Proposed Regulation/Guidance Document:

FDA Draft: "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C - Guidance for Industry and FDA Staff"

Docket No. FDA-2018-D-2074

Comments from: International Society for Pharmaceutical Engineering (ISPE)

GENERAL COMMENTS ON THE DOCUMENT
Although this draft guidance states that a firm need not delay the initiation of a recall pending the FDA's review of their recall strategy, FDA often reviews and comments on recall strategies prior to initiation of a recall, which impacts the timing for initiation of recall activities. Under 21 CFR Part 7, FDA also specifically requests that a firm submit public warnings for FDA review and comment prior to external communications. (21 CFR 7.42(b)(2).) Please revise the guidance to provide context that a firm may need to interact with the agency in order to prepare its recall strategy prior to making external communications such as public warnings. Please also revise the guidance to address the possibility that a firm may need to interact with FDA's office of compliance or division of drug shortage while it is developing its recall strategy for correction or removal of a life-saving or life-supporting medical product.
Please align the terminology in the guidance with the terms that are defined in 21 CFR Part 7. For example, in this guidance, FDA appears to be creating a new term, "initiation of a recall" that is not defined in 21 CFR Part 7, and that may cause confusion, because there are many steps that a firm takes after it has decided to conduct a recall. This guidance also uses the word "initiation" in a different context with the phrase "written recall initiation procedures" as a part of a 'written contingency plan' described in 21 CFR 7.59(a). Please use the phrase in 21 CFR Part 7 to avoid confusion. Please also clarify in this guidance that it may be appropriate for a firm to have different contingency plans and recalls strategies depending upon the classification of the recall. For example, it may be appropriate for recall activities to be executed on longer timelines for a Class III recall than for a Class I recall. On a related, note, it would be very helpful if the agency could provide their classification to firm's as early as possible. In some cases, a firm does not receive the agency's classification until after the recall is near completion.

The guidance provides significant discussion about mock recalls and uses the phrase "should be trained" which may create a perception that mock recalls are a regulatory requirement. Please clarify that mock recalls are one of many tools that a company may employ to train its employees to prepare for a product recall.
Please identify which offices should be consulted during development of the recall strategy.

Specific Comments on the Text

ISPE indicates text proposed for deletion with ~~strikethrough~~ and text proposed for addition with **bold and underlining**.

Line Number	Current Text	Proposed Change	Rationale or Comment
45	***Initiation of a recall*** means a recalling firm's first communication about a voluntary recall, to its direct accounts or to the public.	***Initiation of external communications*** means a recalling firm's first communication about a voluntary recall, to its direct accounts or to the public.	There are several activities that a firm must take prior to communicating with direct accounts or the public, which in some cases includes FDA review of such communications. (see 21 CFR 7.42(b)(2)). The date of contacting direct accounts or the public is simply the date of external execution. Please remove this term or revise it to: "initiation of external communications."
		Initiation of a recall means the date a recalling firm first decides to conduct a recall and begins their internal processes to prepare a recall strategy. This may include notification to the agency or other communications with the agency of the firm's intent to conduct a recall.	We do not believe it is necessary to define the date of initiation of a recall; however, if the agency wishes to do so, please include additional context in the guidance that a firm may need to consult with FDA prior to making external communications.

Line Number	Current Text	Proposed Change	Rationale or Comment
82	The firm should also consider establishing metrics appropriate to its recall plan and take corrective action …. If it is not satisfied with mock recall or actual recall.	After a firm has conducted an actual recall or a mock recall, it may wish to review its processes and make modifications based upon the lessons learned.	This sentence recommends applying metrics to both mock recalls and actual recalls which is not feasible due to the fluid nature of an actual recall.
94	Identify any reporting requirements….	Identify any additional reporting requirements that are specific to the product being recalled ….	Please clarify that these are reporting requirements in addition to any reporting that the firm may submit to the district office to report a correction or removal. It would helpful if the agency would enumerate the additional reporting requirements for each category regulated product (i.e. food, dietary supplementary supplements, etc.). It would also be very helpful to firms if the agency could streamline this process so that firms may submit all reports for a recall (including adverse reports) to their local district office so that firms do not have to engage in duplicative reporting.