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## Additional Information Requests

### Context

During the initial in-depth review of medical device marketing authorization applications presented to FDA's Center for Devices and Radiological Health (CDRH), it is common for the FDA review team to identify areas of the application that are inadequate. To address these areas, the review team will reach out to the applicant to request additional information. The items within these requests are referred to as deficiencies and are typically categorized as major or minor deficiencies. Major deficiencies are gaps in information that are critical to inform the regulatory decision making (e.g., missing testing, unclear methodologies, or unsupported claims in labeling). Minor deficiencies are those pertaining to less substantive issues and are sometimes addressed interactively (typically via email).

### What to Expect

During application review, the FDA team will compile written deficiencies. Then, if there is at least one major deficiency, the file will be placed on hold and a formal request for additional information will be sent in a letter via email to the applicant. Premarket Approval (PMA) and Humanitarian Device Exemption (HDE) processes refer to this as a Major Deficiency Letter, while 510(k) and De Novo processes refer to it as an Additional Information (AI) Request (or Additional Information Letter). Each deficiency should include four components:

- What information was provided in the submission that is the focus of the deficiency
- Why that information or statement is insufficient/unclear
- What new information is needed in the response
- Why that information informs the regulatory decision

### How to Respond

It is then up to the applicant to respond to the deficiencies accordingly. The applicant response must include both the requested information (testing data, materials, documents, etc.) and a letter back to FDA that summarizes separate responses to each deficiency.

If the applicant would like feedback from CDRH on their proposed approach to address issues conveyed in an additional information letter, applicants may submit a Submission Issue Request (SIR). As there is a finite window of time in which to respond to deficiencies, it is important to identify the need for, and submit, a SIR promptly. SIRs are part of the Q-Submission program.

### Timeline for Responding to Additional Information Requests

For 510(k) and De Novo submissions, innovators have 180 days to submit their written reply to FDA. If FDA does not receive a complete response before the deadline, then the application will be considered withdrawn and a new application will need to be submitted.

The applicant typically has 75 days to reply to FDA for an HDE application. The applicant may request an extension up to 360 days if they contact FDA prior to the 75-day deadline. Typically, extensions are not granted for longer than 360 days.

For PMA applications, there is a built-in Day-100 meeting option to review the status of the application after additional information is requested. This meeting needs to be requested no later than 70 days after the FDA has accepted the device submission to allow for a 30-day lead time.

## Regulatory Resources

FDA has issued [guidance](#) on how to respond to requests for additional information. And furthermore, the NIH SEED has compiled tips and best practices in a related article on [written communications](#) with CDRH.

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