



**OMB Watch Comments to the Food and Drug Administration Transparency Task Force
Aug. 7, 2009**

OMB Watch submits these comments in response to the June 3, 2009, *Federal Register* notice, “Food and Drug Administration Transparency Task Force; Public Meeting,” Docket No. FDA-2009-N-0247. OMB Watch commends the Food and Drug Administration (FDA or the agency) for its effort to improve agency transparency and its willingness to include the public in that effort. We appreciate the opportunity to comment. We hope FDA will move to implement a transparency framework that better reveals to the public how the agency makes decisions and how it takes actions to prevent harm and protect citizens from public health threats.

OMB Watch is a nonprofit, nonpartisan research and advocacy organization promoting an open, accountable government responsive to the public’s needs. In these comments, we recommend to FDA new transparency policies that, if implemented, would allow the public to better monitor FDA and hold it accountable for its decisions and actions. Some of the recommendations here reiterate recommendations made to other parts of the Obama administration. These recommendations are detailed in two reports: *Moving Toward a 21st Century Right-to-Know Agenda* and *Advancing the Public Interest through Regulatory Reform*, both released in November 2008.

FDA should disclose more information during the regulatory decisionmaking process.

Transparency in regulatory decisionmaking benefits both the public and the government. Transparency can foster a greater sense of legitimacy, increasing the likelihood of both public acceptance and regulatory compliance. Transparency provides interest groups, citizens, journalists, Congress, and others with the information necessary to hold an agency accountable for its decisions. Interested parties can better determine whether an agency has made a decision in the public’s best interest or whether it has erred. Finally, transparency is critical to public participation, which is required for rulemakings and often encouraged elsewhere, including FDA’s process for setting guidance.

Transparency in Rulemaking

The FDA has room to enhance the transparency of its rulemaking activities. For example, FDA lags behind other agencies in uploading its dockets onto the federal e-rulemaking system (the Federal Docket Management System, or FDMS). FDA’s rules and guidance can be difficult to find on the FDMS public interface, Regulations.gov. Additionally, if a user can find an FDA rule, he or she will usually not find supporting information or public comments – information that other agencies routinely post.

FDA should make the online dockets stored in the federal e-rulemaking system the authoritative docket. Each and every item found in the agency’s paper docket should be uploaded to FDMS thereby allowing for wide and easy public access to the complete docket. The electronic medium is a fast-paced, low-cost means for disclosing information, and the FDA docket should reflect that with timely posting of all documents. The agency should also strive to make rulemaking dockets and the documents within them as easily findable as possible with the use of descriptive titles, metadata and other tagging options.

FDA should strive to make its rulemaking dockets comprehensive and robust. In addition to posting its dockets online, FDA should strive to include all relevant information in its rulemaking dockets, beyond

just the required regulatory paperwork. For example, the agency should disclose all studies, research, or other materials in its possession related to the topic at issue in the rulemaking. FDA should disclose this material regardless of whether it was used to inform the final decision. The public should have access to all information at the agency's disposal so participation in the rulemaking process will be fully informed.

FDA should also disclose certain communications in its rulemaking dockets. OMB Watch recommends the agency disclose the following:

- Written communications among federal officials from different agencies, including White House offices. This should include draft proposed and draft final policies submitted to the White House Office of Information and Regulatory Affairs for review, should such review continue.
- Substantive written and oral communications between the FDA and nongovernmental entities.
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Transparency in medical product approvals

FDA should also provide more information on its decisions to approve medical products. Observers have frequently noted that FDA's premarket approval process is not fully open. This activity can have just as serious and widespread an impact on the public as any agency rulemaking, and as such it should be more open and participatory.

OMB Watch recognizes that we do not possess the substantive expertise to identify specific information sources or data points that should be disclosed during the premarket approval process. However, we believe many of the disclosure requirements recommended for rulemaking in the above section should also be applied to the medical product approval process. Again, FDA should post online all studies available to it, not just those that support its final decision. FDA should also be transparent about decisions *not* to approve medical products. Studies on these products and FDA's rationale for rejecting an application should be made available to the public online.

FDA should also explore the merits of clinical trial data disclosure. In certain cases, this information can be valuable to doctors, patients, and researchers. For example, disclosure could prove useful in identifying a product's effects on certain subpopulations, such as children.

Transparency of Federal Advisory Committees

The FDA has already adopted some of the most aggressive, if not the most aggressive, transparency policies for its advisory committees. However, several additional requirements could prove beneficial to public understanding and monitoring of advisory committee activities. In addition to the information the agency already provides, we recommend FDA post on its website:

- A description of the process used to form the advisory committee, including the process for identifying and vetting candidates and selecting members and how the public can participate in the selection process;
- A clear designation of each member's status (i.e. regular government employee, special government employee, representative, or ex officio); and
- A justification for the use of any representative members.

