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October 19, 2020

Re: FDA Request for Suggestions for the Design and Use of the FDA Progress Tracker for Premarket Submissions

Dear Sir/Madam:

AdvaMed is pleased respond to the FDA request for suggestions for the design and use of the FDA Progress Tracker for Premarket Submissions. AdvaMed believes that a secure, web-based tracker that displays the progress of a medical device marketing submission throughout the FDA's review process would allow the FDA and the submitter of a marketing submission to efficiently manage the review process.

The tracker should provide the information necessary for the submitter to follow the review process, to provide timely response to reviewer requests and to anticipate the completion of the review. The tracker should be easy for the reviewer to maintain with current information and therefore, require minimal use of precious reviewer time.

AdvaMed suggests that FDA implement a tracker pilot and gather user (reviewer and submitter) feedback before finalizing the tracker.

AdvaMed is pleased that FDA is complying with the MDUFA IV Commitments letter, Section III.C: IT Infrastructure for Submission Management and looks forward to working with FDA to develop the tracker.

The following provides AdvaMed responses to the questions posed by FDA in the September 8, 2020 request for feedback on the process tracker for premarket submissions. Note that we have listed the information we would like tracker to provide, but we did not list a "why" for each one. All the items listed below are needed to effectively monitor the review process.

## AdvaMed Responses to Premarket Progress Tracker Questions

| **What information is most useful to you when you have a premarket submission under review?** |
|---|
| **Information** |
| At the beginning of the review process, the following information must be provided to the submitter by the FDA reviewer via email: |
| • Name and contact information for lead reviewer |
| • Submission ID (510(k) number; PMA number, etc.) |
| • Tracker access code (must be provided to the submitter at the beginning of the review process) |
| Date received at the Document Control Center |
| Date payment was verified. |
| Date eCopy was verified. |
| Date RTA review started |
| Date RTA review completed; outcome of the review |
| Date start of substantive review |
| Date when a consult has been requested. List the topic. List the date the consult was completed. |
| Date submission was placed on Hold and type of Hold. |
| Review clock stoppage day (day XX of 90) |
| Due date for response to AI letter (180 days from AI letter issue) |
| Date the AI response was received |
| Date AI letter response was accepted |
| Provide an ongoing clock showing the time the submission has been under review. Clock shows number of days left on the review clock and total time to decision. |
| Date the lead reviewer's decision was submitted to management for review and sign-off |
| Date the review was completed (sign-off) and the decision. |
| |
| **Additional Information For PMA Submissions:** |
| Names of the review team members and identify what portion of the review they were responsible for reviewing |
| List each PMA section, the date the review started and the date the review was completed/closed. |
| Date of inspection, date of inspection decision, and outcome of decision. |
| A grid which identifies the sections where review is complete, sections under review, sections yet to be reviewed and sections where additional information is required. Perhaps in the form of a dashboard: |

Example below:

| Section | Review complete? | Questions? |
|---|---|---|
| Clinical | Yes | Yes |
| Biostats | No | - |
| Animal | No | - |
| Biocompatibility | Yes | Yes |
| Engineering | Yes | No |

| **What additional communication methods may be useful when receiving progress information from the FDA regarding device marketing submissions?** |
|---|
| Minimize the need for submitters to initiate contact with reviewer to discuss status of a review. If the tracker is comprehensive and updated appropriately, there should be no need to have additional communication methods. Submitters should have all the information they need by accessing the tracker for their submission. |
| Ability to 'export' or 'generate' a visual dashboard that has color coding, showing key due/expected response/decision dates for both the submitter and the FDA and show progression throughout. |
| |
| **Other** |
| Pilot the tracker and gather user input before finalizing the tracker |
| Design the tracker to that it is easy for reviewers to complete and require reviewers to complete the tracker in a timely way. Tracker must be current and reflect the current status of the submission. |
| The submitter to name a secondary representative. The primary representative may not be available (illness, vacation, etc.) and the secondary could access the tracker. |
| The tracker should indicate the date the submission is re-assigned to another center (i.e. CBER). A notice should be sent to the submitter. |

Please contact me with questions about the AdvaMed suggestions and for clarification of the information provided. AdvaMed thanks FDA for their efforts in developing the Progress Tracker for Premarket Submissions and looks forward to working with FDA.

Sincerely,

/s/

Ruey C. Dempsey
Vice President
Technology and Regulatory Affairs