From: Boundy, David [mailto:DBoundy@cantor.com]
Sent: Tuesday, January 12, 2010 7:26 PM
To: Patent Practice
Cc: Fraser, Nicholas A.
Subject: Comments on "unappealed claims" Federal Register notice

Ms. Chang: attached are my comments on the "unappealed claims" notice. I am writing as an individual, not on behalf of any client.

<<100112 Boundy letter re Rejected Claims that Are Not Being Appealed 74 FR 66097 100112 FINAL.pdf>>

Mr. Fraser: the Patent Office continues to need your oversight and assistance. See §§ III(C), III(D), and III(E) starting at page 10.

David E. Boundy
c/o Cantor Fitzgerald
110 East 59th St
New York, NY 10022
(212) 294-7848
(917) 677-8511 (FAX)

David E. Boundy
Cantor Fitzgerald, L.P.
499 Park Ave.
New York, NY 10022

January 12, 2010

By Email

Ms Joni Y. Chang
PatentPractice@uspto.gov
Office of Patent Legal Administration
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Cc: Nicholas A. Fraser, Desk Officer for Patent and Trademark Office, Office of Information and Regulatory Affairs, Office of Management and Budget, Nicholas_A._Fraser@omb.eop.gov (Executive Order 12,866 and Paperwork Reduction issues in introductory paragraphs and in §§ III.C, III.D, and III.E starting at page 10)

Re: Procedure for Treating Rejected Claims That Are Not Being Appealed, Request for Comments (no RIN docket number), 74 Fed. Reg. 66097 (Dec. 14, 2009)

Dear Ms. Chang:

This Notice presents four big issues and a host of smaller ones:

- The regulatory effect of the Notice is unambiguously and uniformly negative on the public. The Notice identifies no benefit to either the public or to the Office, but does acknowledge several adverse effects and costs. The PTO does not address these new economic effects or burdens in the manner required by **Executive Order 12,866** or the ***Final Bulletin for Agency Good Guidance Practices***, and the Notice ignores a lower-burden alternative, the procedure that prevailed for decades until May 2008.
- The Notice creates new information collection burdens that require clearance under the **Paperwork Reduction Act**, but contains no estimate of either number of responses or cost per response, and does not commence the process to obtain OMB clearance for those burdens. The PTO has information in its database that would permit the PTO to estimate burden as required by the Act, but the PTO did not disclose the data it has.

- The disagreement among various parts of the PTO that the Notice seeks to correct arose out of the Board's breach of a directive from the Executive Office of the President, the *Final Bulletin for Agency Good Guidance Practices*, and *ultra vires* breach of a policy determination made by the Office that was binding on the Board. The Notice does nothing to acknowledge, let alone cure, those two breaches.
- The Notice will *increase* the workload for the Board—in the future, appellants will appeal claims that would not have been appealed under today's regulations, in order to avoid the adverse effects of the Notice

The Notice proposes to change the procedure that prevailed before 2008, where unappealed claims were "withdrawn from the appeal" but remained pending. This pre-2008 procedure is simple to administer, and is predictable because it is the procedure used by every other judicial or administrative tribunal for almost every issue. The "withdrawn from the appeal" procedure is dictated by current 37 C.F.R. Part 41, and is the only option that appears to be consistent with various provisions of administrative law that bind the PTO. The Administrative Procedure Act, the Paperwork Reduction Act, and two directives of the President point to the proper resolution: the PTO should recognize that *Ex parte Ghuman*, 88 USPQ2d 1478 (BPAI 2008), the purported basis for the Notice, violated administrative law, and should be vacated. The rest of the MPEP should be conformed to "withdrawn from the appeal" procedure.

This Notice is deeply disappointing for its numerous violations of administrative law. Winds of change in fall 2009 raised hopes that the PTO had finally begun to respect its obligations under the Paperwork Reduction Act, Executive Order 12,866, and the Administrative Procedure Act, which operate to protect applicants from PTO overreaching. Instead, this Notice baldly ignores these laws, and other procedural laws that govern the PTO. Strikingly, the Notice ***never mentions*** any of the procedural laws that govern the PTO—which calls into question the PTO's commitment to comply with administrative rule making law. The Notice identifies ***no problem*** with pre-2008 procedure, ***no identified benefit to either applicants or the PTO*** from the proposal, and nothing about the proposed procedure that improves on pre-2008 procedure. The proposal admits that applicants will lose significant rights and may be subject to

additional "information collections" under the Paperwork Reduction Act, but identifies no beneficial *quid pro quo*, indeed, no benefit to *anyone*.

