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3 February 2025

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

Reference: Docket No. FDA-2024-N-4821-0002 for "Food and Drug Administration's Best Practices for Food and Drug Administration Communication with Interested Parties: Draft Report for Public Comment."

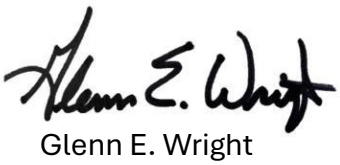
Dear Madam or Sir,

PDA appreciates the opportunity to provide feedback to the FDA as the agency develops and establishes best practices for the efficient prioritization, development, issuance, and use of guidance documents. In our attached comments, PDA offers specific comments and feedback that we believe will be helpful in further developing this program.

PDA is a non-profit international professional association of more than 10,000 individual members who are industry professionals having an interest in fields of pharmaceutical, biological, device manufacturing, and quality. Our comments have been prepared by a committee of PDA members with expertise in the areas covered in the Public Docket on behalf of PDA's Regulatory Affairs and Quality Advisory Board.

If you have any questions, please do not hesitate to contact me via email at wright@pda.org.

Sincerely,



Glenn E. Wright
President and CEO

cc. Josh Eaton, PDA; Carrie Horton, PDA.

PDA Responses to "*FDA Best Practices for Food and Drug Administration Communication with Interested Parties: Draft Report for Public Comment*."

The Parenteral Drug Association (PDA) appreciates the Food and Drug Administration's (FDA) concerted efforts to utilize various tools and platforms for transparent communication with industry, patients, and other stakeholders, particularly during public health emergencies. The innovations implemented during this time, such as webinars and real-time updates, have proven highly valuable and should be retained and further developed as integral components of the FDA's ongoing communication strategy.

PDA commends the initiative's recognition of the importance of clear, concise, and timely communication. Such communication is essential for fostering productive relationships with industry and ensuring the integrity of the public health mission. However, PDA would like to emphasize several recommendations regarding industry feedback and best practices to enhance communication strategies moving forward.

In-Person Engagement: While the FDA has made notable progress in utilizing diverse communication channels, it is vital that these methods do not replace long-standing face-to-face interactions at industry conferences and meetings. Such gatherings are invaluable for fostering dialogue, benchmarking, and building relationships. PDA urges the FDA to continue and enhance opportunities for in-person engagement, as these interactions facilitate a deeper understanding and collaboration on emerging technologies and shared challenges within the industry.

Feedback Mechanisms: While the draft document indicates the FDA's commitment to improving transparency and engagement with stakeholders, it lacks a detailed discussion on mechanisms for gathering feedback from various stakeholders, including National Regulatory Authorities (NRAs) and manufacturers. Establishing formal feedback systems, such as surveys, focus groups, and regular stakeholder consultations, could significantly enhance the FDA's understanding of industry needs and perceptions. This insight is crucial for refining communication strategies and aligning them with the experiences and expectations of those they serve.

Centralized Contact Information: Given the numerous communication channels and contacts within the FDA, the PDA proposes the creation of a centralized master list of general contact email boxes, phone numbers, websites, and their respective purposes. This resource would greatly assist smaller organizations and startups in navigating their interactions with the FDA more effectively.

Identifying Official Sources: The multitude of communication channels can create confusion regarding the location of official information. PDA recommends that the FDA clearly identify and label a primary channel—potentially the Federal Register or regulations.gov—as the official source for regulatory announcements. All supplementary channels should direct users to this single source to ensure that important updates are not overlooked.

Recommendation:

- **Active Solicitation of Feedback:** The FDA should actively seek input from stakeholders on topics of concern rather than solely providing information. This engagement can guide future directions and communication efforts. For example, the FDA could adopt a model similar to the annual meetings between the EMA Inspector Working Group and Interested Parties, which have effectively facilitated the sharing of insights and addressing of concerns.

- **Utilization of Public Dashboards and Advisory Committees:** PDA encourages the continued use of public dashboards and advisory committees. These tools are effective in highlighting important areas of focus and improving stakeholder engagement.

- **Prioritization of Recommendations from the Reagan-Udall Foundation Report:** PDA recommends that the best practices document clearly highlight which initial recommendations from the Reagan-Udall Foundation report the agency prioritizes. Communicating these priorities transparently will lead to a more efficient deployment of strategies and appropriately set expectations for stakeholders.

- **Implementation of FAQs and Templates:** The FDA should implement FAQs and templates to minimize repetitive queries. Providing consolidated and prompt answers to common stakeholder questions can streamline communication and improve efficiency.

- **Integration of Scenario-Based Webinars:** PDA suggests that the FDA consider the integration of scenario-based webinars to demonstrate how guidance applies in real-world situations. Ensuring that critical information is accessible and understandable to a broad audience is essential. Striking a balance between detailed technical information for experts and clear communication for the general public is vital for fostering transparency and engagement.

- **Implementation of a "Track Changes" System:** The FDA should implement a "track changes" or change log system for revised guidance or regulations. This would allow users to easily identify the reasons for changes. This approach will pave the way for greater use of artificial intelligence, streamlining the discovery of new expectations and aiding in regulatory compliance.

The FDA's commitment to improving communication with industry stakeholders is commendable. By integrating these insights and best practices into the final document and its implementation plans, the FDA will be better positioned to foster a more engaged and informed relationship with the industry, ultimately supporting its mission to protect public health. Furthermore, as the dynamics of communication differ between public and industry stakeholders, it is imperative that the FDA defines a clear and accommodating pathway for industry representatives to engage with the agency, especially when seeking clarification on FDA observations or guidance.

Thank you for the opportunity to provide feedback on this important draft report. We look forward to continuing collaboration with the FDA to enhance our collective efforts in advancing public health.

About PDA Regulatory Commenting

PDA submits comments to regulatory agencies and pharmacopeial bodies when draft guidance or legislation is issued for public comment. Members of the PDA community work together to provide feedback regarding the content to ensure a broad industry perspective is presented and considered for inclusion or revision of the draft document.

PDA Regulatory Commenting documents are consensus documents, prepared by member-driven teams (listed below) comprised of content experts, including scientists and engineers working in the pharmaceutical/biopharmaceutical industry, regulatory authorities and academia.

The final working draft is reviewed by the PDA Advisory Board(s) aligned to the PDA Commenting Effort subject matter. PDA's four Advisory Boards are classified as Science, Advanced Therapy Medicinal Products, Biopharmaceuticals, and Regulatory Affairs and Quality.

While PDA goes to great lengths to ensure each commenting document is of the highest quality, all readers are encouraged to contact PDA about any scientific, technical, or regulatory inaccuracies, discrepancies, or mistakes that might be found in any of the documents. Readers can email PDA at: sci_reg@pda.org

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