January 9, 2006

BY ELECTRONIC DELIVERY

Dr. John D. Graham, PhD., Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
The Executive Office of the President
725 17th Street, NW
New Executive Office Building
Room 9013
Washington, DC 20503

Re: Proposed Bulletin for Good Guidance Practices

Dear Dr. Graham:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Proposed Bulletin for Good Guidance Practices (the "Proposed Bulletin"), released by the Office of Management and Budget (OMB) on November 23, 2005. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

As the representative of an industry committed to discovering new therapies and ensuring patient access to them, BIO is pleased that the

Proposed Bulletin promotes "clear and consistent agency practices for developing, issuing and using guidance documents."[1] From our experiences with the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), and other agencies, we understand the importance of guidance documents in establishing policies regarding the development and coverage of biological therapies. Because the policies announced and implemented through guidance documents can have far-reaching effects, it is critical that these documents be created through transparent and predictable procedures, with substantial stakeholder input. We share OMB's concern with ensuring that agency guidance documents are "developed with appropriate review and public participation, accessible and transparent to the public, of high quality, and not improperly treated as binding requirements."[2]

In general, BIO supports the Proposed Bulletin's requirements for approval procedures and standard elements. By requiring each agency to implement written procedures for internal clearance of significant guidance documents, and by requiring approval by appropriate senior agency officials,[3] the Proposed Bulletin would ensure that agencies give careful thought to their significant guidance documents. The Proposed Bulletin also would create basic requirements for significant guidance documents, including use of standardized language and labeling of documents that will encourage the development of clearer guidance documents.

BIO strongly supports the Proposed Bulletin's requirements for announcement of and public feedback on significant guidance documents and economically significant guidance documents. We agree that agencies should be required to offer the public a simple means to learn about current and proposed guidance documents, provide feedback, and request that guidance documents be created, modified, or reconsidered.[4] Given the tremendous amount of policy that is made outside the Administrative Procedure Act's (APA) rulemaking requirements, it is important that stakeholders have an opportunity to comment on all significant statements of policy, not just those currently subject to the APA's requirements.

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1 OMB, Proposed Bulletin for Good Guidance Practices, at 1.

2 Id. at 3.

3 Proposed OMB Bulletin for Good Guidance Practices, § II.1.b.

4 Id. at §§ III and IV.

BIO and its members fully appreciate that agencies such as CMS operate in a highly complex and technical environment, and often must utilize less than formal means to convey operational instructions or technical clarifications to stakeholders in order to ensure timely implementation of critical public health programs. Methods such as manual provisions, contractor instructions, and posting on agency websites responses to certain questions received by the agency are normally helpful to stakeholders and necessary for efficient program management, and thus largely should be exempt from the requirements of the Proposed Bulletin. For example, in implementing the new Medicare Part D program, CMS has posted literally hundreds of agency responses to informal questions it has received on the technical and operational aspects of the program, which have helped health-care plans, vendors, patients, and manufacturers understand how to participate in the program most effectively and efficiently.

But, in some cases, agencies can use – and have used – these informal processes or documents to make significant policy judgments, or even to make changes to prior formal regulatory policy. For example, in CMS' final regulations implementing the Medicare drug benefit, the agency concluded that "weight loss agents may be covered for the treatment of morbid obesity" when they meet the Part D statutory requirements and are prescribed for a medically accepted indication.[1] The agency reached this decision based on a public comment to the proposed regulation. Despite this fact, CMS later reversed its position in an informal response to a question placed on the agency's website. Specifically, the posted answer stated, "Since agents when used for anorexia, weight loss, or weight gain are excluded under section 1860D-2(e)(2)(A) of the Act, an agent when used for treatment of morbid obesity – even if not used for cosmetic purposes – would be excluded as a Part D drug."

This example shows precisely how agency instructions or other informal documents can be significant in terms of policy-making. An agency should not be permitted to overturn or attempt to alter an important policy decision made through the notice and comment rulemaking process with an informal posting on its website of a question and answer. In such cases, it is essential that the Proposed Bulletin's good guidance practice requirements of notice and opportunity for comment be followed.

We recommend that OMB instruct agencies to certify that they either followed good guidance practices in developing a document or determined that the requirements do not apply to the document. Such requirements would encourage agencies to take care in deciding whether each document is subject to the Proposed Bulletin's requirements. Additionally, it would inform the public of the agency's treatment of the document and would help to familiarize the public with OMB's good guidance practice requirements.

Finally, we note that the Proposed Bulletin does not explain how an agency's compliance with these requirements would be monitored or enforced. All of the Proposed Bulletin's procedures to ensure that agencies develop policy in an open, transparent, and predictable manner with substantial public input will have little effect if there is no oversight and stakeholders have no means to contest agency actions. We urge OMB to develop oversight and enforcement mechanisms and remedies for agency failures to comply with good guidance procedures.

In particular, we recommend that the OMB guidelines require the inclusion of a process by which individual aggrieved parties can petition either OMB or the relevant agency for public reconsideration of an issued guidance document that should have been, but was not, issued in compliance with the good guidance practices regarding notice and opportunity for comment, including with respect to guidance documents issued by agencies prior to the finalization of the Proposed Bulletin.

We sincerely hope that OMB will give thoughtful consideration to our comments and will incorporate our suggestions. Please contact Jayson Slotnik at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President & CEO
Biotechnology Industry Organization