Strikingly, the pre-2008 procedure that the Notice displaces was the *simplest* procedure for the Office (the Office literally had to do *nothing*); under the Notice, the Board proposes to cancel claims, nearly the most-severe expropriation that could be imposed, even if the PTO has to *go out of its way to do so*. The Notice also fails to recognize the adaptive responses that applicants will take—claims that go unappealed today will be appealed in the future—which will increase the Board's workload.

The Director should exercise his authority to vacate *Ghuman*.[1] The rest of the MPEP should be conformed to pre-2008 "withdrawn from the appeal" procedure. If the PTO believes a change from "withdrawn from the appeal" is warranted, the PTO must observe the laws that govern administrative rule making: at the very least the PTO must identify a problem, and make a cost-benefit showing vis-à-vis that problem. In all likelihood, the PTO will find that there is no alternative to pre-2008 "withdrawn from the appeal" procedure that is consistent with the Paperwork Reduction Act and Executive Order 12,866, and will decide to amend or vacate all written documents (including *Ghuman*) that conflict with "withdrawn from the appeal."

I. Pre-2008 "withdrawn from the appeal" procedure—established, sensible, legal, simple, predictable

Column 2 of the Notice correctly states that until May 2008, "non-appealed rejected claims were considered ***withdrawn from the appeal***." Those claims remained pending, though rejected. This is the simplest possible way to handle the matter: the Board needs to do literally *nothing*. Any issue not argued stands as decided by the

[1] The Director has such authority over the Board. For example, 37 C.F.R. Part 41 issues on the authority of the Director, not the Board. The Director has issued orders in the past overruling the Board to oversee the Board's compliance with PTO regulations, *e.g.*, *In re Oku*, 25 USPQ2d 1155, 1157 (Comm'r Pats. & TM 1992) (Director has jurisdiction to review "the important question of whether the Board followed PTO regulations established by the [Director]. In appropriate circumstances the [Director] may exercise his supervisory authority" over actions of the Board).

examiner, with whatever *res judicata* effect applies to examiner decisions, no more, no less.[2] At the conclusion of the appeal, unappealed claims have exactly the same status they had at the beginning of the appeal. This mirrors that procedure before all other tribunals: an uncontested issue is just that, and is not an admission or waiver of any other issue.

In August 2005, MPEP § 1205.02 was amended to largely track the "withdrawn from the appeal" procedure, and now reads as follows:

> **1205.02Appeal Brief Content [R-3]**
> …If a ground of rejection stated by the examiner is not addressed in the appellant's brief, that ground of rejection will be summarily sustained by the Board

MPEP § 1205.02 is *almost* correct: when unappealed claims are "withdrawn from the appeal," the Board is to take *no action at all*, not even "summarily sustain." The claims remain *pending in the application*, though rejected and not appealed, and emerge at the end of the appeal in the same posture as they entered, for whatever further prosecution the applicant and examiner see fit.

There are several important conveniences for the PTO and for applicants that flow from pre-2008 procedure that simply leaves the claims pending, rejected, and withdrawn from the appeal. First, if the unappealed claims have dependent claims that ***are*** appealed, the dependent claims are in formally-sufficient form, and there is no need for the appellant to file a gratuitous amendment to put the claims in independent form. Second, because the claims are withdrawn from the appeal, the Board has the simplest possible task: do ***nothing***. Neither *Ghuman* nor the Notice identifies any benefit to the PTO to requiring more. Third, the unappealed claims can reenter prosecution at the conclusion of the appeal, with only minimal procedural fuss, for example, a Rule 312

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[2] "[P]recedent has long supported the right of an applicant to file a continuation application despite an unappealed adverse Board decision, and to have that application examined on the merits." *In re Kaghan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (1967). "Where the Patent Office has reconsidered its position on patentability in light of new arguments or evidence submitted by the applicant, the Office is not forbidden by principles of preclusion to allow previously rejected claims." *Abbott Laboratories v. TorPharm Inc.*¸ 300 F.3d 1367, 1379, 63 USPQ2d 1929, 1936–37 (Fed. Cir. 2002), *citing See In re Craig*, 411 F.2d 1333, 1335–36, 162 USPQ 157, 159 (1969).

amendment to make them dependent on allowed claims. Most important, applicants are not forced to choose based on an unforeseeable future or to file a gratuitous amendment to claims whose rejections might be affirmed.

