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24 June 2019

Mr. Peter Fox
Office of Regulatory Affairs
Food and Drug Administration
12420 Parklawn Dr. Rm. 4146
Rockville MD 20857

Re: Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C; Draft Guidance for Industry and FDA Staff (Docket No. FDA-2018-D-2074)

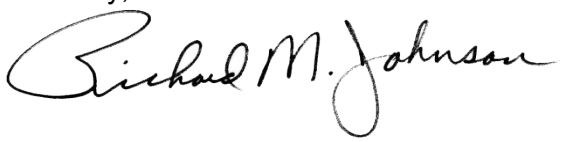
Dear Mr. Fox:

PDA appreciates the opportunity to comment on FDA's Draft Guidance for Industry and Staff regarding Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C. In general, the draft guidance provides useful information. In our attached comments, PDA offers specific suggestions that may provide clarity for agency staff and regulated industry.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments have been prepared by a committee of volunteers with expertise in pharmaceutical and biopharmaceutical manufacturing on behalf of PDA's Regulatory Affairs and Quality Advisory Board and Board of Directors.

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

Sincerely,



Richard Johnson
President and CEO

cc: Tina Morris, PDA; Ruth Miller, PDA

U.S. Food and Drug Administration
Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff
June 24, 2019

General Comments

General Comments	Rationale
For general usability, please update the hyperlinks to reflect the recent FDA website redesign.	Some of the links in footnotes and within the document, including those in lines 231, 278, 308, and 312 and footnotes 4 and 26, do not work as a result of the recent FDA website redesign. These broken links make it more difficult for users to fully understand the agency's intentions and identify other relevant information.

Specific Comments to the Text

Line No.	Current Text	Proposed Change	Rationale
42	…	Please include the definition of "correction" from 21 CFR 7.3.	Just as regulated industry and the public benefit from FDA's inclusion of the regulatory definition of "recall," inclusion of the definition of "correction" would be extremely helpful as well. That term is used throughout this guidance but may not be well understood.
89	The firm should consider identifying specific points-of-contact ahead of time, and should maintain draft templates that help it issue recall communications promptly, e.g., notification letters to direct accounts….	The firm should consider identifying specific points-of-contact ahead of time, <u>including the names, phone numbers, email addresses, and mail addresses of key contacts within direct accounts. The firm also</u> should maintain draft templates that help it issue recall communications promptly, e.g., notification letters <u>or electronic notifications</u> to direct accounts….	Use of email or other electronic communications with direct accounts can speed recall implementation, as compared with first class mail. While 21 CFR 7.49(b) specifically references recall communications made by telegram, mailgram, or first class letter, PDA believes that the language of that section is broad enough to allow for other methods of communication as well. PDA encourages FDA to use this guidance document to encourage the use of electronic communications for recall information. We note that, in addition to email, some participants in the U.S. distribution chain utilize sophisticated ordering software that could be utilized to communicate recall information.

Line No.	Current Text	Proposed Change	Rationale
155	A firm's written recall initiation procedures should assign responsibility and describe the steps to perform all actions related to initiating a recall, including the following, as appropriate: • Ceasing distribution, shipment, and/or sales of affected product(s).	Clarify	PDA suggests clarifying the differences between ceasing "distribution," "shipment," and "sales." With these different terms, does FDA intend to suggest different levels of recall priority or intensity? If, on the other hand, "distribution" and "shipment" are generally synonymous, FDA might consider deleting one of the words.
168	Communication with appropriate points of contact at each direct account is the most effective way to ensure that direct accounts know the product is being recalled and is consistent with our general guidance on recall communications in 21 CFR 7.49(a).	Add the following text: <u>As they develop a recall strategy, the recalling firm may tailor the existing general recall communications plan to the specific situation at hand.</u>	PDA believes that the guidance is clear on page 3 that a general communications plan should be established proactively. It may be beneficial to remind industry, however, that this general communications plan may need to be tailored to fit the specific needs of each recall.
198	Examples of such indicators may include: • Consumer complaints about a product, including reports of adverse reactions	Examples of such indicators may include: • <u>A trend in consumer complaints about a product, and/or an adverse trend in adverse reactions</u>	A single complaint may not be an indicator in all cases, where as a trend may be. An adverse trend in adverse reactions may be an indicator that recall is necessary, whereas a single adverse event may not.
200	Examples of such indicators may include: • Out-of-specification testing results for a product.	Examples of such indicators may include: • Out-of-specification testing results that impact released product<u>. For instance, for</u>	PDA recommends that FDA be more specific in its discussion of out-of-specification (OOS) results that might indicate a problem with a released batch or product. For pharmaceuticals, OOS results in pre-release testing are likely to require additional testing and/or mitigation before the product batch is

Line No.	Current Text	Proposed Change	Rationale
		pharmaceuticals, an out-of-specification result on a stability test.	considered for release, and generally are not relevant in considering recall. Only new OOS results received after the batch has been released to the public might indicate an unresolved problem that potentially warrants recall. FDA might wish to provide specific examples of the types of OOS results that would be relevant for the different categories of regulated products addressed by this draft guidance.
210	The firm's procedures should assign responsibility and describe the steps to investigate a potential problem with a distributed product, which may include: • A prompt evaluation by a qualified person…	• A prompt evaluation by an appropriate person Or • A prompt evaluation by a person qualified by level of training and authority	Because the term "qualified person" has a clearly defined meaning under EU pharmaceutical requirements, the use of this phrase is likely to create confusion within pharmaceutical companies initiating recalls. PDA suggests that FDA can convey the agency's meaning and intent without using the EU-defined term.