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FDA proposes rule to codify existing guidance on supervisory review of CDRH decisions

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On January 17, 2018, the U.S. Food and Drug Administration (FDA or the Agency) issued a proposed rule to update the framework for requesting internal agency supervisory review of certain decisions related to devices regulated by the Center for Devices and Radiological Health (CDRH).[1] If finalized, this proposed rule will reflect the recommendations in a September 2017 FDA guidance document and will follow the procedures and timeframes under the Federal Food, Drug and Cosmetic Act (FDC Act). Of note, the proposed rule defines "significant decisions" and provides new procedural requirements and timelines for requesting supervisory review within CDRH of decisions made by CDRH that are not considered "significant decisions."

According to the proposed rule, the changes are intended to enhance transparency and predictability while achieving the Agency's mission to protect public health and foster innovation. The rule is also part of FDA's implementation of Executive Orders (EOs) 13771 and 13777, reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will reduce burden without interfering with FDA's public health mission and fulfillment of statutory obligations.

Background

Section 517A of the FDC Act, enacted via the FDA Safety and Innovation Act (FDASIA) of 2012, requires FDA to provide "a substantive summary of the scientific and regulatory rationale for any significant decision" by CDRH related to a 510(k) notice, premarket approval (PMA), Investigational Device Exemption (IDE), or request for designation as a breakthrough device. It also established procedures and timeframes for requesting supervisory review of "significant decisions" in 21 C.F.R. § 10.75 and FDA responses to such requests. A 2013 FDA guidance document addressed the options for seeking reconsideration of CDRH regulatory decisions, including a § 10.75 appeal.[2] However, the statutory term "significant decision" had never been defined; this guidance merely stated, "the term 'significant decision' will refer to significant decisions pertaining to" the submissions listed in this context in the FDC Act. This has made it difficult for manufacturers to anticipate their options in cases where they believe a determination by FDA with respect to one of their devices is erroneous or incomplete.

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[1] 83 FR 2388, *Internal Agency Review of Decisions; Requests for Supervisory Review of Certain Decisions Made by the Center For Devices and Radiological Health*, available at:https://www.federalregister.gov/documents/2018/01/17/2018-00646/internal-agency-review-of-decisions requests-for supervisory-review-of-certain-decisions-made-by-the

[2] *Center for Devices and Radiological Health (CDRH) Appeals Processes* (May 17, 2013), available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf

In an effort to address this, FDA issued another guidance document in July 2014, *Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A*.[3] This guidance, which was updated in September 2017 to incorporate additional elements established by the 21st Century Cures Act, describes how CDRH intends to interpret which decisions qualify as "significant" under the FDC Act standard and further explains how FDA understands key provisions of Section 517A. The Agency has now proposed a rule to codify that interpretation by promulgating 21 C.F.R. §§ 10.75(e) and 800.75.

Definition of "Significant"

Consistent with the framework set forth in FDA's guidance, the proposed rule identifies the following decisions as "517A decisions" (*i.e.,* significant decisions):

- 510(k) Notice:
    - Not substantially equivalent
    - Substantially equivalent
- Premarket Approval (PMA) and Humanitarian Device Exemption (HDE):
    - Not approvable
    - Approvable
    - Approval
    - Denial
- Request for "breakthrough" designation for devices subject to 510(k), PMA, or de novo:
    - Grant of request
    - Denial of request
- Investigational Device Exemption (IDE):
    - Disapproval
    - Approval
- Failure to reach agreement on a protocol under FDC Act Section 520(g)(7)
- "Clinical Hold" determinations under FDC Act Section 520(g)(8)

Of note, the proposed list of 517A decisions does not include marketing authorization decisions on *de novo* petitions.

Under the proposed rule, a request for supervisory review of a 517A decision must be received by CDRH no later than 30 days after the date of the decision in question. FDA then typically has 45 or 60 days to issue a decision, depending on whether the requester seeks a meeting with the Agency.[4]

[3] Guidance originally issued on July 30, 2014 and re-issued September 29, 2017, available at: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm352254.pdf

[4] If the request is referred to external experts, such as an advisory committee, these timeframes do not apply.

Additional highlights

The proposed rule also provides an additional measure of predictability for industry by setting forth procedures and timeframes for supervisory review of CDRH decisions that do not meet the significance standard, *i.e.,* non-517A decisions. In line with FDA's guidance, these include but are not limited to 510(k) Requests for Additional Information (RAIs), PMA Major Deficiency letters, 510(k) and PMA Refuse to Accept letters, postmarket surveillance orders under FDC Act § 522, Warning Letters, and responses to 513(g) Requests for Information. Supervisory review of any non-517A decision must be sought within 60 days of the decision date. However, the proposed rule does not specify a timeframe for FDA's completion of such a review (for "non-significant" decisions).

The proposed rule also establishes a "gatekeeping" requirement applicable to all requests for CDRH supervisory review. Specifically, while requests may be made to the next organizational level or higher above the individual who made the initial decision, the proposed rule requires any appeal seeking to bypass more than one level of supervisory review, *i.e.,* a telescoped review, to include a rationale. The ultimate decision as to whether this is allowed would remain solely at CDRH's discretion. Moreover, appeals may only be made to the CDRH Director level after first being considered at the next-lower supervisory level.

Conclusion

The proposed rule effectively codifies "significant", or "517A," decisions, and provides some added clarity around supervisory review and timelines for non-517A decisions. However, the Agency's omission of marketing authorization decisions on *de novo* petitions from the definition of 517A decisions is surprising given the similar regulatory status of these decisions to those made by CDRH on 510(k) and PMA submissions, and the hefty user fee now attached to such submissions. We expect that stakeholder comments submitted to the docket may seek clarification of this issue in the final rule. Comments may also ask FDA to commit to a set timeframe for supervisory reviews of non-517A decisions.

Comments on the proposed rule may be submitted to docket number 2018-00646 through April 17, 2018.

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