"Withdrawn from the appeal" is stated in the plain text of 37 C.F.R. § 41.37. § 41.37 carefully makes clear that appellants have the right to appeal some claims and not others. *E.g.*, § 41.37(c)(1)(iii) requires two separate designations, "status of all the claims in the proceeding (*e.g.*, rejected, allowed…)" and "an identification of those claims that are being appealed…" § 41.37 clarifies that "rejected" and "appealed" are not coextensive. If § 41.37 required that all rejected claims be either appealed or cancelled, then the two separate status identifications required in § 41.37(c)(1)(iii) would be superfluous. Any attempt to make them coextensive is inconsistent with the language, and to the degree it burdens applicants, that attempt would be illegal.

As will emerge below, it is hard to conceive of any other procedure that could possibly be consistent with the Office's duties under the Paperwork Reduction Act and Executive Order 12,866, or consistent with the *text* of Part 41, without the PTO exceeding its authority.

II. The Board exceeded its authority when it issued *Ghuman* without observance of procedural law

"Withdrawn from the appeal," or its close analog MPEP § 1205.02, is more than common sense. The procedural rights in favor of applicants are legally binding on the Board, under several provisions of administrative law.

First, the Board was required to obtain intra-agency pre-clearance of any departure from the MPEP, pursuant to a directive Bulletin from the Executive Office of the President.[3]

Second, the *Ghuman* decision is inconsistent with the Federal Circuit's decisions in *Kaghan* and *Abbott Laboratories*, cited in footnote 2. The *Ghuman* panel did not

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[3] Executive Office of the President, *Final Bulletin for Agency Good Guidance Practices*, § II(1)(b), OMB Memorandum M-07-07, http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf at page 20 (Jan. 18, 2007), 72 Fed. Reg. 3432, 3440 (Jan. 25, 2007).

explain how its ruling was consistent with Federal Circuit precedent. Indeed, the *Ghuman* panel cited no statutory or Federal Circuit authority whatsoever—it appears that the Board believed it was writing on a clean slate, and had no obligation to consider any law other than its own precedent. But that is beyond the Board's authority.[4]

Third, the *Ghuman* panel relied on MPEP § 1215.03 to support its power to cancel or order cancellation of claims. The *Ghuman* panel violated one of the most basic principles of administrative law: the MPEP is a guidance document, and was not issued with the procedures required by statute before the PTO can bind or adversely affect the public. Without those procedures, the MPEP cannot bind or adversely affect on the public.[5] Under administrative law statutes[6] and express instructions from the Executive Office of the President,[7] ***the MPEP may not be cited adversely to applicants***. The *Ghuman* decision was illegal when it was issued. *Ghuman* is an error to correct, not to propagate.

Fourth, provisions of agency guidance documents that run in favor of the public, such as MPEP § 1205.02, are binding throughout the agency.[8] Interpretative rules,

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[4] Just last week, the Federal Circuit "remind[ed] … the Board that they must follow judicial precedent instead of 37 C.F.R. § 41.200(b) … because the PTO lacks the substantive rulemaking authority to administratively set aside judicial precedent." *Koninklijke Philips Electronics N.V. v. Cardiac Science Operating Co*., App. 2009-1241 at p. 17 (Fed. Cir. 2010).

[5] 5 U.S.C. § 552(a) (an agency "may not adversely affect" any member of the public based on documents such as the MPEP). To be sure, the MPEP is ***binding on Office personnel*** (including the Board) to the degree it operates in favor of applicants, as a "housekeeping" rule for internal agency operations. 5 U.S.C. § 301, also known as the "housekeeping statute" ("The head of an Executive department … may prescribe regulations for the government of his department, the conduct of its employees…")

[6] *E.g.*, 5 U.S.C. §§ 552(a) and 553, 44 U.S.C. §§ 3506 and 3507, etc.

[7] *Good Guidance Bulletin*, footnote 3, *passim* (reiterating over and over again that guidance documents are *not* to be treated as binding on the public, and the agency is required to have established procedures for handling complaints from the public when the agency illegally does so).

