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FDA Proposes to Clarify and Formalize the De Novo Classification Process for Medical Devices

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On December 7, 2018, the U.S. Food and Drug Administration ("FDA") published a proposed rule ("Proposed Rule") that, if finalized, would clarify the de novo classification process for medical devices, including (1) the format and contents of a de novo request and (2) the criteria for accepting or denying a de novo request. FDA intends to "enhance regulatory clarity and predictability… [and] provide a regulatory framework that sets clear standards, expectations and processes for de novo classification" through this proposed rulemaking.[1]

FDA regulates medical devices based on risk and has established three general classifications: "class I" (general controls required to provide reasonable assurance of the safety and effectiveness of the device), "class II" (special controls required), or class III (premarket approval required). The regulatory framework for class III devices is especially stringent—FDA reviews class III device safety and effectiveness under a premarket approval ("PMA") application that takes six months or more to approve, if the device is found suitable for marketing. The 510(k) "premarket notification" submission, however, enables lower-risk devices that are "substantially equivalent" to existing, legally marketed ("predicate") devices not subject to a PMA to obtain marketing clearance without a PMA. Under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), new devices receiving not substantially equivalent ("NSE") determinations are automatically designated a class III device. The de novo process serves as an alternative pathway for receiving marketing authorization for class I or II devices.

In the Proposed Rule, FDA seeks to clarify and formalize the de novo pathway for novel devices without predicates. Many of these proposals are contained in various recent guidances from FDA.[2] Below we break down key components of the Proposed Rule:

FDA Reviewing Procedures: Facility Inspections Proposed

Perhaps the most controversial component of the proposed de novo pathway is a provision that enables FDA to conduct premarket manufacturing inspections of "relevant facilities" as part of its de novo review process. Although these manufacturing inspections are authorized under the FDCA as an element of the PMA application review, the FDCA does not grant this authority to FDA for de novo review.[3] If this provision remains upon rule finalization, de novo requesters must have their quality systems prepared for inspection. Failing to permit an authorized FDA employee to inspect a relevant

facility results in automatic “withdrawal” of the de novo request.

This provision may also be problematic in light of FDA’s proposed timeline for de novo request acceptance. The Proposed Rule requires FDA to grant or decline a de novo request within 120 days from when it receives the request or any additional information. While de novo request devices are required to be classified within the same timeframe under the FDCA, 120 days is rarely met. According to the Medical Device User Fee Amendments 2017 (“MDUFA IV”), FDA articulates that it aims to “issue a MDUFA decision within *150 FDA days* of receipt of the submission *for . . . 55% of de novo requests* received in FY 2019.” (emphasis added). FDA’s self-stated goals appear to make the proposed 120-day codification lofty, especially considering FDA’s authorization and intention to make premarket manufacturing inspections during its de novo request reviews.

Notable De Novo Request Content Requirements

The Proposed Rule intends to clarify the minimum content requirements as prescribed in section 513(f)(2) of the FDCA. Most of these components are consistent with de novo guidance recommendations, but there are a handful of new proposed requirements:

- Bibliography of “all published reports” and other unpublished “identification, discussion, and analysis of any other data, information, or report” relevant to the safety and effectiveness of the device. This practice is typically reserved to higher-risk PMA applications under 21 C.F.R. 814.20(b)(8).
- Samples of the device and its components (if requested by FDA). This practice is typically reserved to higher-risk PMA applications under 21 C.F.R. 814.20(b)(9).
- Proposed advertisements and labels for the device. Although not uncommon for companies to include sample labeling information in 510(k) notifications, this proposed provision would now make it a requirement in de novo requests, similar to PMA applications under 21 C.F.R. 814.20(b)(10).
- Information about “known or reasonably known existing [device] alternative[s].”
- Statement that provides (1) a list of any required information that is omitted in the de novo request and (2) “a justification” for any omissions.

Acceptance Review

FDA proposes an acceptance review stage for de novo submissions during which FDA makes a “threshold determination” as to whether the de novo request contains sufficient information to warrant substantive review. Within 15 days of receiving the de novo request or additional information, FDA must complete the acceptance review and notify the requester—after 15 days, the de novo request is automatically accepted for substantive review. The Proposed Rule identifies several “deficiencies” that warrant a refusal to accept (“RTA”), including: (1) incorrect de novo request format; (2) incomplete submission of required content; and (3) the failure to provide a “complete response” to FDA requests for additional information or deficiencies identified by FDA in any prior submissions for the same device. These deficiencies are similar to the Refuse to Accept Policy for 510(k)s guidance and “Acceptance Checklist[s]” issued by FDA in January 2018.

Confidentiality Provisions

FDA sets forth confidentiality provisions that are similar to other FDA marketing submissions. FDA must maintain confidentiality of the requester’s de novo application until it issues

an order *granting* the request. FDA must also maintain confidentiality of all information provided in the request. Public disclosure by the requester, however, renders these confidentiality requirements inapplicable.

The preamble makes it clear that FDA is proposing this rule to bring greater structure, clarity, and efficiency to the de novo classification process. This rule essentially formalizes many of the criteria recommended in various FDA guidances and provides more certainty (albeit less flexibility) for both de novo requesters and FDA enforcement.

The Proposed Rule is available for public comment until March 7, 2019. If finalized, FDA the regulations would go into effect 90 days after the final rule is published.

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[1] 83 Fed. Reg. 63,129 (Dec. 7, 2018).

[2] *See, e.g.*, U.S. FDA, *Guidance: De Novo Classification Process (Evaluation of Automatic Class III Designation)* (Oct. 30, 2017), *available* here; U.S. FDA, *Draft Guidance: Acceptance Review for De Novo Classification Requests* (Oct. 30, 2017), *available* here.

[3] In fact, the FDCA expressly *prohibits* FDA from conducting these premarket facility inspections in its 510(k) review ("other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially presents a serious risk to human health"). *See* FDCA Sec. 513(f)(5).

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