



1201 Maryland Avenue SW, Suite 900, Washington, DC 20024
202-962-9200, www.bio.org

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2009-N-0247: FDA Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency By Promoting Greater Access to the Agency’s Compliance and Enforcement Data; Availability

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA or Agency) for the opportunity to submit comments on the “Draft Proposal for Public Comment to Increase Transparency By Promoting Greater Access to the Agency’s Compliance and Enforcement Data; Availability.” We support the goals of this initiative and we are pleased to see the Agency’s continued commitment to advancing the principles of transparency, consistency, and accountability by leveraging modern communication tools and re-evaluating Agency processes. Clear, consistent, and open communication with the public and regulated industry, conducted in a manner that balances the importance of protecting competitive commercial information, is a critical FDA function and essential for protecting and promoting public health.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

GENERAL COMMENTS:

BIO thanks the FDA for considering our previous comments and recommendations on FDA's Transparency Initiative, particularly as they relate to compliance activities.¹ FDA is responsible for a broad range of compliance and enforcement activities, and it is important that initiatives to improve Agency transparency apply across all enforcement actions, including clinical trial investigators and Institutional Review Boards (IRBs), and not just to inspections related to regulated industry. We agree that increased disclosure of FDA's inspectional findings can help facilitate transparency within the regulated industry, make firms more accountable to the FDA and the public at large, and provide an incentive to correct violations. However, efforts to increase transparency must respect the well-established laws and regulations that protect trade secrets and confidential information – a framework that is critical for the promotion of innovation and protection of incentives for product development.

I. Disclosures Should be Aligned with Public Health Goals and Accompanied by Adequate Context

While we understand FDA's goal of promoting openness in government, as a general principle we believe it is important that FDA's disclosure policies be fully aligned with public health objectives by ensuring that information is released in appropriate context so as to be informative while also minimizing the risk of generating improper conclusions. Without a determination that the information to be released actually would promote or protect public health, the disclosure may lead to greater confusion or misunderstanding. BIO urges FDA to assess whether each type of information identified in the Draft Proposals in fact would be understandable and useful to healthcare providers, patients, and the general public.

Transparency is only meaningful to the extent that FDA provides full, fair, and balanced context for the information to be disclosed. The release of incomplete and potentially misleading information can cause more confusion rather than less. For example, the release of an inspectional classification "Voluntary Action Indicated (VAI)," without any accompanying explanation or without posting the firm's response, may lead to greater confusion. Thus, FDA should ensure that release of information, no matter how well intentioned, does not cause misimpressions that achieve the opposite of transparency.

II. Achieving Transparency that is Full, Fair, and Balanced

BIO supports FDA's efforts to improve data quality and facilitate more timely data disclosure. FDA frequently has stated that they want industry to learn from inspections of peer companies. The current system of annually updating the most common official inspection classifications based on the Turbo-EIR² language on FDA's website is of limited value to the regulated industry

¹ Biotechnology Industry Organization, *FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies*, July 20, 2010, available at <http://www.bio.org/sites/default/files/20100720a.pdf>.

² FDA's automated Form 483 and Establishment Inspection Report system

and other stakeholders— to be of value, updating should occur more frequently, for example monthly or weekly. To achieve disclosure that is full, fair, and balanced, the Agency should consider publishing redacted versions of Form 483 in addition to the official inspection classification. Moreover, the Agency, with prior company consent, should also publish the company's full redacted response.

Providing only the most common inspection observations will be of only marginal utility to the regulated community if the observations listed are not sufficiently detailed. For example, deficient investigations (21 CFR 211.192) have been a problematic category for many years. In the past several years, though, the Agency has focused citations on deficient investigations resulting from Out-of-Specification (OOS) events and customer complaints. Thus, the value is in the specific deficiency observed at the company, not so much in the more broad finding statement.

Since FDA Form 483 does not constitute a final determination on whether or not there is a violation of the Federal Food, Drug, & Cosmetic Act (FFDCA) or any of its regulations, publishing only a copy of the redacted Form 483 or Turbo-EIR language will not achieve full and fair disclosure or provide the appropriate contextual balance to prevent misinterpretation. If the Agency releases 483s with only the “canned” Turbo-EIR language in the documents, then the Agency also should release the redacted version of the Form 483 and, if the company grants prior consent, the redacted company response. Such a system promotes transparency that is full, fair, and balanced while also ensuring the continued protection of company proprietary information.