[8] *Morton v. Ruiz*, 415 U.S. 199, 235 (1974) ("Where the rights of the individuals are affected, it is incumbent upon agencies to follow their own procedures."); *Vitarelli v. Seaton*, 359 U.S. 535, 546-47 (1959) (Frankfurter, J. concurring) ("An executive agency must be rigorously held to the standards by which it professes its action to be judged …").

such MPEP § 1205.02, are binding on an agency, including the agency's ALJs.[9] The *Ghuman* panel had no discretion to silently ignore MPEP § 1205.02. If the panel disagreed with the PTO's determination to grant procedural rights to applicants and state them in the MPEP, then the panel was obligated to work through the MPEP revision process, including the Paperwork Reduction Act, not to casually ignore published procedures.[10]

In a prior case, the Board identified its basis for refusing to be bound by the authority of the Director, or follow pronouncements of policy-making offices of the PTO.[11] Judge Barrett, in *Ex parte Bilski*,[12] wrote:

> The Board is not bound by [the § 101 Interim Guidelines][8]
>
> [8] From the movie Pirates of the Caribbean (Disney 2003):
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> Elizabeth: You have to take me to shore! According to the Code of the Order of the Brethren.
>
> Barbossa: First, your return to shore was not part of our negotiations nor our agreement, so I 'must' do nothin'. And secondly, you must be a pirate for the pirate's code to apply, and you're not. And thirdly, the code is more what you call guidelines than actual rules. Welcome aboard the Black Pearl, Miss Turner.

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[9] *Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71, 80 (2nd Cir. 2006) ("An interpretative rule binds an agency's employees, including its ALJs"); Kenneth C. Davis & Richard J. Pierce, Jr., ADMINISTRATIVE LAW § 6.3 (3d ed. 1996 & Supp.1997).

[10] *Atchison, Topeka and Santa Fe Ry. v. Wichita Board of Trade*, 412 U.S. 800, 805–08 (1973) ("Whatever the ground for the departure from prior norms, …, it must be clearly set forth so that the reviewing court may understand the basis for the agency's action and so may judge the consistency of that action with the agency's mandate."); *Ramaprakash v. Federal Aviation Admin*., 346 F.3d 1121, 1124 (D.C. Cir. 2003) (Roberts, J.) (an agency departing from its precedent must provide "a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.").

[11] The Board was wrong. *Service v. Dulles*, 354 U.S. 363, 374–76 (1957) (agency manual was binding, and violation of that manual was ground for setting aside agency action); *Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71, 80 (2nd Cir. 2006) (addressing an agency staff manual: "An interpretative rule binds an agency's employees, including its ALJs,"); *Good Guidance Bulletin*, footnote 3.

[12] *Ex parte Bilski*, http://www.uspto.gov/ip/boards/bpai/decisions/inform/fd022257.pdf, 2006 WL 4080055 at *35 (BPAI Sep. 26, 2006) (informative)

The *Bilski* panel did not explain why a statement of a ***fictional pirate***—a paradigmatic scofflaw—should be followed as if it were law. The *Bilski* panel did not explain why it neglected to consult any administrative law treatise or any primary authority[13] to determine whether the Board was obligated to follow the PTO's published policy determinations, or whether the Board is bound by instructions issued with the authority of the Director.

Illegal acts of two rogue panels of the Board (*Bilski* footnote 8 and *Ghuman*) should not mature into PTO policy, especially where the policy proposed in the Notice imposes costs on the public with no identified benefit to anyone.

III. Breaches of procedural and substantive law

A. The proposal is a "rule" that requires APA procedure, including Notice and Comment, and requires compliance with the Regulatory Flexibility Act

The proposal in the Notice is unquestionably a "rule" for purposes of the Administrative Procedure Act.[14] The Notice nowhere attempts to explain that the proposed procedure is anything other than an APA "rule" – it certainly identifies no exception to § 551(4). Yet, with that concession implied, the Notice inexplicably fails to follow the law that governs rule making.

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[13] See footnote 9.

[14] *Batterton v. Marshall*, 648 F.2d 694, 700–01 (D.C. Cir. 1980), one of the key administrative law cases from the D.C. Circuit notes as follows:

> The Administrative Procedure Act (APA), 5 U.S.C. §§ 551 *et seq.*, broadly defines an agency rule to include nearly every statement an agency may make:
>
> > (4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing (.)
>
> 5 U.S.C. § 551(4) (1976). The breadth of this definition cannot be gainsaid….

The PTO cannot engage in submarine rule making through mere Federal Register notice. The White House[15] and several federal courts have repeatedly reminded the PTO in the last few years that the PTO cannot add burdens by rule or adjudication without full compliance with regulatory review procedure, cannot add burdens or requirements by stating requirements in the MPEP or other informal guidance documents, and is not permitted to circumvent various statutory rule making obligations.[16]

If the PTO wishes to implement the "procedure" set forth in the Notice without running directly contrary to a holding of the federal court with most-direct supervision of the PTO,[17] the PTO will at the least have to run the proposal through notice and comment.

Because this is a rule that requires notice and comment, the PTO must also observe the Regulatory Flexibility Act, 5 U.S.C. §§ 603, 604, and Executive Order 13,272. The Notice reflects no acknowledgement of the existence of these laws, let alone any attempt to comply.

