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Submitted electronically to **http://www.regulations.gov**

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Re: Docket Number FDA-2022-D-0810

Re: **Conducting Remote Regulatory Assessments Questions and Answers, Draft Guidance for Industry. Docket No. FDA-2022-D-0810**.

The Consumer Healthcare Products Association[1] (CHPA), as the leading national trade association representing manufacturers and marketers of consumer healthcare products, including over-the-counter drugs and dietary supplements, and consumer medical devices, is dedicated to upholding the highest standards in providing safe and reliable consumer healthcare products. We appreciate this opportunity to respond to the Food and Drug Administration's (FDA) Draft Guidance for Industry, "Conducting Remote Regulatory Assessments Questions and Answers" (2024 Guidance), as published in the Federal Register on January 26, 2024.

CHPA acknowledges and supports FDA's endeavors to modernize inspection and compliance strategies through the integration of Remote Regulatory Assessments (RRAs), recognizing the opportunity they present to enhance resource utilization, maintain a targeted on-site inspection program, and ensure the prompt verification of necessary corrections by facilities. This approach, when harmonized with other regulatory oversight tools, has the potential to contribute significantly to a more efficient, risk-based, and focused inspection system. CHPA welcomes this opportunity to provide constructive feedback to improve the effectiveness and efficiency of this regulatory tool.

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org

1. Dietary Supplement Facility Voluntary RRAs, Efficiency and Industry Participation

CHPA members that manufacture dietary supplements emphasize that the time and resources required for a voluntary RRA can exceed those of an in-person FDA cGMP inspection, without a discernible benefit to the manufacturer. CHPA members emphasize the need for specific and limited RRA information requests within a reasonable time frame to reduce the burden on manufacturers and increase industry participation in voluntary RRAs.

CHPA members reported experiences with voluntary RRAs that included extensive document requests, as compared to the same member's experience with onsite inspections. In one example the FDA initially requested four years of detailed information, which was a significant amount of material to prepare for secure electronic transfer to FDA. When the member explained to the FDA staff the high volume of documents being requested and the resources required to respond, the time frame was negotiated down to two years of records. The member suggests that such extensive requests, especially for low-risk facilities, can be a significant challenge and may discourage voluntary participation.

Concerns exist that industry participation in voluntary RRAs may be hindered without a clearer understanding of the process, resource commitments, and tangible incentives. FDA has reported that it inspects around 500 to 600 dietary supplement manufacturing facilities annually, which is about 5% of known facilities. CHPA strongly encourages FDA to provide additional information about how it can use information from voluntary RRAs to incorporate into a risk-based inspection schedule to help FDA use inspectional resources more efficiently and effectively, suggesting potential benefits for participating facilities with a record of regulatory compliance. In addition, CHPA encourages FDA to use RRAs as a tool to significantly increase the overall number of foreign and domestic dietary supplement facilities assessed for compliance, and quickly screen for non-compliant facilities for further evaluation.

In summary, for facilities with a positive regulatory history, an on-site FDA inspection is perceived as a more efficient use of a manufacturing site resources as compared to an RRA. CHPA advocates for establishing reasonable limits, clear document scopes, predetermined time limits, and precise definitions of voluntary RRAs to boost industry participation. In addition, the dietary supplement industry would have incentives to participate in voluntary RRAs if there were assurances from FDA that

this would increase FDA's ability to identify and initiate enforcement action against the most egregious non-compliant facilities.

2. Method for Contacting the Company and Scheduling Considerations for RRAs:

We acknowledge the FDA's intention to contact establishments through their designated point of contact, by email or phone. However, based on feedback from our members, we would like to recommend a more specific and secure method for initiating contact, especially for large facilities that manufacture multiple product categories. CHPA members have expressed concerns about potential gaps in the current proposed method, which may lead to a RRA request being missed by a large facility. CHPA members have reported receiving FDA Form 4003, FDA Inspection Records Request, which lacked a specified indicator informing whether it was voluntary or mandatory. To address this concern, we propose that the FDA consider incorporating a certified letter or another guaranteed form of communication that is explicit in distinguishing between a voluntary or mandatory request when reaching out to establishments before considering that an RRA has been refused.

Certified letters provide a trackable and verifiable means of communication. This would ensure that the point of contact receives and acknowledges the RRA request and is clear if it is mandatory or voluntary, reducing the risk of oversight or missed communication. Utilizing a certified letter adds a level of formality to the communication process, emphasizing the importance of the request. It also establishes accountability, as the FDA receives confirmation of delivery. We believe that incorporating a certified letter or an equivalent guaranteed form of communication that is clear about FDA's mandatory or voluntary request would strengthen the reliability of the process and ensure that RRA requests are effectively communicated.

In addition, CHPA requests additional information regarding the scheduling of RRAs, emphasizing the importance of flexibility. For example, CHPA members with global facilities note the importance of accounting for time zone differences and allowing manufacturers to propose alternative times or dates for valid reasons during voluntary or mandatory RRAs.

