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September 23, 2022

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

Re: Docket No. FDA-2022-D-0810—Draft Guidance for Industry: Conducting Remote Regulatory Assessments: Questions and Answers.

Dear Sir or Madam:

On behalf of the Advanced Medical Technology Association ("AdvaMed"), we provide these comments in response to the Food and Drug Administration (FDA or "Agency") "Draft Guidance for Industry: Conducting Remote Regulatory Assessments: Questions and Answers" (hereinafter "draft guidance").

AdvaMed represents manufacturers of medical devices, digital health technologies, and diagnostic products that transform healthcare through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. Our member companies manufacture lifechanging technologies ranging from cardiovascular and orthopedic implants to cancer diagnostics, surgical instruments, and digital health products.

GENERAL COMMENTS

AdvaMed supports the concept of Remote Regulatory Assessments (RRAs). We appreciate FDA issuing a guidance document to outline current thinking regarding the program. For devices, RRAs are voluntary. Until legislative authority is granted, we believe the voluntary nature of the program for devices in any FDA guidance must be further underscored.

FDA should revise the guidance overall to stress the voluntary nature of the program, to reiterate FDA's commitment to its existing statutory obligations, and to acknowledge the differences between on-site inspections and voluntary RRAs, particularly regarding staffing levels necessary to support RRAs by both FDA and industry.

The changes we propose throughout the guidance are intended to create a viable program and encourage manufacturers to participate. We are concerned that, as structured in the current draft, some manufacturers may not participate because the benefits will not be perceived to be strong enough to outweigh potential burdens associated with participation and the removal of key protections provided in a traditional in-person inspection.

FDA should add to the draft Guidance a question that addresses who at FDA is authorized to initiate a request for an RRA, the mechanism for tracking RRAs within the Agency, and intra-Agency coordination.

We seek additional clarity surrounding who within the Agency has authority to request an RRA, the mechanism for tracking the RRAs within the Agency, and intra-Agency coordination of RRAs. For example, we would propose addressing the following questions:

- Who within the Agency has the authority to initiate an RRA?
- What approval processes within the Agency are needed to initiate an RRA, e.g., can a center employee open an RRA on their own?
- How many RRAs within a company, including specific establishments, can be open at one time?
- Does the Agency need to coordinate the RRAs through a single point of contact within the Agency?
- What specific training will be developed and provided for FDA officials with authority to initiate RRAs? How will such training rely upon, or differ from, the Investigations Operation Manual (IOM)?
- What are the limitations on the types of documents an FDA employee can request for that specific type of RRA, e.g., distinctions between a pre-approval inspection versus routine inspection?
- If there is a concern with the conduct of employee initiating and/or conducting the RRA, who is a firm supposed to contact, e.g., chain of command, or is the only option to decline further participation?
- What kind of oversight/analysis will be performed, and metrics employed, to ensure the program is running smoothly?
- Will information on the success of the program be publicly disclosed, similar to the inspections database?
- Will FDA track and report how many RRAs are conducted, the duration of each, how many are requested and declined, how many are agreed to and then withdrawn, or how often, and how soon, inspections are conducted after a completed RRA or after a denied RRA?
- Will the firm be able to agree to an RRA with limitations?

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- Will there be a standard written document outlining the terms of participation?
- Who within the company needs to authorize participation, e.g., would the most senior person at a site or designee need to authorize participation?
- Will all responses to an RRA become part of the final official record of a submission review?

Clear expectations on the part of all parties, including FDA and industry, will be critical to ensuring a successful program.

FDA should highlight throughout the document the potential benefits of less frequent or reduced duration/scope of inspection for participants in an RRA

We request that FDA include language in several instances in the document denoting the possible benefits of participating in the RRA in terms of reducing the frequency, scope, and duration of inspections. Consideration of participation in an RRA can be incorporated into FDA's risk-based inspection schedule and lead to less frequent inspections at an establishment, reduced duration of time spent at the establishment, and/or reduced scope of inspection. This would allow FDA to focus its inspection resources on the more significant risks to public health, benefitting both industry and FDA. While the current draft guidance includes some language along these lines, the point could be more explicit. In our specific comments that follow, we propose specific areas in the guidance where such language could be added.