B. What is this Notice?

The Notice does not identify itself as an Advance Notice of Proposed Rulemaking, Notice of Proposed Rulemaking, Request for Comment on a Proposed Information Collection, or anything else. It contains none of the rule making discussion

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[15] http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=4 (White House "directed" the PTO to withdraw the Continuations, Claims, and IDS rules from any request for approval)

[16] *In re Donaldson Co.*, 16 F.3d 1189, 1194, 29 USPQ2d 1845, 1849 (Fed. Cir. 1994) (the mere fact that "the PTO may have failed to adhere to a statutory mandate over an extended period of time does not justify its continuing to do so."); *Tafas v. Dudas*, 541 F.Supp.2d 805, 814–15, 86 USPQ2d 1623, 1630 (E.D. Va. 2008) (35 U.S.C. § 2(b)(2) "makes it clear that the USPTO must engage in notice and comment rule making when promulgating rules it is otherwise empowered to make"), *reinstated after PTO stipulation of acquiescence sub nom. Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009)

[17] *Tafas v. Dudas*, 541 F.Supp.2d at 814–15, 86 USPQ2d at 1630.

that would be required for a Notice at any stage of rule making proceedings. What is the current procedural status for this rule?

This Notice *could* have been an attempt to "consult with members of the public" as required by 5 C.F.R. § 1320.8(d)(1), but because the PTO disclosed none of the information required by § 1320.8(d)(1), there is nothing for the public to comment on. So it fails to serve even that role. So where are we?[18]

C. The Notice breaches Executive Order 12,866

Executive Order 12,866[19] requires agencies to fully consider the consequences of rules, even rules stated outside of the Code of Federal Regulations (underline added)

> **Section 1.** *Statement of Regulatory Philosophy and Principles*. (a) *The Regulatory Philosophy*. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, <u>including the alternative of not regulating</u>. … Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits …, unless a statute requires another regulatory approach.
>
> (b) *The Principles of Regulation*. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:
>
> (1) Each agency <u>shall identify the problem</u> that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

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[18] In passing, I have to observe that many of the errors that lead to the Board's high appeal case load arise when PTO personnel fail to read the relevant law, or else make up exceptions on the fly. The improvisational nature of this Notice is symptomatic of the problems that pervade PTO proceedings. If we could all start with the understanding that (a) the law is what is written down in documents promulgated with appropriate procedure, (b) both applicants and the Office are obligated to follow the law as it exists in writing, (c) the Office may not impose requirements that do not exist in writing, and (d) the Office may not excuse itself on grounds that do not exist in writing, many problems and delays could be averted.

[19] As amended in 2007, E.O. 12,866 may be found at http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf. The Executive Order is currently under revision within the White House, and indications are that the revision will be closer to the 2007 version than the 1993 version. Going forward, the PTO would be well advised to use the 2007 version as its pole star, rather than the 1993 version discussed in this letter.

The Notice identifies no problem arising under the pre-2008 "withdrawn from the appeal" procedure—no inefficiency, no risk of error. The only issue identified in the Notice is an intra-PTO disagreement arising out of *Ghuman*'s departure from the PTO's "withdrawn from the appeal" procedure.

> (2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively..

Ghuman created the problem, and is an "existing regulation (or other law)." The President directs the PTO to abrogate *Ghuman*, not to add an additional regulatory burden. The Notice reflects no attempt by the PTO to follow the President's instructions.

> (6) Each agency shall assess both the costs and the benefits of the intended regulation and … propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

The Notice does not identify any benefit of the proposed procedure vis-à-vis "withdrawn from the appeal," either to applicants or to the PTO. The Notice's only cost/benefit analysis of the proposed procedure, at least compared to "withdrawn from the appeal," is to identify disadvantages and costs imposed on applicants. The Notice makes no attempt to justify the costs of the proposed procedure vis-à-vis "withdrawn from the appeal." The Notice fails to acknowledge that the number of appealed claims will increase, or to evaluate the costs of those added appealed claims on the Board.

> (7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

Nothing in the Notice reflects the PTO's recognition of, let alone compliance with, this requirement of the Executive Order.

> (8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

The Notice totally ignores the pre-2008 *status quo*, "withdrawn from the appeal," as an alternative regulation. There is no "assessment," evaluation, or cost/benefit comparison between the proposed procedure and "withdrawn from the appeal."

