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17 November 2023

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

Reference: Docket No. FDA-2023-D-3031 for “Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications”; Draft Guidance for Industry

Dear Madam or Sir,

PDA appreciates the opportunity to provide feedback to the FDA as the agency provides clarification on its intent to use alternative tools to assess drug manufacturing facilities identified in a marketing application. In our attached comments, PDA offers specific comments and feedback that we believe will be helpful in the further development of this important guidance.

PDA is a non-profit international professional association of more than 10,000 individual member scientists 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 Wright
President and CEO

cc. Josh Eaton,PDA; Carrie Horton,PDA; Jessie Lindner, PDA; Danielle Bretz, PDA

Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications Guidance for Industry

Section IV.C.: PAIs and PLIs With FDA Remote Subject Matter Experts (lines 262-324)

Line number(s)	Current Text	Comment	Proposed Change	Rationale for Change
293-296	"The request would indicate: (1) the name, address, and FDA Establishment Identifier or unique identifier of the facility to be inspected; (2) the application or supplement number; (3) the reasoning for FDA's use of remote resources; and (4) the names and positions of the remote personnel, if known in advance."	Many of the processes and documentation reviewed by FDA are proprietary and reveal company intellectual property. If FDA intends to create a record of the video, screen sharing, etc., it would be prudent to inform the entity inspected. Local regulations in some countries (e.g., Germany) restrict the recording of personnel in the workplace.	PDA recommends the addition of the statement "**FDA will inform the inspected entity if recording of the livestream video, screen share or teleconference will occur. If recording occurs, the Agency will ensure that the recorded or electronic information remains secure and is protected from cyber security attacks, accidental or intentional transmission to nonagency. The video footage cannot be obtained through a Freedom of Information Act request."**	PDA feels the addition of this statement allows the inspected entity to better assess IP risk and prevent non-compliance with local regulations.
298 to 303	"Upon the facility's agreement to Agency use of remote resources, FDA will facilitate the planning and coordination of the inspection and involvement of a remote SME. The on-site inspection team lead	There is no mention of the path or consequences when the facility disagrees with the use of remote SMEs (could be not equipped to do so...) Would the inspection be delayed?	PDA recommends providing guidance or a statement to clarify what regulatory actions might occur if you decline the use of a remote SME during a facility inspection.	This will improve clarity for the reader.

	will schedule a virtual meeting with the facility to discuss logistics and expectations. When a facility agrees to the involvement of a remote SME during an inspection, FDA expects the same level of cooperation and transparency with remote FDA personnel as expected with the on-site inspection team."			

Section V: THE EFFECTS OF USING ALTERNATIVE TOOLS (lines 327-340)

Line number(s	Current Text	Comment	Proposed Change	Rationale for Change
329-340	"In general, the use of alternative tools will help FDA fulfill its commitments to meet user fee goal dates and to make timely application decisions. If observations are identified by FDA through the use of alternative tools, a written list of observations may be presented by FDA to the facility. A facility should submit any responses or corrective actions to FDA within	FDA does not define what would be the fate upon completion of RRAs in terms of any written list of observations, either to be made publicly available with any applicable redaction of information that is otherwise exempt from public disclosure. In addition, no information is provided regarding observations that may be subject to a request under the Freedom of Information Act at the time the	PDA requests that the FDA clarify the outcome and anticipated timeframe regarding the observations made outside of a 483. One potential solution could be the provision of a flowchart visual aid to show how determinations are made and to clarify the specific type of	Additional clarification will aid in understanding for the reader.

	15 U.S. business days for consideration in the application assessment. Responses received after 15 U.S. business days may be deferred for further assessment in the next application assessment cycle. If FDA determines that there is insufficient information available to make a determination on the acceptability of a facility and an inspection is needed to address concerns, FDA will communicate this determination in application milestone meetings, action letters, postaction letters, and/or communications regarding scheduling of the inspection, as appropriate."	disclosure to the establishment is first made (21 CFR 489 20.101(a).	communication outputs from the Agency and the anticipated, typical timeframe.	