FDA should engage in an interactive discussion with the company detailing the contours of the RRA in advance of requesting a company to agree to participate

We believe there needs to be an interactive discussion for each RRA, in advance, before anything is agreed to in terms of participation, of the contours of the RRA, including technology and duration. It appears from the language in the draft that FDA will first reach out to confirm participation in an RRA (lines 287-290) in writing, and only after such commitment will FDA provide details as to the contours of the RRA such as timing, technology requests, records for review. This is the opposite of the order we would expect. Firms will need to understand at least some of the contours of the requested RRA before being able to decide whether to voluntarily participate. Following the interactive discussion, the mutually agreed parameters of the RRA should be set out in a standard document for both parties to approve.

For participation to be truly voluntary, there needs to be an interactive discussion between FDA and the company where everyone involved understands the parameters and then the company agrees. Setting out the parameters before participation is confirmed will also help ensure success of the program. Feedback during the pilot indicated that miscommunications and lack of understandings may have reduced the success of the program. For these reasons, we propose revising to include details of the requested RRA, e.g., timing, technology requests, records for review, in the initial request outreach.

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As part of this interactive process at the outset, we recommend that when requesting an RRA, FDA also work with the site to set up a "pre-RRA planning session" where industry and the Agency can set expectations about what is available at the site. For example, if FDA is interested in video streams of parts of the facility, what video quality specifications are adequate for FDA to use. As industry becomes more familiar with the RRA process, these planning sessions would allow for both sides to be prepared on next steps and allow industry the opportunity to provide an overview of resources available at each site, acknowledging this will not be the same across industry or even across a company.

FDA should provide daily, interactive, updates during the RRA

During a typical inspection, and as outlined in FDARA, there is a review each day. The process for RRAs should follow the same practice to ensure that FDA communicates to the firm on progress and concerns, including estimation of time until completion.

To minimize errors and misunderstandings, it important that FDA makes every effort to communicate with the establishment during an RRA. Frequent informal interactions during the review of the records will help to facilitate the efficient and timely review and evaluation by FDA of the records.

Overall, the program should constitute a two-way dialogue between the manufacturer and FDA. If the manufacturer agrees to a voluntary RRA, feedback from FDA should be provided. Updates from FDA are particularly needed as any written observations and/or response from the manufacturer is potentially publicly available via Freedom of Information Act (FOIA).

Communications during the RRA provide an opportunity to clarify any information or misunderstandings and to ensure an accurate and complete outcome. It may also enable the Company to address concerns swiftly during the RRA, which FDA can then verify prior to concluding the RRA.

FDA should outline appropriate protections for documents and data received from the establishment as part of the RRA.

Industry needs to understand how FDA will treat documents and data that FDA receives during an RRA. In a typical inspection, a company employee only has the documents that they carry into a room and all requests for items are reviewed and logged before being shared with the investigator. Document and data sharing will look very different in a remote environment. The unique considerations of a remote environment must be considered and detailed in the guidance.

It is important to understand whether FDA must abide by all the rules relating to documents and inspections, even if the documents are asked for by Center staff who are not also investigators (this is where training will be important). In inspections, an investigator may view a document, but not necessarily take a copy of the document. In an RRA, will all documents reviewed be

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retained by FDA? Will live video feed count as "providing" documents? Can a Company employee in a live chat take time to review a document before showing the document to FDA?

We recommend that the guidance state that no audio or video recordings, or screenshots/image capture by FDA be allowed during an RRA, and that if FDA intends to keep a copy of a document or information shared in an RRA, that FDA clearly identify which documents or information will be retained. Furthermore, many documents shared during an RRA or inspection are highly confidential. We request FDA provide information on the Agency's efforts to protect these documents.

During any RRA, we do not believe it is appropriate to allow anyone other than a company's employees to have access to any company systems, even read-only access. There are significant IT authentication protocols, security restrictions and cybersecurity risks related to remote access of any system, most of which are managed through the use of multi-factor authentication and limited to company personnel only. Security features at the company may require a company email address and two-factor identification requiring either a specific device or software to be employed. These features would be inappropriate for use on any asset not owned or managed by the company, including any for a government computer. Moreover, companies require a significant amount of training for their own employees before allowing access to, and use of, the validated systems.

Need for issuance of report for all voluntary RRAs and understanding public availability of report.

The Agency should issue a formal report for all device RRAs. The final report should not be optional. The firm should be sent a written copy of the RRA report so there is record of the outcome.