> (11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

The Notice reflects no consideration of the additional costs and disadvantages imposed on applicants by changing from "withdrawn from the appeal" to the proposed cancellation of claims, let alone an attempt to "tailor its regulations" to be no more burdensome than "withdrawn from the appeal."

D. The December 2009 Notice neglects the PTO's obligations under the Paperwork Reduction Act

The Notice unquestionably constitutes a "modification" of an "information collection" that is "sponsored" by the PTO, and the Notice's only effect on burdens is to increase them. Thus, the Notice triggers obligations under the Paperwork Reduction Act, specifically 5 U.S.C. § 3507(h)(3) and 5 C.F.R. §§ 1320.5(g) and 1320.11. The Notice reflects no recognition by the PTO of its Paperwork obligations, let alone any attempt to comply. The PTO is already in breach of the law when it enforces *Ghuman* without Paperwork clearance, and will be in further breach if it fails to seek clearance for the proposal in the Notice.

On December 22, 2009, the White house granted the PTO Paperwork clearance for appeals, but on terms of clearance ***expressly limited to the 2004 rules***.[20] The PTO would be in breach of its terms of clearance if it attempted to modify appeals procedure without observing the requirements of 44 U.S.C. §§ 3506 and 3507, and 5 C.F.R. § 1320.11.

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[20] http://www.reginfo.gov/public/do/DownloadNOA?requestID=216727

E. The Notice neglects to account for adaptive responses that will increase workload for the Board and Paperwork burden for the public

If unappealed claims will be abandoned, appellants will argue claims in the future that are not argued today.

The Notice will *increase* the workload on the Board.

It will also increase workload for appellants. The PTO must estimate this increase in burden, and seek clearance under the Paperwork Reduction Act.

F. The PTO has no statutory authority to act as proposed in the Notice

Canceling claims is a substantive act. The PTO has no authority to grant itself substantive authority by rule making, let alone by mere Federal Register notice.[21] The Notice identifies no statute that grants the PTO authority to cancel claims, to "deem" claims cancelled, or to require applicants to cancel them. The Notice appears to be *ultra vires*.

G. The Notice compromises the new cooperation the PTO hopes to foster by failing to analyze the issues with legal or factual precision

Disturbingly, the Notice reflects an absence of care to ensure truthfulness or careful legal analysis. Parties only cooperate with each other when they trust each other to be truthful, accurate, and fair. Several statements in the Notice are simply wrong, reflect the PTO's habitual lack of care to investigate facts and law before committing opinion to paper, and lack of concern for basic fairness. Careless assertions in Office Actions are a major cause of the PTO's backlog and large appeal load; carelessness in a formal Federal Register Notice, and expropriating applicants' rights with no identified benefit, does not foster trust in the PTO's senior legal staff, and will delay building cooperation between the bar and the Office.

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[21] *Cooper Technologies Co. v. Dudas*, 536 F.3d 1330, 1336, 87 USPQ2d 1705, 1709 (Fed. Cir. 2008) ("To comply with § 2(b)(2)(A), a Patent Office rule must be 'procedural'—*i.e.*, it must 'govern the conduct of proceedings in the Office.' … We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue 'substantive' rules.")

Column 2 of the notice states "There is no provision in 35 U.S.C. 134 or 37 C.F.R. 1.113 for an applicant to appeal only part of the examiner's decision." The inference that the PTO draws from absence reflects a profound misunderstanding of one of the most fundamental principles of American administrative law. 5 U.S.C. § 552(a), 5 U.S.C. § 553, 44 U.S.C. § 3512, and the President's *Final Bulletin for Agency Good Guidance Practices* all make the same point, that if the PTO has not promulgated a rule with force of law to either require or forbid an act by an applicant, then the act is permitted and optional. As the Notice repeatedly concedes, Part 41 contains nothing to forbid appeals-in-part. Thus, an appeal-in-part is permitted and optional. The supposition behind the Notice, that applicants may act only where the PTO has extended a benevolent grant of permission, reflects a complete upending of the very foundations of American administrative law.

The Notice states "Therefore, if appellant does not wish to contest one of the rejected claims, appellant must file an amendment canceling that claim. The amendment must be filed separately for the notice of appeal and appeal brief." The Notice cites no authority having force of law for this "must." The PTO cannot create "musts" by just saying so; if the PTO wants to make a rule, it must do so in the manner prescribed by law.

The mention of 37 C.F.R. § 1.113 reflects further confusion. § 1.113 governs "replies to final rejection" before the examiner, as an implementing regulation for 35 U.S.C. § 132(a). An appeal brief is filed under 37 C.F.R. Part 41, the implementing regulations for 35 U.S.C. § 134. If § 1.113 has *any* relevance to appeals, the basis for that relevance is not explained in the Notice.

