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CDRH issues final rule on appeals, excluding De Novos from 517A

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On 2 July 2019 the U.S. Food and Drug Administration (FDA or the agency) issued a final rule[1] updating the processes for appeal of certain FDA decisions related to medical devices regulated by the Center for Devices and Radiological Health (CDRH). The final rule, which takes effect on 1 August 2019, represents the culmination of the rule-making proposed in January 2018 (the proposed rule, discussed here),[2] finalizing the category of "517A decisions," previously termed "significant decisions," which are specified by section 517A of the Food, Drug, and Cosmetic Act (FDCA). The final rule also confirms the timeframes for requesting supervisory review and for FDA's responses to such requests as outlined in the proposed rule.

In conjunction with the 2 July final rule, FDA issued two final guidance documents that revise, update, and replace several preexisting guidances.[3] The first guidance, entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers about 517A" (Q&A guidance), finalizes a draft of the guidance released on 29 September 2017 and replaces a 2014 guidance explaining FDA's approach to implementing FDCA Section 517A.[4] The second guidance, entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes" (appeals guidance), finalizes a draft guidance issued on 28 December 2011 and supersedes three prior final guidances.[5]

Of note, this final rule and associated guidance documents relate to formal appeals of FDA decisions, which should generally come after an "informal" interaction with the agency to resolve issues. The appeal process is distinct from interactive review communications (e.g., 10-day clarification calls and submission issue meeting requests), and those invoking FDA's new least burdensome flag provisions for 510(k) notices, which can be used to request supervisory review of discrete issues raised in FDA requests for additional information.

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[1] 84 Fed.Reg. 3147, Internal Agency Review of Decisions, Requests for Supervisory Review of Certain Decisions Made by the Center for Devices and Radiological Health.
[2] 84 Fed.Reg. 3147, Internal Agency Review of Decisions, Requests for Supervisory Review of Certain Decisions Made by the Center for Devices and Radiological Health.
[3] The new guidance documents supersede: "Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A" (29 September 2017), "Center for Devices and Radiological Health Appeals Processes" (17 May 2013), "Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel" (2 July 2001), and "Medical Device Appeals and Complaints: Guidance for Dispute Resolution" (February 1998).
[4] Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A (2 July 2019).
[5] Center for Devices and Radiological Health (CDRH) Appeals Processes (2 July 2019).

Final rule closely tracks proposed rule, excluding De Novos from 517A decisions

The final rule takes effect on 1 August 2019 and proposes almost the exact regulatory language as the 2018 proposed rule. Notably, while acknowledging the importance of De Novo decisions, FDA declined to expand the definition of "517A decisions" to include the grant or decline of a De Novo request, despite comments to the proposed rule that requested such an expansion. FDA's decision rests on the fact that Section 517A of the FDCA does not identify decisions on requests under Section 513 as one of the types of significant decisions subject to that section.

FDA also explained that, as in the proposed rule, it decided not to call decisions subject to Section 517A of the FDCA "significant decisions" but rather "517A decisions" because the agency did not want to imply that other CDRH decisions were "non-significant" in terms of importance. Decisions not subject to this section are termed "non-517A decisions." The final rule also retains the proposed timelines for requesting appeals of 517A and non-517A decisions outlined in the proposed rule, as well as FDA's timelines for responding.

Notable changes to the final guidances

The Q&A guidance, which takes effect on 1 August 2019 and which had not been updated since the draft released in 2017, has now been updated to reflect the changes in both the proposed and final rules, described in our prior alert and above.

The final appeals guidance differs from its prior version in several notable ways:

- The section on supervisory review has been updated to reflect the proposed and final rules regarding 517A decisions.
- The supervisory review section has been updated to reflect the reorganization of CDRH, specifying that the general order of appeal is Division of Health Technology → Office of Health Technology → Office of Product Evaluation and Quality → Center → Commissioner.
- A new section regarding bias and retaliation has been added, which recommends referral of allegations of bias or retaliation after challenging an agency decision to the Ombudsman in most cases. This section also describes the possibility of bringing such claims to the FDA Office of Internal Affairs or the Department of Health and Human Services Office of the Inspector General.
- Interestingly, the appeal guidance also discusses referral of a matter in dispute to external experts, often referred to as a "Panel Homework Assignment," and notes that the agency will draft a document stating the issues in dispute and attach relevant documents for review. It states that the review authority "may provide to the submitter a copy of the document for comment and may also allow the submitter to suggest areas of expertise relevant to the issues in dispute, although the final version of the document and the specific individuals selected as SMEs are determined by the review authority." This is in contrast to our recent experience, where the agency has generally kept such homework assignments confidential.
- The guidance also states that FDA intends to follow the 517A-decision response time frame even for non-517A-decision responses, with the significant caveats that it is not required to do so and this will only be done if resources permit. This could be helpful for appeals of De Novo decisions, which are non-517A decisions, though it is clearly not binding on the agency.

- The appeals guidance provides a bit more leeway for including new information in appeals, stating that, while the inclusion of new information may cause the appeal to be referred back down for reconsideration, as is typically done, the review authority may also allow the inclusion of new information in order to expedite a decision.

Key takeaways

- The final rule regarding 517A decisions is largely consistent with the proposed rule providing updates and clarifications on use of FDA's appeals process, including considerations of when an appeal is appropriate and procedural requirements for filing an appeal.

- The agency's decision to exclude De Novo decisions from 517A decisions is significant, given that decisions on De Novo requests have similar regulatory consequences as decisions on 510(k)s and premarket approval applications – not to mention the significant user fee associated with these requests. In the past, our clients have requested and obtained from FDA substantive summaries of De Novo decisions consistent with the requirements of 517A(a) of the FDCA, which requires that this information be available detailing the scientific and regulatory rationale for any significant decision, suggesting some inconsistency within agency practice regarding the status of such decisions. FDA's hesitancy to include decisions on De Novo requests within the scope of 517A, which is grounded in their absence in the underlying statutory text, implies that a legislative amendment might be necessary to reverse course. The narrow construction and interpretation of the applicability of what is considered a 517A decision ripe for appeal and therefore subject to strict timelines for review underscores the importance of detailed interaction with FDA during the regulatory strategy development phase and prior to the issuance of final decisions.

- The Q&A guidance and appeals guidance were updated to reflect the final rule, and the appeals guidance includes additional changes, such as inclusion of a section indicating that the process should not be used to raise allegations of bias or retaliation. The appeals guidance further notes that the agency intends to follow 517A time frames for non-517A appeals as well; however, this is a nonbinding commitment and it remains to be seen how CDRH will handle the timing of non-517A appeals, particularly those related to De Novo decisions.

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