It is not practical for a company to use the FOIA process to obtain the observations from the RRA because the FOIA process is impractically slow, and it will be challenging to have timely internal communication for improvements.

Also, a written report from a regulatory agency has substantially more influence than a verbal information from the Agency if cross-functional groups need to be involved in an improvement based on the RRA assessment.

We also wish to understand how much time after an RRA closure (assuming there is a clear end date) will be needed for the company to obtain the report. We recommend the report be made available to the public only once it is confirmed a firm has received the report and had a chance to review the report. We believe the company should have an opportunity to redact any portion of a report that could become public. We also request that the guidance outline who within the Agency a company should contact for updates on when it should expect to receive the report.

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We would recommend closing any RRA before any inspection, or specifying than an RRA will automatically close with the initiation of an inspection.

We are unable to envision a scenario where it would be appropriate, in the voluntary context, to keep the RRA open and initiate an inspection. If an RRA is still open during an inspection, it would be very difficult for a company to staff both the RRA and the inspection. Moreover, we do not believe it would be appropriate for a company to "voluntarily" decline the RRA while an inspection is ongoing. FDA has the opportunity to re-initiate an RRA if it would like to after the close of an inspection. There should not be overlap of an RRA and inspection for clarity for both FDA staff and industry staff.

FDA should provide additional public documents outlining the RRA process and internal procedures.

As RRAs become more common, industry needs additional clarity surrounding their scope, role, and how they will be executed. There are currently several helpful public documents detailing how FDA conducts inspections, including publicly available QSIT (Quality System Inspection Technique), IOM (Investigations Operation Manual) and MAPPs (Manual of Policy and Procedures). We recommend release of similar publicly available documents for RRAs.

CONCLUSION

AdvaMed appreciates the opportunity to provide comments. Detailed recommendations are included along with our specific comments to assist FDA as it works to develop the final guidance. Please do not hesitate to contact me at 202-434-7230 or jwolszon@advamed.org if you have any questions.

Respectfully submitted,

/s/

Jamie Wolszon
Vice President
Technology & Regulatory Affairs

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"Draft Guidance for Industry: Conducting Remote Regulatory Assessments: Questions and Answers"

Line No	Proposed Change	Comment/Rationale
General	We recommend that FDA consider the needs of a global company to coordinate internally, including among countries.	Clarification of this process will help establishments better prepare for an RRA, including coordination within the company to account for time zones, translations into English, and availability of subject matter experts.
General	We recommend that FDA provide details on the process of how the RRA scope and findings will be shared with appropriate investigators.	Clarification of this process will help ensure that RRA scope and findings are shared appropriately to feed into the risk-based schedule and inspection scope.
General	Clarify that RRAs will not apply to establishments participating in Medical Device Single Audit Program (MDSAP).	It is not clear from the guidance whether FDA intends to conduct RRAs with establishments that are participating in MDSAP. We expect RRAs will not apply to MDSAP audits.
General	Revise use of "observations" as it relates to RRAs to "potential concerns" throughout document.	Using the terminology "observations," causes confusion since this is the terminology used in a Form 483, and the Guidance states that a Form 483 will not be issued. We suggest that the language throughout the document is revised to reduce potential confusion.
116-118	Align with 21 CFR 807.3 definition of an "establishment"	To ensure consistency and predictability, it will be important for the definition of "establishment" to align with the definition within the regulations.
128-135	Please elaborate about "significant benefits" FDA has recognized and which type of products/establishments participated in the pilot program.	As discussed in our general comments, providing this information will help support the benefits of participation.

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130-131	Revise as follows: RRAs have also provided information about ~~deficient practices~~ potential concerns, which led FDA to take regulatory actions, conduct inspections, and have informed future inspection planning.	The use of "deficient practices" is new language not reflective of other wording used by FDA. Since the concerns raised during RRAs are not formal observations, "deficient practices" should not be utilized since it suggests that FDA has already concluded that there is a confirmed issue. We suggest that the language be revised to reflect that these are potential concerns instead of confirmed issues.
164	Need to define what "oversight activities" are when used within the RRA framework.	The reference to "oversight activities" is overly broad and vague. FDA should define what this means as industry needs to understand what elements of statutory requirements the FDA is covering in the oversight, who is involved, and which entities within FDA have decision-making authority.
Add at 170	RRAs remain voluntary for all other FDA regulated products other than drugs (including biologics) and FSVP	Clarify that unless drugs or food importer where RRA mandated, RRA is voluntary for all other FDA regulated products, including devices.
171-173	Make the following change: "… and other applicable FDA authorities, but RRAs may be utilized by FDA as a factor in the Agency's risk-based inspection schedule and to potentially limit the scope of inspections.	As mentioned in our general comments, it is important to underscore benefit of RRAs to manufacturers.