The Notice states that "it has long been USPTO practice that an appellant must either appeal from the rejection of all rejected claims or cancel those claims not being appealed. *Ex parte Benjamin*, 1903 C.D. 132 (1903)." This is false. A more truthful statement would be "Over a century ago, before the enactment of the Administrative Procedure Act, before the 1952 Patent Act, before the Paperwork Reduction Act, and under appeal rules quite different from today's, it ***was*** PTO procedure to…" However, since at least 1961, old 37 C.F.R. § 1.191 *et seq.* and Part 41 have required applicants

to separately identify the claims that are appealed, and have permitted appeal of less than all claims rejected. The Notice's representation that *Benjamin* "has long been USPTO practice" at best reflects a careless choice of verb tense and careless reasoning, and is certainly misleading. The Notice reflects ***no consideration whatsoever*** of the text of today's § 41.37—a case arising under a totally different rule is totally irrelevant. Overt carelessness, verging on misrepresentation, is harmful to the trust between the bar and the PTO that will be required to improve operations.

The discussion of *Benjamin*, over a century old, neglects to account for intervening changes in facts. First, before the 1960's, final rejection and post-appeal practice—to the degree they existed at all—were quite different from today's, and the rationale underlying the decision in *Benjamin* is simply irrelevant now. Second, *Benjamin* turns on a concern that the Office had no means of knowing an applicant's intent—but that concern is fully resolved by today's § 41.37(c)(1)(iii), which provides exactly the information that the PTO sought in *Benjamin*.

The Notice several times mentions § 41.31 and the lack of any requirement in a Notice of Appeal to identify particular claims[22]—but the Notice identifies no problem that is not fully ameliorated by the "identification of claims to be appealed" in the Appeal Brief (§ 41.37(c)(1)(iii)). First, as noted above, the lack of any stated requirement is effectively a grant of permission to applicants to do that which is not forbidden, and the Notice identifies no provision of law that would create an exception to that general provision of administrative law. Consider Forms 1 and 3 to the Federal Rules of Appellate Procedure: both require an appellant only to identify the final judgment, not the individual issues in that final judgment that will eventually be appealed. FRAP 28, much like § 41.37, makes clear that issues presented for appeal need not be identified until the opening brief.

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[22] See also the definition of "agency action" in 5 U.S.C. § 551(13) ("'agency action' includes the whole or a part of an agency … order, … or the equivalent or denial thereof"). It is commonplace to subdivide agency actions for different legal treatment.

IV. The PTO should implement internal procedures to ensure compliance with the Paperwork Reduction Act, Executive Order 12,866. and the *Good Guidance Bulletin*

Six times in the last two years, the PTO has been forced to withdraw major rules or guidance publications because of failures to observe the Paperwork Reduction Act, Executive Order 12,866, the *Good Guidance Bulletin*, and similar laws governing rule making procedure. Why are the same failures repeated here? What is the PTO 's view of its obligations under the Paperwork Reduction Act, Executive Order 12,866, and the *Final Bulletin on Agency Good Guidance Practices*—does the PTO have any intent or schedule to implement compliance with the law? What problem with "withdrawn from the appeal" or MPEP § 1205.02 is the PTO trying to solve via the Notice? When the Notice describes additional costs and burdens the PTO plans to impose on appellants, but can identify no practical utility and no problem to be solved, how does the PTO explain itself under Executive Order 12,866 and the Paperwork Reduction Act? The Notice's failure to even pretend to follow these laws speaks volumes.

The President's *Good Guidance Bulletin* (see footnote 3) will be three years old in two weeks. I (and several others) have brought the *Bulletin* to the attention of the Office of Patent Legal Administration and the Board in several notice and comment letters, Petitions, and emails, yet there is no indication that the PTO has implemented the *Bulletin*. At what point does OPLA's and the Board's failure to follow Presidential instruction tip from carelessness to deliberate mutiny against the President and the rule of law? Is three years a good dividing line?

The PTO should implement the following provisions of the *Good Guidance Bulletin*:

- Predictability of PTO procedures (particularly Board appeals) would be significantly improved if the Board and OPLA staff received the training in basic principles of administrative law that the President urges in the *Bulletin*.[23]

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[23] *Good Guidance Bulletin*, footnote 3, preamble § C(I), .../m07-07.pdf at 11, 72 Fed.Reg. 3436, col. 2 ("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)").