III. Graphical User Interfaces Improve Transparency and Understanding only if Populated by Meaningful, High Quality Data

Data must be presented in a meaningful way to show how the regulated industry is performing over time as a result of FDA enforcement efforts. FDA should solicit input on how the regulated industry and the public are using the data. It would be desirable for some of this information to come from the comments on this initiative. In general, elaborate web-based tools are of limited value in the absence of high quality underlying information and data.

Graphical representations of data depicting the number of observations or categories of findings should be calibrated by the number of inspections performed so that both the regulated industry and the public can measure over time the rate of improvement of industry practices based on Agency enforcement efforts. If data are presented without leveraging the number of inspections, a strict number of findings over time may not be useful, as the number of inspections may outpace the number of findings. Therefore, the Agency first should focus on providing meaningful content, which in and of itself will draw more users and drive accurate and useful analysis.

SPECIFIC COMMENTS ON DRAFT PROPOSALS

- **Draft Proposal #1:** *FDA should explore different ways to improve data quality and facilitate more timely data disclosure by expediting data entry, expediting inspection review and classification, and/or updating the data more frequently. Tools to improve data quality and speed disclosure may include, for example, providing new technologies to investigators, introducing other process improvements, and/or implementing administrative incentives. To implement these types of tools effectively, FDA should explore how frequently data should be updated in order for it to be useful to stakeholders.*

As discussed above, it is the timely availability of actual data that will permit the public and regulated industry to perform their own meaningful data analyses. Moreover, the initial volume of data to be transferred to the public domain more than likely will exceed the Agency's staffing capacity. Tools to consider for increasing data quality and facilitating more timely disclosure could include prioritizing items of higher concern to the Agency, industry, and the public, as a first-in, first-out approach may suppress more urgent matters. Automation solutions should be evaluated to migrate data seamlessly from the point the inspection is reviewed by the applicable district or Center. Creating automation solutions ensures adherence to defined timelines for data updates and reduces personnel workload constraints. With limited resources, FDA should focus on providing timely information and appropriate redaction of commercially sensitive and proprietary information and leave detailed analysis to individual companies or trade publications.

- **Draft Proposal #2:** *Although FDA's inspections database webpage currently provides an e-mail address where stakeholders can submit questions about the database, FDA should explore whether: (1) reporting buttons, or other tools specifically focused on error reporting, would allow stakeholders to more easily identify potential errors in compliance and enforcement data, and (2) the Agency can implement procedures for investigating potential errors and correcting data, when appropriate, that would enable the Agency to remedy the errors more expeditiously.*

BIO supports the development of more responsive error reporting mechanisms and procedures for investigating potential errors and correcting data on an expeditious basis. However, the overall focus should be on ensuring the data are accurate at the time they are posted rather than developing systems for allowing the public to correct the data. The posting of inaccurate information by FDA may have significant adverse effects not only to regulated industry but also to patients who may lose confidence in industry processes and products.

Reporting buttons and similar strategies at the very least should be supplemented with a feedback mechanism to ensure that the Agency acknowledges the error reporting entity. A feedback mechanism helps ensure that the Agency will address error reports in a timely manner. Moreover, the Agency should define a timeline in which the regulated industry can expect resolution of errors. Without a feedback mechanism, industry may not utilize reporting tools

because of lack of certainty that their concerns will be addressed in a timely and meaningful manner.

- **Draft Proposal #3:** *FDA should explore how to present its compliance and enforcement data graphically and better utilize mobile web applications to draw more users to its compliance and enforcement webpages, and to encourage data analysis.*

As discussed above, we suggest FDA initially focus on publishing actual raw data rather than addressing graphical representations of data and mobile web applications. Meaningful content will help to drive accurate and helpful data analysis, which can lead to the development and adoption of web-based tools. However, to the extent that the Agency explores graphical representations, the focus should be on representing metrics relating to repeat-type errors, deficiencies to understand patterns, and opportunities for improvement.