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177	"…or FDA opts against exercising its mandatory RRA authority for drugs (FD&C 704 (a)(4)) and importers of food (FD&C 805) in a certain instance…"	Clarify that FDA's opting not to exercise authority applies to scope of current statutory authorities.
180-184	The guidance does not address combination products that involve both a device, for which the program is voluntary, and a drug, for which the records request is mandatory. We request clarification of the application to combination products.	We believe clarification is needed on how FDA intends to apply to combination products.
196-207	It should be noted that remote requests for FSVP records are under the authority of section 805(d) of the FD&C Act and FDA's implementing regulation. These record requests function as inspections in that FDA uses these records requests to evaluate a food importer's compliance with FSVP (Foreign Supplier Verification Program).	We would propose reorganizing to provide the answer first followed by the content.
219	"Regulatory decision"	Please explain what constitutes a "regulatory decision" for purposes of this guidance. Focus should be on those with a time-sensitive nature such as a market access inspection, including getting out from under a warning letter or import alert with adverse implications for market access.
222	"supporting the review of a marketing submission as allowed by regulation (i.e., BIMO inspection, for PMAs)."	The example provided in line 222 "supporting the review of a marketing submission" is very broad and could open the door for FDA to conduct an RRA for complex 510(k) submissions, EUA (emergency use authorization) requests or *de novo* applications. Currently, FDA is allowed to conduct BIMO

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		(bioresearch monitoring) inspections and inspections to support a PMA (premarket approval). We suggest adding guardrails as proposed in the Proposed Change.
224-227	Provide a clear process on how the different FDA Centers will assess risk.	The draft guidance notes that Programs and Centers within FDA may assess risk differently based on the products. To ensure consistency and predictability, it is important to have additional guidance on the risk factors that will be used by the different Centers.
240-242	When an RRA precedes an inspection, FDA will ~~generally~~ conclude the RRA, including providing a written report, prior to initiating the inspection. FDA may combine any information gained from the RRA with any resulting observations from the subsequent inspection. In such circumstance, FDA would first confirm any ~~observations~~ potential concerns ~~from the~~ during the RRA with the establishment and provide opportunity for the establishment to clarify any information or misunderstandings and/or address concerns swiftly during the RRA, and then for any concerns not resolved, discuss them with the establishment during the inspection before including them on the Form FDA 483 Inspectional Observations. FDA will provide the company with a written report during, or at the conclusion of, the RRA.	As noted in our general comments, FDA should complete the RRA before initiating an inspection. Moreover, as mentioned in our general comments, a report should be provided to the company.

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245-246	Please add language indicating that FDA would not engage in such activities without separate guidance.	There are logistical concerns with hosting an in-person inspection and a livestream for a separate regulator at the same time. Additionally, understanding who is leading and to whom the company should be responding can already be somewhat difficult when FDA arrives with another regulator, but given that the other regulator would be conducting an inspection, and an RRA is not considered an inspection, the rules would vary between the two. It will be quite challenging for a firm to "decline" the FDA RRA when another regulator is conducting an authorized inspection and could be misconstrued by the other regulator as the firm being uncooperative. If FDA wants to accompany another regulator, they should do so in person under a 482 inspectional notice. FDA is noting an intention to partner with other parties such as state and foreign authorities and participate via livestreaming in those respective oversight/inspection efforts. This greatly expands FDA's reach. Technology tools are not mature enough right now to do this in an appropriate manner.
257-260	Provide an example on how RRAs could reduce the time FDA is present at the establishment during an inspection.	As discussed in our general comments, to provide clarity on how FDA will utilize RRAs to reduce inspection time and the associated FDA process, it will be helpful for FDA to provide an example in the guidance.