- "Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence."[24]
- "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 website, the name and contact information for the office(s)."[25]
- "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…; (c) Invite public comment on the draft document; and (d) Prepare and post on the agency's website a response-to-comments document."[26]

V. Conclusion

The Notice offers no rational basis for departing from "withdrawn from the appeal," the procedural course used by every other tribunal. Rather, the Notice confirms that pre-2008 "withdrawn from the appeal" procedure is the PTO's best vehicle for complying with its obligations under the law. PTO statements that are inconsistent with "withdrawn from the appeal" procedure, including *Ghuman* (and footnote 8 of *Bilski*) should be expunged. The PTO should implement the President's directives in the *Final Bulletin for Agency Good Guidance Practices*.

Sincerely,

/s/ David E. Boundy

Vice President, Ass't Gen'l Counsel
Intellectual Property
Cantor Fitzgerald L.P.
499 Park Ave.
New York, NY 10022
(212) 294-7848
(917) 677-8511 (FAX)

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[24] *Good Guidance Bulletin*, footnote 3, § II(1)(b).

[25] *Good Guidance Bulletin*, footnote 3, § III(2)(b).

[26] *Good Guidance Bulletin*, footnote 3, § IV(1).

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

January 18, 2007

M-07-07

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS
AND AGENCIES

FROM: Rob Portman

SUBJECT: Issuance of OMB's "Final Bulletin for Agency Good Guidance Practices"

The Office of Management and Budget (OMB) today issued a bulletin applicable to all departments and agencies entitled "Final Bulletin for Agency Good Guidance Practices." This Bulletin establishes policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch departments and agencies and is intended to increase the quality and transparency of agency guidance practices and the significant guidance documents produced through them.

This Bulletin is one aspect of a larger OMB effort to ensure and maximize the quality, utility, objectivity and integrity of information disseminated by Federal agencies, pursuant to the Information Quality Act.

This Bulletin has benefited from extensive public and agency comments received on a draft released by OMB on November 23, 2005.

If your staff has questions about this guidance, please contact Margaret Malanoski at (202) 395-3122 or Margaret_A._Malanoski@omb.eop.gov.

Attachment

Bulletin No. 07-02

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 Fed. Reg. 71,866 (November 30, 2005). Upon request, OMB extended the public comment period from December 23, 2005 to January 9, 2006. 70 Fed. Reg. 76,333 (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.

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

FOR FURTHER INFORMATION CONTACT: Margaret Malanoski, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, N.W., New Executive Office Building, Room 10202, Washington, DC, 20503. Telephone (202) 395-3122.

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.

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[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 websites 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").

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]

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

[4] Id., at 72.

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

[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 76,333

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,

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(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 22,041 (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 7,987 (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).

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

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

[17] 21 C.F.R. § 10.115; 65 FR 56,468 (Sept. 19, 2000).

[18] Pub. L. No. 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.

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 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 C.F.R. § 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 § 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 § 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]

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

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, § II(2)(h) clarifies that, given their legally nonbinding nature, significant guidance documents should not include mandatory language such as "shall," "must,"

[22] See FDA's Good Guidance Practices, 21 C.F.R. § 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."

"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 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

[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.

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 website a list of all of an agency's significant guidance documents. Under § III(1)(a), agencies will maintain a current electronic list of all significant guidance documents on their websites in a manner consistent with OMB policies for agency public websites and information dissemination.[24] To assist the public in locating such electronic lists, they should be maintained on an agency's website – or as a link on an agency's website to the electronic list posted on a component or subagency's website -- 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 websites.

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 websites with the goal of making all of their significant guidance documents currently in effect publicly available on their websites by the effective date of this Bulletin.[25] Other requirements of this Bulletin, such as § 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 website 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 § 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 listserve or

[24] U.S. Office of Management and Budget, Memorandum M-05-04, "Policies for Federal Agency Public Websites" (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 websites statements of general policy and interpretations of general applicability. See 5 U.S.C. § 552(a)(2).

similar mechanism for members of the public who would like to be notified by email 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 website 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.

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

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

[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

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, § 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 website.

E. Notice and Comment on Economically Significant Guidance Documents

Under § 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 websites and information dissemination, the agency must post the draft on its website, 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.

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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 websites 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).

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 website 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 website. 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 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 § IV(2).

Though economically significant guidance documents that fall under the exemption in § 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.

[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.

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, § 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, § 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, § 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, § 3).

II. Basic Agency Standards for Significant Guidance Documents.

1. Approval Procedures:
   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 website -- or as a link on an agency's website to the electronic list posted on a component or subagency's website -- 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 website 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 website 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 website, 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 website 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.