Center for Regulatory Effectiveness

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May 31, 2002

Mr. James V. Scanlon
Director, Division of Data Policy
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 440D
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Information Quality Comments: FDA

Dear Mr. Scanlon:

I am writing on behalf of the Center for Regulatory Effectiveness (CRE) to share with you the Center's comments on FDA's recently proposed information quality guidelines, issued pursuant to the Data Quality Act (44 U.S.C. § 3516, note). These comments are specific to FDA, and CRE has submitted additional comments regarding the Data Quality guidelines of other HHS agencies under separate cover. As you may be aware, the Center had a leading role in passage of the Act and maintains a strong ongoing interest in this important issue. I invite you to visit the CRE website (www.TheCRE.com) for further details.

In light of the deference the public pays to governmental information and its significant role in regulation and resource allocation in both the public and private sectors, the quality of the federal government's information is a matter of critical importance. Consequently, CRE appreciates this opportunity to provide its views and recommendations to HHS/FDA in order to achieve the intent of Congress in enacting this new "Good Government" law and of OMB in promulgating its guidelines containing government-wide Data Quality standards (67 *Fed. Reg.* 8452, Feb. 22, 2002).

To assist FDA in meeting its obligations under the Data Quality Act and OMB's guidelines, CRE has prepared and enclosed the following attachments, in addition to the specific comments concerning FDA's proposed guidelines which round out this letter.

(1) CRE General Comments to All Federal Agencies Related to Data Quality Guidelines

- This paper outlines a number of cross-cutting issues related to Data Quality guidelines which are applicable to all agencies and contains CRE's recommendations on how such issues should be addressed.
  - CRE strongly believes that proper action on these key issues will help ensure that the guidelines issued by the agency are workable, effective, and in keeping with the requirements of both the statute and the government-wide standards set by OMB.
- In the paper, CRE identifies and evaluates a number of agency approaches to these cross-cutting issues. Such examples include positive agency proposals which might be emulated, as well as problematic agency proposals to be avoided.

(2) Legal Memorandum on the Data Quality Act's Applicability to All Public Information

- CRE is concerned by several agencies' attempts in their proposed guidelines to exempt certain categories of public information from the Data Quality Act's standards. Consequently, CRE retained Multinational Legal Services (MLS) to examine this important issue. Attached is a legal memorandum which summarizes the MLS inquiry into the Data Quality Act's applicability to all public information. In short, MLS found:
  - Analysis of the Data Quality Act, the Public Information provisions of the Paperwork Reduction Act, and legislative history demonstrate that Congress intended Data Quality Act standards to apply to all public information.
  - Thus, neither OMB nor any other federal agency has discretion to violate this legislative intent by exempting categories of information from the standards set forth pursuant to the Data Quality Act.

(3) CRE Comments on Specific Provisions of the FDA's Proposed Data Quality Guidelines

(A) *APPLICABILITY OF THE DATA QUALITY GUIDELINES TO THE WORK OF THE RISK ASSESSMENT CONSORTIUM*

FDA should explicitly state in its Data Quality guidelines that such guidelines will apply to the information products disseminated by the federal interagency Risk Assessment

Consortium (RAC), which FDA chairs. (Please see CRE's attached letter dated April 19, 2002 to the HHS Acting Chief Information Officer regarding this topic.) Established pursuant to Executive Order 13100, the RAC's main purpose is to improve food-related risk assessments, thereby reducing risk. Given its leadership role in federal food safety initiatives, FDA should:

- Work through HHS to ensure the establishment of uniform Data Quality standards and measurements for reduced risk initiatives throughout the government, provided such standards comply with OMB's government-wide Data Quality guidelines..

- State in its guidelines that the Data Quality guidelines apply to third-party data submissions that are submitted to the agency, including information submitted pursuant to the correction process. (See CRE Generic Comments at page 10 for a detailed discussion of the third-party submissions issue.)

- State clearly in its guidelines that the standards and correction process set forth in the FDA guidelines apply to any agency determinations as to the effectiveness of any proposed risk reduction initiatives.

(B) ***APPLICABILITY OF THE DATA QUALITY GUIDELINES TO FDA WARNING LETTERS***

CRE is pleased to note that FDA's guidelines apply to the agency's issuance of drug Warning Letters, which, while not explicitly referenced, clearly do not fall in any of the categories of specific exceptions discussed in the FDA guidelines.

However, CRE recommends that FDA *explicitly* state that its Data Quality guidelines do apply to Warning Letters. The Center believes that such clarifying action is warranted because these letters are information intensive and may have serious health consequences for consumers and financial impacts on manufacturers. Therefore, the agency should leave no doubt as to the guidelines' applicability in this important context where information quality is so critical.

