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Food, Drug & Device Law Alert - FDA Releases Final Guidance On Expedited Access Program For Medical Devices

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Less than a year ago, we published an alert on a draft guidance issued by the FDA titled, “Expedited Approval Program for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life-Threatening or Irreversibly Debilitating Diseases or Conditions.” The FDA has already revised this guidance and issued it in final form, under the slightly-revised title, “Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions.” The revised title reflects the fact that the final guidance extends the Expedited Access Program (EAP) to include de novo devices as well as PMA devices.

Although acknowledging the roots of the EAP in the Innovation Pathway program piloted in 2011, the final guidance states the “EAP is a new voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions and are subject to PMAs or de novo requests.” To facilitate earlier patient access to devices that address unmet medical needs, under the EAP FDA states that it intends to engage with sponsors of EAP devices earlier and more interactively during the device’s development, assessment, and review. FDA may make more senior management available during this process and assign a case manager. Further, FDA states that it will work closely with sponsors of EAP devices to develop a Data Development Plan for the device that provides, among other elements, a description of the premarket and post-market data collection, with the goal of significantly reducing the time and cost from device development to FDA marketing decision, while still meeting the statutory standards for device approval.

In addition to the sponsor’s request and the FDA’s agreement, the guidance identifies the following criteria for participation in the EAP program:

- The device is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition.
- The device meets at least one of the following criteria for addressing an unmet need:

  a. No appropriate alternative treatment or means of diagnosis exists.

  b. The device represents a breakthrough technology that provides a clinically meaningful advantage over existing legally marketed technology.

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c. The device offers significant, clinically meaningful advantages over existing legally marketed alternatives.

d. The availability of the device is in the best interest of patients (e.g., addresses an unmet medical need).

- The sponsor submits an acceptable draft Data Development Plan.

The 44-page guidance includes much more discussion and explanation on each of these points.

The guidance also discusses the following features of the EAP:

- **Interactive Review:** The guidance states FDA intends to work with the sponsor to finalize a Data Development Plan prior to submission of the PMA or de novo request. The plan will be developed in a manner that is predictable and least burdensome, while allowing for some measure of flexibility and adjustments as appropriate.
- **Senior Management Involvement:** Where appropriate and resources permitting, FDA will involve office and center-level senior management and experienced review staff in a proactive, collaborative, cross-disciplinary review.
- **Case Manager:** Again where appropriate and resources permitting, FDA may assign a cross-disciplinary case manager to facilitate efficient review of the Data Development Plan.
- **Priority Review:** FDA expects that the PMA for an EAP Device will receive priority review. The guidance states that the FDA expects the sponsor to make the project a priority also.

The guidance includes several sections addressing other aspects of the EAP, the highlights of which are summarized below:

Benefit-risk determinations for EAP devices that require a PMA: The EAP guidance refers to the FDA's earlier guidance titled, "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications," issued on March 28, 2012. The EAP guidance states that "as part of FDA's benefit-risk determination for EAP Devices subject to a PMA, FDA may consider the amount of data that may be collected in the post-market setting, rather than pre-market, and the level of acceptable uncertainty in the benefit-risk profile at the time of approval."

Types of clinical evidence that may support approval of EAP Devices subject to a PMA: According to the guidance, devices qualifying for the EAP program may receive PMA approval based on intermediate or surrogate endpoints, two phase studies, or prospective clinical studies or retrospective data related to use of the device, such as data collected in a registry or data from outside the U.S. that is nonetheless applicable to the U.S. population. Such approval may be conditional on post-market data requirements.

Manufacturing considerations for EAP Devices subject to a PMA: The guidance states that FDA may allow a sponsor to provide

less manufacturing information in its PMA for an EAP device in certain circumstances, such as when the sponsor has a good track record for quality systems compliance and there are not new, unique manufacturing issues that could adversely impact product quality or performance.

Program evaluation: Beginning one year from the effective date of the guidance and annually thereafter for the next three years, FDA intends to evaluate the EAP program and make a report available to the public.

A copy of the final guidance document can be found here.

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