3. Enhancing Interaction and Context in Remote Regulatory Assessments

CHPA members express reservations about Remote Regulatory Assessments (RRAs) generating extensive documentation devoid of context or human interaction, which

could potentially lead to confusion or misunderstandings. In alignment with comments submitted to FDA in response to the 2022 draft guidance by the Consumer Brands Association[2], CHPA supports the recommendation that, following the provision of documents and records for review in a RRA, the FDA schedules one or more meetings with the facilities point of contact(s). These meetings are essential to afford the facility's point of contact(s) the opportunity to offer context for the shared information. This becomes crucial as, in an RRA, the facility's point of contact(s) won't be physically guiding FDA inspectors through the facility or providing nuanced details about the manufacturing site, standard operating procedures, and records, as typically done in an on-site inspection. Given these constraints, providing context becomes imperative for an accurate and comprehensive review of the obtained documents and materials.

In response to Question 16 posed by FDA in the 2024 Draft Guidance, *what may occur upon completion of an RRA*? - CHPA concurs once again with the Consumer Brands Association 2022 comments, which emphasize the need for a mandatory meeting between FDA and the company/facility's key personnel at the conclusion of a voluntary RRA. It is proposed that the final guidance language should assert, "FDA will have a meeting with the establishment's management" instead of "FDA may have a meeting with the establishment's management." This post-voluntary RRA meeting serves as a valuable opportunity for FDA to share and elucidate any RRA observations, provide a written summary of the assessment if available, and allow facility representatives to seek clarification, ask questions, and address any lingering queries that the FDA might have.

4. Technology and Records Submission

CHPA aligns with the recommendations presented by the Consumer Brands Association in their September 22, 2022, comments to the FDA. These suggestions propose that FDA engages or communicates with the designated point of contact(s) at the facility to confirm technological capabilities (e.g., Zoom, Teams, WebEx, etc.), discuss the type and overall scope of the RRA, outline the list of documents and records that will be requested and reviewed, and establish timelines for the assessment – prior to the facilities agreement to participate in the voluntary RRA. By doing so, both the facility and FDA can make informed decisions about its technology capabilities and adequately prepare for the RRA. CHPA expresses support and appreciation for FDA's commitment to minimizing the quantity of records

[2] Consumer Brands Association Comments to Docket No. FDA-2022-D-0810, September 23, 2022.

requested for review during an RRA, as this streamlined approach encourages facilities to volunteer for RRAs, anticipating increased operational efficiencies, potentially resulting in more focused and shorter on-site inspections.

Furthermore, CHPA seeks clarification on the time allowed to submit RRA records through the FDA electronic portal in response to a records request, as well as more information addressing information, date, and software protection and security concerns. CHPA members have significant concerns about FDA remote assessor's being provided "read only" access to software. As software meddling and Artificial Intelligence grow more frequent there are significant concerns that allowing remote access to software and data exposes a manufacturing site to potential risks that wouldn't be a consideration in a normal inspection.

5. Conclusion

In conclusion, CHPA appreciates the opportunity to contribute feedback to the FDA's Draft Guidance for Industry on Conducting Remote Regulatory Assessments Questions and Answers. While acknowledging and supporting the FDA's pursuit of modernizing inspection and compliance strategies through the integration of RRAs, CHPA underscores key industry concerns that warrant consideration. The discrepancy in resource requirements between voluntary RRAs and on-site inspections, particularly for low-risk facilities, poses a challenge and may potentially dissuade industry participation. To address this, CHPA recommends revisiting information request parameters, advocating for reasonable limits, clear document scopes, predetermined time constraints, and precise definitions for voluntary RRAs.

Furthermore, CHPA echoes concerns about the potential gaps in the proposed method for contacting establishments, emphasizing the need for a more specific and secure communication approach, especially for large facilities. The proposal to incorporate a certified letter or an equivalent guaranteed form of communication is put forth to ensure the effective transmission and acknowledgment of voluntary RRA requests, minimizing the risk of oversight. Additionally, CHPA stresses the importance of considering time zone differences and providing flexibility for manufacturers to propose alternative dates during voluntary RRAs, enhancing the overall efficiency of the process.

Addressing the critical aspect of human interaction and context in RRAs, CHPA aligns with the recommendation that the FDA schedules pre- and post-assessment meetings with facilities' points of contact(s). These meetings offer a crucial

opportunity for the provision of context to the shared information, compensating for the absence of physical guidance through the facility, a common practice during on-site inspections. Moreover, CHPA supports the mandatory nature of a meeting between FDA and the company/facility's key personnel at the conclusion of a voluntary RRA, emphasizing transparency and effective communication.

CHPA looks forward to continued engagement and collaboration with the FDA to refine the regulatory framework, ensuring a balanced, efficient, and risk-based approach to safeguarding consumer self-care products.

Best Regards,

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