(C) ***INTERNATIONAL HARMONIZATIONS OF TECHNICAL REQUIREMENTS REMAIN SUBJECT TO THE DATA QUALITY GUIDELINES***

While FDA appropriately participates in a variety of international harmonization efforts related to the technical requirements of its product review activities, a simple assertion that such procedures have been followed should not be sufficient evidence to dismiss a Data Quality Act petition. The scientific process is based upon the concept of testing accepted principles. Thus, while FDA may weigh compliance with such internationally accepted principles in reviewing a Data Quality Act petition, the agency should undertake a thorough review which analyzes the merits of the Data Quality challenge. The same reasoning applies to the Good Review Practices (GRPs) being developed by the agency.

(D) ***OVERLY RESTRICTIVE FDA DEFINITION OF "INFLUENTIAL INFORMATION"***

While OMB left agencies some flexibility in defining the term "influential information," CRE believes that FDA's proposed definition ("disseminated information that results from or is used in support of regulatory actions that are expected to have an annual effect on the economy of $100 million or more" Sec. VII.A.) is overly restrictive. While a $100 million economic impact would presumably deserve "influential information" status, clearly there are other circumstances where agency actions could have a significant impact without achieving that dollar level or where such quantitative impact is unknown. For example, FDA determinations which impact the availability of drugs or devices which may improve the quality of lives are clearly influential regardless of economic impact.

FDA appears to have relied upon the definition of "significant regulatory action" from Executive Order 12866, but that definition goes on to discuss regulatory actions which "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, of State, local, or tribal governments or communities." Clearly, agency actions can have broad and important impacts, even if they are below $100 million in effect.

For example, a pharmaceutical company may seek to challenge a warning letter issued by the agencies involving one of its drug products. While it is clear that the Data Quality guidelines would apply to such an agency pronouncement, such a warning letter could have a major impact upon consumers who use that drug and the company that manufacturers it. Depending upon how wide-spread use of that drug is, the agency's pronouncement could be viewed as influential information.

In sum, CRE suggests that the agency should devise a more expansive and detailed list of information falling in the "influential" category. However, FDA might consider shifting the burden to challengers to demonstrate that this higher standard has not been met, for certain categories of information.

(E) ***"SPECIAL CONSIDERATION FOR AGENCY DISSEMINATION"***

In Section VIII of the FDA guidelines, the agency discusses four instances when it says that it may disseminate information without fully complying with the Data Quality guidelines. However, CRE believes that the agency needs to modify its thinking regarding these emergency situations as follows:

Public Health Emergencies

- It is reasonable that emergency situations may require FDA to disseminate information without out subjecting it to normal internal Data Quality review procedures. *However*, after the emergency has passed, if such information is still

being disseminated, the Data Quality guidelines should apply to such information and the public should have an opportunity to seek correction thereof. In that sense, the Data Quality guidelines should be considered to merely be in abeyance, rather than not applying at all.

Statutory or Other Legal Requirements

- While FDA may be required to implement certain policies and concomitant information disseminations in an expedited fashion due to statutory or other legal requirements, once in place, the agency should subject such information to the process established under the Data Quality guidelines after the fact and then make any necessary adjustments. Again, the Data Quality guidelines should clearly apply, although their application may have to be postponed.

Proprietary Information

- FDA's statement regarding how it intends to handle proprietary information is troubling. OMB in its guidelines has acknowledged that the agency may not be able to disclose certain proprietary information, but the that does not means that the agency should not apply the important principles of the Data Quality guidelines to such information.

- Especially because the public cannot view such information itself to assess its quality, OMB has tasked the agencies with conducting robustness checks to ensure "that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision." 67 F.R. 8452, 8457 Feb. 22, 2002).

- Consequently, FDA should acknowledge its responsibility to conduct such robustness checks and discuss its planned process for applying the Data Quality guidelines to proprietary information and other confidential business information. (See CRE Generic Comments at pages 23-25 for a detailed discussion of confidential information issues.)

Other Circumstances

- While unforeseen circumstances may indeed arise, this vaguely-defined term should not be the basis for non-application of the Data Quality guidelines. It is hard to believe that Congress would leave it to the agency to cite "unforeseen circumstances" as a reason not to comply with the law.

- Again, if such emergency situations arise, the Data Quality guidelines should clearly apply, although their application may have to be postponed.

Finally, CRE believes that in light of the ongoing importance of the Data Quality issue, all federal agencies should adopt Data Quality as a Performance Goal in its Performance Plan under the Government Performance and Results Act. Not only would this assist the agency in regularly monitoring and improving its information quality activities, but it would also serve to increase the transparency of the agency process for Congress and the interested public.

CRE would be happy to answer any questions related to its comments and supporting materials. Please contact us at (202) 265-2383, if we might be of further assistance.

Sincerely,

Jim J. Tozzi
Member, CRE Board of Advisors

Attachments