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Line No	Proposed Change	Comment/Rationale
265-266	"Providing FDA additional information to incorporate into a risk-based inspection schedule, which may help decrease the inspection frequency for an establishment, thereby helping FDA use inspectional resources more efficiently and effectively."	As discussed in our general comments, the added language clarifies the benefit of the RRA, which can be incorporated into the risk-based inspection schedule and lead to less frequent inspections at an establishment. This would allow FDA to focus its inspection resources on the more significant risks to public health.
277	When requesting an RRA, FDA will include the following details: how long FDA plans to conduct the RRA, the scope of the RRA and requested records, and how the requested records meet the purpose and scope of the RRA. In addition, FDA will provide a contact name for the establishment to seek clarification on the requested RRA.	As discussed in our general comments, it is important to have a clear process on notification and clarification of scope before agreeing to participate. This will enable the establishment to provide the requested records, manage workflow, and assemble the experts needed. In addition, for voluntary RRAs, it will be important that establishments have this information before determining participation.
276		Is there internal clearance/authorization on when an FDA employee, particularly at the Center, can invoke this power, which is historically performed by ORA staff with specialized training? If Center staff do not understand the limits of what is required to be provided, firms may consistently be in a challenging position of pushing back or explaining the limitations, or potentially appearing uncooperative.
281-282	"FDA will contact the official correspondent ~~an establishment through the establishment's point of contact~~, by email or phone, once we determine an RRA is appropriate based on FDA mission needs."	FDA should contact the official correspondent, not the establishment.

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281, Footnote 18		FN 18 – how will this be determined? Is this the same as for an inspection? What will that look like for a Center-based RRA on submission review? Firms will need to retrain leadership to understand what these outreach requests may look like and how to respond.
283	For voluntary RRAs, the communication from FDA will clearly indicate that the request is an RRA pursuant to this Guidance.	The guidance states that FDA will not issue a 482 (see Footnote 14 and lines 304-305), but rather correspondence. We believe it will be helpful, for purposes of clarity, that the communication from FDA clearly indicate that the request is an RRA operating under the terms of the Guidance (for voluntary RRAs).
283	If FDA contacts an establishment by phone, FDA intends to follow up via email with information on dates and scope of the RRA.	To provide the establishment with clarity and predictability, it is important that FDA provides the dates and scope in writing. A written request from FDA also provides the establishment with confirmation that the interaction is with federal employees of the FDA and not some other actor.
287-290		Does this person need to provide credentials or otherwise confirm they are an FDA employee duly authorized to conduct an RRA?
291-294	Propose revising to include details of the requested RRA, e.g., timing, technology requests, records for review, in the initial request outreach.	Please see general comments.
305	Regardless of whether an RRA is voluntary or mandatory, FDA will not issue a Form FDA 482, Notice of Inspection. FDA will provide a written request, after an interactive process with the company, to define the scope of the RRA.	As discussed in the general comments, there is a need to provide a written request to ensure the scope is clearly defined for both the FDA and the establishment. This ensures that the scope of the request can be fulfilled by the establishment at the initiation

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		of the RRA assessment and that the scope does not change during the RRA. The scope needs to be clear so that FDA, for example, does not make an RRA request to the establishment listed as the Specification Developer and then ask for production information on specific lots which is within another Establishment listing.
304-305	FDA should develop a process and establish form templates for notification, closure, and reports to ensure establishments understand what official communications will look like. FDA should also provide guidelines on expected timeframes for closure of the RRA following completion of RRA correspondence.	It will be important for industry to have clear expectations.
316-317	Please clarify the intent behind the phrase "may continue during the course of an RRA."	Feedback from pharmaceutical industry partners that have participated in RRAs is that RRAs may continue for a very long time with no clear end. It is unclear whether intervening conversations during an "open" RRA will be considered to be part of the RRA. It will be important for there to be a record retained by FDA of all the requested items and a firm's response.
320-321	FDA shall ~~may~~ provide updates to the establishment on observations and outstanding issues, whenever feasible, throughout the RRA. Or FDA intends to make every reasonable effort to ~~may~~ conduct an interactive review of the establishment's records and to	Please see our general comments.