- **Draft Proposal #4:** *FDA should explore whether it can better integrate its compliance and enforcement data, as well as its other publically available data on regulated firms, to make the data more user-friendly and easier to analyze.*

BIO agrees that an integration of compliance and enforcement data in a more user-friendly format would be ideal. BIO believes this is achieved best by opening a dialogue with regulated industry as to the type of compliance and enforcement data that would be the subject of this exploration, to be able to provide the Agency with ideas as to how that information can be presented in a way that is useful and easily analyzed. If the Agency's intent is to have industry perform in-depth analysis, it would be beneficial for the Agency to seek input from the regulated industry on how best to present compliance and enforcement data. Presentation of data on FDA's websites may be useful to the Agency for analysis of its own metrics. However, the regulated industry may have different needs and may benefit from having data presented that allow it to perform its own analyses and better react to FDA enforcement efforts.

- **Draft Proposal #5:** *FDA should explore whether additional, or more specific search criteria (e.g., criteria that would enable individual product-specific or violation-specific searches), or more sophisticated search capability (e.g., predictive name searches) would make the inspections database more user-friendly and the data easier to analyze.*

In general, additional and/or more specific search criteria and more sophisticated search capacity make databases more user-friendly and data easier to analyze. However, as discussed above, such additional capacity is most helpful when it is built on top of good quality data that facilitate meaningful data analyses by the regulated industry and the public.

- **Draft Proposal #6:** *FDA should explore whether posting additional data compilations or analysis, such as the Agency's most common inspections observations or the warning letter compilations, both of which it already posts, would increase transparency or better inform the Agency's own compliance efforts.*

As discussed above, FDA should focus first on providing meaningful “raw” data, since each company and user has its own process for analysis of this information. However, BIO recognizes that performing additional analysis may be helpful, if it complements the disclosure of meaningful raw data.

- **Draft Proposal #7:** *FDA should explore ways to better utilize social media, such as Facebook and Twitter, as well as Agency-sponsored webinars and automatic e-mail notifications, to better communicate with the public regarding its compliance and enforcement efforts.*

While social media have their place and purpose, FDA should, for the time being, defer communication of compliance data to Twitter and Facebook or other social media. Before considering additional information avenues, the Agency should manage its raw compliance data effectively, as discussed above.

Care needs to be exercised in using social media. Thought needs to go into how comments will be handled and the opportunities for deliberate or accidental misinformation. BIO encourages FDA to consider the appropriateness of the use of this medium by FDA. Just because a medium exists does not make it appropriate for use by FDA. Security concerns over social media exist and confusion may arise over unauthorized messages posted through such forums. While FDA.gov is a recognized and secure website, entities using fake FDA accounts may communicate inaccurate messages that do not represent the Agency's position and could trigger unintended and negative reactions by both industry and the public.

- **Draft Proposal #8:** *FDA should provide appropriate context for the compliance and enforcement data it discloses, to help ensure that the data is not misinterpreted or misused. Depending on the circumstances, appropriate contextual information may include, for example:*
 - *Information regarding how frequently data the data is updated,*
 - *Information regarding the reliability of the data,*
 - *Information regarding the average lapse of time between inspection and the posting of inspection classification information,*
 - *Definitions of inspection classification types (i.e., Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI)), and*
 - *A statement explaining the website's lack of information regarding a particular facility does not imply compliance or non-compliance (i.e., users should not infer that facilities that have not been inspected recently, or at all, are (or are not) in compliance with FDA's laws and regulations).*

BIO supports the Agency's efforts to provide appropriate context for the compliance and enforcement data it discloses. Despite the fact that it is practically impossible to prevent misinterpretation completely, the data provided should still be granular and meaningful to the regulated community. Compliance and enforcement data, especially in Form 483, tend to be highly technical, and attempts to ensure that the general public will not misinterpret the data should not prevent access. Providing the information outlined above will help ensure that data are not misinterpreted or misused. Moreover, providing appropriate context (e.g., how frequently types of observations described occur and whether violations result in product safety issues) also requires informing users that Form 483 conclusions do not constitute a final FDA decision on whether there has been a violation of the FFDCa or any of its relevant regulations. It is important that users understand that before the Agency determines what action is appropriate, if any, to protect the public health, it considers not just the Form 483, but also the Establishment Inspection Report, all evidence collected onsite, and any responses made by the company.

CONCLUSION:

BIO appreciates this opportunity to comment on the "Draft Proposal for Public Comment to Increase Transparency By Promoting Greater Access to the Agency's Compliance and Enforcement Data; Availability." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Managing Director, Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)