June 24, 2019

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


To Whom It May Concern:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to provide input on the Food and Drug Administration’s (“FDA” or “Agency”) Initiation of Voluntary Recalls Draft Guidance for Industry and Food and Drug Administration Staff (“Draft Guidance”).\(^\text{1}\) AdvaMed represents manufacturers of medical technology and diagnostic products that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies.

We commend FDA for the development of this Draft Guidance and appreciate the Agency’s desire to bring additional clarity to its Part 7 processes concerning voluntary recalls. In general, we believe the Draft Guidance provides a good overview of what a firm should consider when developing its recall processes and procedures.

At the outset, we would like to address an issue most relevant to the medical device industry. Specifically, the Draft Guidance at footnote 2 identifies that the Agency’s Part 806 requirements—applicable to medical devices—are not “negate[d]” by this Draft Guidance. This is further reinforced at footnote 25. While we agree that a guidance cannot negate a regulation, it is not clear whether FDA intends the Draft Guidance to supersede interpretations within the Preamble to Part 806.

In this regard, additional clarity is required for devices subject to the Part 806 rules concerning the issue of when a recall is initiated. The Draft Guidance defines “Initiation of a Recall” as the “firm’s first communication about a voluntary recall, to its direct accounts or to the public.” Draft Guidance, lines 45-47; see also lines 45-47.

In contrast, while Part 806 does not define “Initiation of a Recall,” FDA stated in the preamble to this rule that the Agency “believes that the initiation or initiating of a correction or removal is that moment in time when a firm makes the first contact within or outside the firm that begins the correction or removal action.” 62 Fed. Reg. 27188 (May 19, 1997)

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(emphasis added). The Draft Guidance and this comment in the preamble to Part 806 provide conflicting interpretations as to which applies in the context of medical devices, and particularly for purposes of Part 806 of the Agency’s rules.

We believe FDA should determine that the definition used in the Draft Guidance applies for purposes of Part 806. The Draft Guidance provides an appropriate definition for “initiation” and one that is most commonly understood across commodities, including by device consignees and the public. Harmonization will avoid industry, consumer, and FDA confusion that can occur with multiple interpretations of the same term. Additionally, harmonization will reduce regulatory burdens, particularly for firms manufacturing both devices and drugs and for firms manufacturing combination products.

We also offer the Agency the following comments to the Draft Guidance:

1. Line 24: We recommend revising this sentence to: “... products in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) other than minor violations, for which the Agency would not initiate legal action.” Part 7 of the rules provides that a “market withdrawal” is not a recall and includes actions undertaken to address “minor violations” of the Act.

2. Lines 48-52: We believe this Guidance creates the opportunity to provide additional clarification of the phrase, “and against which the agency would initiate legal action, e.g., seizure.” Additional examples and criteria to apply this element is requested, including both examples of when the agency would initiate legal action and when the agency would not initiate legal action.


4. Lines 228-230; 243: We believe FDA should commit to a specific timeframe to respond to a firm’s inquiry. For example, we believe a five-day response period is appropriate due to the generally time-sensitive nature of a recall.

5. Lines 234-235: We recommend FDA revise this sentence as follows: “A firm should initiate a voluntary recall by promptly sending recall communications to each affected direct account, as applicable, and by issuing a press release or other public notice, if appropriate.” We believe this statement should be appropriately qualified to reflect that not all recalls will involve communications to customers (e.g., a device design correction).

6. Line 252: We note that 21 C.F.R. § 7.46(a) references a non-existent provision of the Agency’s rules (21 C.F.R. § 5.115). It appears 21 C.F.R. § 5.1100 is the correct citation that the rule, 21 C.F.R. § 7.46(a), should point to.
7. Line 298: We recommend revising the phrase, “the firm fails to initiate a recall effectively,” to: “the firm fails to initiate a recall.”

8. Hyperlinks in Footnotes 4 and 26, and in lines 231, 308 and 312 are not valid.

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AdvaMed would like to thank the FDA for its consideration of these comments. Please do not hesitate to contact me at 202-434-7224 or zrothstein@advamed.org if you have any questions.

Respectfully submitted,

/s/

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