Line No	Proposed Change	Comment/Rationale
	provide updates to the establishment on the status of the RRA, ~~observations~~ potential concerns, and outstanding issues, whenever feasible, as they are observed, or on a daily basis, throughout the RRA.	
333-334	~~However, when an establishment declines FDA's request to conduct a voluntary RRA, FDA may not be able to conduct timely assessment of the establishment's activities due to insufficient information."~~	This language appears to be inconsistent with the voluntary nature of the program. This language indicates that as a result of declining the request, FDA may not be able to meet premarket decision timelines. We do not believe it is appropriate to condition meeting performance metrics and commitments on participation. FDA still has to meet performance metrics and commitments under the MDUFA agreement.
378	FDA will not conduct any audio or video recordings during an RRA. In addition, FDA will refrain from taking any screen shots or capturing any images during live streaming during an RRA.	Please see general comments.
393-394	Define scope of "product quality reports".	To provide more clarity around the scope of records that may be requested, we request for FDA to clarify the scope of "product quality reports".
404-406	~~Read-only~~ ~~access~~	As discussed in our general comments, we do not believe it is appropriate to allow for remote, read-only access due to significant IT authentication protocols, security restrictions and cybersecurity risks.
415	FDA-regulated ~~research~~ clinical study	The term "FDA-regulated research" is too broad.

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428-429	~~Determine whether an establishment or product is or is not in compliance with certain FD&C Act or PHS Act requirements, and other applicable FDA requirements.~~	Compliance can only be determined by an on-site inspection and not through an RRA.
432-433		Recall and enforcement activity require the Agency to make an affirmative decision/assertion that a law/regulation has been violated. If an RRA is not an inspection and all information from an RRA is to be confirmed during an inspection before inclusion on a 483 (see line 241), we believe it does not logically follow that documents from an RRA alone would be used in support of enforcement activities.
442	"A 'reasonable amount of time' will be an element to be agreed upon between FDA and the company at the outset in advance of the company agreeing to participation."	It will be important for the company to have clear expectations in advance of agreeing to participate. For instance, a translation would take longer than other documents.
457-458	"…submitted to the Agency…"	We believe this is vague and request clarification, including what qualifies as "submitted." Is the term "submitted" limited to items affirmatively delivered to the Agency or does this also include items seen in screen share or livestream mode?
459-461	Requested documents maintained in paper format should be scanned ~~as searchable Portable Document Format (PDF) files, when possible,~~ and sent by the secure means identified by FDA.	Many documents may need to be shared as images, if they are maintained on site in paper form. The scanning process could change the validity and accuracy of a document and given the quantity of documents that may need to be shared, this would create significant burden.

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460-461	We request additional clarification on the meaning of the phrase "sent by secure means identified by the FDA".	As discussed in the general comments, many documents shared during an RRA or inspection are highly confidential. We request FDA provide information on the Agency's efforts to protect these documents.
480	Clarify that the default should be for the FDA to have a meeting with the establishment's management upon completion of an RRA.	The Guidance states that FDA "may" have a meeting. To further compliance and to ensure that establishments can promptly address any issues, FDA should have a meeting with the establishment's management to provide clarity on the observations. We also are interested in whether there will be an opportunity for an update meeting if desired by the company.
480-482	"If there are RRA observations, FDA will ~~may~~ present a written list and describe and discuss…"	If there are any observations, they should be written and discussed.
484	". . . conducting the RRA, that indicate ~~a potential violation~~ potential concerns of the laws enforced by FDA."	Concerns raised during RRAs should not be considered "potential violations" since it suggests that FDA has already concluded that there is a confirmed issue. We suggest that the language throughout the document is revised to reflect that these are potential concerns instead of confirmed issues or potential violations.

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487-491	"An establishment should be aware that any written list of observations may be subject to a request under the Freedom of Information Act at the time the disclosure to the establishment is first made (see 21 CFR 20.101(a)) and may be made publicly available with any applicable redaction of information that is otherwise exempt from public disclosure (see, e.g., 5 U.S.C. § 552(b), 18 U.S.C. § 1905, 21 U.S.C. 331(j), 21 U.S.C. 360j(c), 21 U.S.C. § 360nn(e), 21 U.S.C. 387f(c), and 21 CFR part 20).	Please see our general comments.
480-499	RRA observations do not appear to be deemed as official Agency observations, yet they are encouraging establishments to respond in a closing meeting or provide written responses to "unofficial" observations within 15 days.	Recommend increased clarity around if they are official observations, then a formal response is required. If they are "potential violations", establishments may be less likely to respond.
502-504	"…FDA will ~~ordinarily~~ prepare…"	As discussed in our general comments, FDA should provide a final report for all voluntary RRAs.
504	"…narrative…"	FDA should provide the entire RRA report, not just the narrative portion.