We also encourage FDA to begin to add to its website video recordings of committee meetings, in addition to the transcripts currently provided. This medium has become much easier and more affordable for agencies and provides the public with a more engaging record of events than simple minutes or even transcripts.

These requirements are included in the Federal Advisory Committee Act Amendments, H.R. 1320, currently being considered by Congress.

FDA should provide more information about regulatory performance.

The FDA has a responsibility to ensure public health by overseeing the nation's food, medical product, and cosmetic supplies. To meet this responsibility, FDA utilizes its resources to monitor industries and police product supplies subject to FDA regulation. The public, regulated entities, and public officials both inside and outside of FDA have incentives to hold the agency accountable and to make sure it is performing efficiently.

Ensuring optimal regulatory performance first requires the availability of quality data. Resource allocation, enforcement activity, and workload data are all key components of the agency's ability to provide the public with an accurate understanding of regulatory performance.

Resource Allocation

In recent years, FDA has posted online its annual budget justification submitted to Congress. The agency should not only continue this practice, but should expand it.

The budget justification currently posted by the FDA does not provide great enough detail. In order to facilitate a full understanding of how the agency is distributing resources, FDA should provide detailed budget and staffing figures at the program level. Specifically, it would be useful for FDA to indicate how much money is going to individual enforcement programs, such as those that investigate adverse event reports, approve applications, or inspect facilities. Similarly, FDA should provide detailed employment information for these programs, such as number of inspectors.

Enforcement Activities and Workload

FDA currently maintains databases on its website that detail some of its regulatory enforcement activities and maintains other internal databases not readily available to the public. The agency could enhance the transparency of its enforcement activities by creating a unified, publicly available, online database that contains detailed information on the actions it takes to ensure public health.

OMB Watch recommends a database that contains the following:

- The number of medical product applications received, approved, and rejected;
- The number of medical product applications pending;
- The number of medical products on the market and subject to FDA regulation;
- The names of establishments registered with FDA, as required by any law or regulation;
- Metrics of the sizes of the sectors subject to FDA regulation, such as product volume;
- Information on inspections, including establishment inspections (both foreign and domestic), product inspections, import inspections, clinical trial site inspections, clinical data verifications, and any other inspections the agency performs;
- The number of samples collected and analyzed by the agency;
- The number of adverse events reported and the number reviewed;
- The number of advertising or promotional material submissions and the number reviewed;
- Information on civil and criminal penalties assessed;
- Information on product recalls, both mandatory and voluntary, that includes the reason for the recall and updates on the level of recalled products recovered;
- Information on warnings and safety alerts.

FDA already provides some detailed information on the last two bullets: recalls and warnings and safety alerts. Because of its importance to public health, FDA should continue to find ways to highlight this information outside of any database.

Where applicable and allowable (considering various national security and FOIA exemptions) the agency should include in the database the name of the firm, the reason for the enforcement action, and the office or program performing the action, as well as any other relevant information.

Some of this information is already available on FDA's website. In those cases, existing databases, such as CDER's approved drug product database, should be folded into a larger regulatory performance database.

FDA should also provide the public with information on the size of the various communities subject to FDA regulation. In many cases, FDA resources and enforcement activity need to keep pace with increases or decreases in the scope of the regulated community. A better understanding of the number of entities operating under various FDA regulations would permit the public to better gauge how thorough an enforcement job the agency is doing.

The agency should include other information as it sees fit and update the database with new fields as circumstances so dictate. (If passed, the Food Safety Enhancement Act of 2009 would grant FDA new responsibilities and compel new enforcement activities. Similarly, the Family Smoking Prevention and Tobacco Control Act, signed into law June 22, has expanded the FDA's regulatory enforcement portfolio.)

A database of this kind would serve two purposes. First, it would educate the public about the actions FDA takes to ensure public health and safety. Second, it would allow the public to hold the FDA accountable. The public could investigate whether the FDA is adequately monitoring a particular firm or industry, how the agency's actions are trending over time, and whether enforcement actions meet public needs.

OMB Watch appreciates the agency's attention to our comments. We understand that many of the transparency measures recommended here would challenge the agency, both in terms of implementation and as a result of the public scrutiny that would follow. However, we firmly believe that the policies outlined here would enhance public understanding of FDA's activities and contribute to a more conscientious and effective regulatory agenda at FDA.

Please contact Matt Madia at 202-683-4813 or mmadia@ombwatch.org if you would like to further discuss any of our recommendations or comments.