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September 22, 2022 VIA ELECTRONIC SUBMISSION

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

Re: Docket Number FDA-2022-D-0810
Conducting Remote Regulatory Assessments Questions and Answers, Draft Guidance for Industry

The Consumer Healthcare Products Association ("CHPA") is the leading national trade association representing manufacturers and distributors of over-the-counter medications, dietary supplements, and consumer medical devices. Our association is committed to maintaining the highest levels of safety in the manufacture and regulation of consumer self-care products. We appreciate this opportunity to provide comments on the Food and Drug Administration's ("FDA" or "Agency") Draft Guidance for Industry, "Conducting Remote Regulatory Assessments Questions and Answers" (2022 Guidance), published in the Federal Register on July 25, 2022.

CHPA supports FDA's attention and consideration to continued use of the Remote Regulatory Assessment (RRA). Voluntary RRAs are not new and were used during the COVID pandemic; therefore, CHPA members have experience with FDA voluntary RRAs. CHPA supports FDA's efforts to improve efficiencies and to increase visibility into more OTC drug, dietary supplement, and medical device manufacturing facilities. We appreciate this opportunity to provide important feedback.

CHPA Agrees FDA RRAs can be an Important Tool for Ensuring the Safety of FDA regulated commodities.

1. **FDA needs to address industry feedback that a voluntary RRA takes more time and resources and is without benefit to those who volunteer.**

   a) CHPA members, who have participated in voluntary RRAs, have noted the time and resources needed for an RRA far exceeds an in-person FDA cGMP inspection. In addition, a manufacturer who successfully undergoes an RRA does not realize a benefit to justify the increase in resource expenditure.

   b) CHPA appreciates RRAs may improve FDA's use of resources. CHPA has concerns that industry may not participate in voluntary RRAs without a better understanding of the time and resources needed to complete the process and a clear incentive to agree to a voluntary request from FDA.

   c) Even for a facility with a positive regulatory history and striving for 100% compliance with every aspect of current Good Manufacturing Practice (cGMP), some CHPA manufacturer members feel an onsite FDA inspection is a more efficient use of time and resources.

   d) Since the FDA staff could still conduct an onsite inspection after an RRA, this results in less incentive for responsible industry to agree to a voluntary RRA.

e) One example, related to excess time and resources for an RRA, a CHPA member received an RRA request that included an eleven-page document request list. In the member's experience, the time required to upload the substantial number of PDF documents exceeded the time it would have taken to provide the documents to an onsite investigator in a meaningful way. In this example, the time and resources saved by FDA do not translate to time saved by the manufacturer.

f) RRA should be voluntary. Contract Manufacturers in the CHPA network have advised they prefer on-site inspections, as opposed to RRAs. This is not only because of the extended time and resources required to participate, but there is also a reduced ability to interact with the investigator onsite to answer questions in real-time. Industry veterans concur that the ability to interact in person with a cGMP investigator has intangible benefits to both the manufacturer and FDA.

g) CHPA requests the RRA 2020 Guidance establish:
   a. A reasonable limit or clear scope of documents requested during the RRA,
   b. Establishment of a pre-determined, reasonable time limit for conducting the RRA, and
   c. Clearly define the scope of voluntary RRAs.

   We feel this may help encourage industry and increase participation.

2. CHPA requests additional information regarding the scheduling of an RRA.

a) The timing of an RRA is an important consideration. FDA needs to account for time zone differences when scheduling video calls and interviews.

b) In addition, for voluntary RRAs there should be an FDA process for manufacturers to recommend alternative dates to conduct an RRA assuming a valid reason (e.g., facility is undergoing concurrent inspection, key staff is unavailable, international parent company, etc.).

3. CHPA requests FDA clarification and additional information regarding the technology and time allowed to submit requested RRA records through the FDA electronic portal.

a) The 2022 Guidance is vague regarding the time required to provide records to the FDA via the electronic portal. Our member network is concerned these details are not clearly defined and ask for specific information on the time requirement.

b) CHPA members have raised concerns regarding information security and request this be addressed. Our network would like FDA to evaluate new technologies to account for privacy, confidentiality, and security concerns for RRA documents submitted to the FDA portal.

c) Finally, CHPA would like FDA to recognize electronic systems may not keep records in PDF format. Our members have expressed concern that when submitting RRA records to the electronic portal, additional time and resources are necessary versus during and onsite inspection. During and onsite inspection, records can be photocopied and provided directly to the investigator.

4. FDA should address the benefits for industry participation in RRAs including how participation in an RRA could reduce the time necessary to conduct subsequent on-site inspections.

a) CHPA members believe RRAs should be voluntary. This 2022 Guidance explains the distinct categories of voluntary and mandatory RRAs. However, there is no explanation of the benefit or risk if a firm chooses to say “no” to a voluntary RRA request. Can FDA provide additional insight on its response to a voluntary RRA that is not accepted? Are there repercussions by saying “no” to a voluntary RRA request?

b) CHPA agrees an RRA should not replace an onsite inspection. However, CHPA would like to understand how information gathered from an RRA will be used by FDA to develop a risk-based inspection schedule. If FDA inspectional resources are used to identify high risk facilities, there is an opportunity to spare FDA resources for low-risk facilities that undergo successful RRAs.

   For example, low risk facilities should be provided a less frequent on-site inspection schedule. CHPA believes there will be more participation in voluntary RRAs through transparency into how demonstration of compliance with an RRA may have benefits.

c) In the draft guidance there is no period of validity defined for the documents provided to the FDA.

   For example, USP moved to remote inspections in 2020. These remote inspections included a significant amount of documentation and Standard Operating Procedures were provided remotely. In responses to more recent audits, USP staff has referred to documents electronically provided in previous years.

   Will the FDA staff utilize previously provided documents during future inspections?

5. **FDA should consider addressing additional questions in the Question-and-Answer format of this 2022 Guidance. Additional CHPA questions include:**
   a) Will participation in a voluntary RRA, with a satisfactory regulatory outcome, reduce the number or frequency of on-site inspections?
   b) When would the FDA use an RRA over an inspection?
   c) Would an RRA extend the current inspection period and to what extent? Current industry understanding is that a high-risk facility would be inspected approximately every three years and a low-risk facility, approximately every five years. Could the time between on-site FDA inspections be increased for those who voluntarily participate in an RRA?
   d) What is the process to request alternate dates?
   e) What is the consequence to “refusing” to participate in a voluntary RRA?

CHPA members believe RRAs could be a valuable tool for the FDA once this system is well-established. However, our member network believes RRAs should remain voluntary, should be risk-based with a limited and specific scope for document requests, and should utilize a clear and uniform procedure for conducting the RRA. The RRA should be conducted by well-qualified staff to help ensure consistency and timeliness of the assessment. Finally, CHPA feels the Agency should carefully evaluate the technology for submitting documents through the FDA portal.

Thank you for your time and consideration.

Respectfully,

Larisa Pavlick
Senior Director, Quality Assurance and Technical Affairs