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De Novo requests: FDA releases updated RTA checklist

9 September 2019

On 9 September 2019 the U.S. Food and Drug Administration (FDA or the agency) issued its final guidance document entitled "Acceptance Review for De Novo Classification Requests." The guidance replaces the 30 October 2017 draft guidance of the same name and describes the administrative steps FDA will take to either Refuse to Accept (RTA) or file a request for an evaluation of automatic class III designation (De Novo request).

What's new?

Although the guidance is explicit that it does not change FDA's standard for when a product should follow the De Novo pathway, it does include some significant additions compared to the prior draft that manufacturers will need to heed. Particularly with respect to combination products regulated through the medical device pathways, sponsors must indicate whether a request for designation is needed and whether they have provided the certification or statement of notice related to patent that is required for therapeutic biologic and drug products.

These new provisions, which arose from the 21st Century Cures Act, are discussed in the guidance (VI. sections G, H, and I), and can be found in question A.2 of the RTA checklist.

Checklist updates

The fact that the RTA checklist has been updated is noteworthy in itself. Although the RTA checklist and review process already existed, in our experience, FDA has not uniformly enforced the RTA checklist for De Novo requests. The agency's current attention to the checklist is consistent with its approach to other premarket applications which have similar associated checklists, such a 510(k) notices, premarket approval applications and most recently, Humanitarian Device Exemptions, and may signal a new interest in enforcement and standardization of the De Novo request administrative acceptance process. (See our analysis of the new benefit-risk determination worksheet and the role of uncertainty in premarket reviews.)

Although administrative in nature, carefully following the RTA checklist is critical for all marketing submissions to ensure that the initial review process by FDA will go smoothly. We suggest providing a completed version of the RTA checklist within the relevant submission, including pointers to the location of all necessary information in the marketing submission.

FDA will hold a webinar to discuss this final guidance on Wednesday, 18 September 2019.

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