the agency or required to be disclosed under the Freedom of Information Act, 5 U.S.C. § 552.

5. The term "economically significant guidance document" has the same meaning given in Section I(3)(i) of this Bulletin, except that economically significant guidance documents do not include documents on Federal expenditures and receipts.

II. Basic Agency Standards.

1. Approval Procedures:
    a. Agency employees may depart from significant guidance documents only with appropriate justification and supervisory concurrence.
    b. Each agency shall develop or have written procedures for the approval of significant guidance documents. Those procedures shall ensure that issuance of significant guidance documents is approved by appropriate senior agency officials.
    c. Agencies may not circumvent the significant guidance document requirements by using alternate means of communication to disseminate new or different regulatory expectations to a broad public audience for the first time. This Bulletin does not apply to positions

taken by agencies in litigation, or in any way affect their authority to communicate their views in court or other enforcement proceedings.

2. Standard Elements: Each significant guidance document shall:

(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 people 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 identify the document that it replaces;

(vi) Provide the title of the guidance, and any docket number, if one exists; and

(vii) 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.

III. Public Access and Feedback.

1. Internet Access:

a. Each agency shall maintain on its Web site a current list of its significant guidance documents. The agency shall provide a link from the current list to each significant guidance document that has been made public. New significant guidance documents and their Web site links shall be added promptly to this list, no later than 30 days from issuance.

b. Each agency shall annually post on its Web site a comprehensive list of its significant guidance documents. The comprehensive list shall identify significant guidance documents that have been added to the list, revised, or withdrawn from the list since the previous comprehensive list.

c. The guidance document lists shall include the name of each guidance document, any document identification number, and issuance and revision dates.

2. Public Feedback:

a. Each agency shall establish and clearly advertise on its Web site a means for the public to electronically submit comments on significant guidance documents, and to electronically request that significant guidance documents be created, reconsidered, or modified.

b. Public comments under the above procedures are for the benefit of the agency, and no formal response to comments by the agency is required.

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:

(i) Publish a notice in the Federal Register announcing that the draft guidance document is available;

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

(iii) Invite public comment on the draft guidance document; and

(iv) Respond to the public comments.

2. Exemptions: Agencies may, in consultation with OMB, identify particular guidance documents or classes of guidance documents for which the procedures of this Section are not feasible and appropriate.

V. 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.

VI. Effective Date.

Unless otherwise specified, the requirements of this Bulletin shall take effect 90 days after issuance in final form.