FDA Draft Guidance for Industry: "Field Alert Report Submission: Questions and Answers."

Docket No. FDA-2018-D-2326

Comments submitted by: ISPE (International Society for Pharmaceutical Engineering)
7200 Wisconsin Ave., Suite 305, Bethesda, MD 20814
regulatorycomments@ispe.org

GENERAL COMMENTS ON THE DOCUMENT
Overall the document is well –written. However, little more details around written/paper submissions would be helpful.
We would also like the **Agency to consider extending the time period for NDA FAR initial reporting**. The current 3-day initial reporting period may be too short such that many global manufacturers are able to provide only limited information that is preliminary in nature. We believe the Agency and public health would benefit from extending the timeline to 10 days so that NDA holders can improve the quality of the information that they report.

Specific Comments on the Text

Line Number	Current Text	Proposed Change	Rationale or Comment
Line # 125	*d. Does every consumer complaint warrant submission of a FARs?* No. Every consumer complaint should be evaluated within 3 working days to determine if the information provided in the complaint meets the criteria outlined in 314.81 (b)(1). You must	We encourage the Agency to either delete the question or to provide a balanced answer that encourages firms to conduct a thorough investigation especially if the reportability cannot be determined based on the limited information available in a single consumer complaint. For example, if the Agency maintains this	The response to this question indicates that a single consumer complaint may warrant filing of a FAR and therefore each consumer complaint should be evaluated within three working days. In our experience it is unlikely that a single complaint would give rise to information warranting filing of FAR.

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	submit a FAR within that time frame if you determine that the information identified in the complaint meets the criteria for a FAR.	question, consider the following answer: No. Each consumer complaint should be evaluated within three working days to determine if the information provided in the complaint meets the criteria outlined in 314.81(b)(1); however, a single consumer complaint may not contain sufficient information to warrant submission of a FAR. If additional information is required (potentially from sources other than the original complaint), the firm should work diligently to collect the additional information and determine if filing of an FAR is warranted. The firm should submit an FAR within three working days when sufficient information is obtained to meet the criteria outlined in 314.81(b)(1).	
Line 140-144	*f. If the product approved under an NDA/ANDA is only distributed outside the United States, am I still subject to the FAR requirements?* Yes. Any drug product marketed under an approved NDA or ANDA, whether distributed domestically or abroad, is subject to FAR requirements.	**Proposed change:** A firm is subject to the FAR requirements if they are the holder of an approved NDA or ANDA. FARS are part of an early warning system to protect patient health. When performing an analysis under 21 CFR 314.81 (b) (1), the firm should consider all facilities that are identified in the currently registered NDA or ANDA. A FAR may be warranted for issues described in 21 CFR 314.81(b)(1), where a product has been manufactured at a facility that is specifically identified in the NDA or ANDA and there may be a risk to health to patients in the United States.	Please provide additional clarification for scenarios that are encountered by global manufacturers. Many manufacturers have multiple facilities that manufacture the same product, and some of the facilities are located in the United States while others are located outside the United States. In addition, some of these facilities manufacture product that is specifically designated for distribution in the United States, while others manufacture product that is specifically designated for distribution outside of the United States. Thus, a FAR is not required in all scenarios. Please clarify the Agency's answer to question f, because the answer as it is currently written can be misread to apply to all domestic and foreign facilities that manufacture the product even if they are not

Line Number	Current Text	Proposed Change	Rationale or Comment
			specifically identified in the NDA or ANDA
Line 283, etc.	FDA District Office	**Proposed change**: Appropriate field office terms consistent with FDA's new Office of Pharmaceutical Quality Operations, e.g., Division 4 (DEN, LOS, SAN, SEA).	Please provide additional clarification regarding the correct "district office" to list on the FAR given FDA's new Office of Pharmaceutical Quality Operations (OPQO) structure.
Line 291, etc.	your headquarters	**Proposed change:** your US headquarters or US agent	Many manufacturers have a global headquarters and a US headquarters. This proposed change would clarify confusion regarding the particular unit that should submit the FAR.