FDA Proposes Expedited Access Program for Devices Addressing Unmet Medical Needs for Life Threatening or Irreversibly Debilitating Diseases or Conditions

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On April 23, 2014, the Food and Drug Administration (FDA) announced a proposed new program to provide earlier access to high-risk medical devices that are intended to treat or diagnose patients with serious conditions whose medical needs are unmet by current technology.[1]

The proposed Expedited Access Premarket Approval Application for Unmet Medical Needs for Life Threatening or Irreversibly Debilitating Diseases or Conditions (EAP) program features earlier and more interactive engagement between sponsors and FDA staff during device development, assessment, and review and a more effective process for the review of investigational device (IDE) applications and premarket approval (PMA) applications. Participation in the EAP is only at the request of the sponsor and with FDA's agreement.

EAP is not a new pathway to market, but rather a more collaborative approach to facilitate product development under the agency's existing regulatory authorities. While other existing device programs have focused on reducing the time for the premarket review, EAP also seeks to reduce the time associated with product development. The EAP program incorporates features from the Center for Device and Radiological Health's Innovation Pathway, piloted in 2011, to expedite the development and review of breakthrough technologies. In addition, the EAP program is based, in part, on FDA's experience with programs used by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to accelerate the development and review of new drugs that address unmet medical needs in the treatment of serious or life-threatening conditions.

To be eligible for participation in the program, the medical device must meet three criteria:

1. Be intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition

2. Represents one of the following:

    - no approved alternative treatment or means of diagnosis exists, or
    - a breakthrough technology that provides a clinically meaningful advantage over existing technology, or
    - offers a significant, clinically meaningful advantage over existing approved alternatives, or
    - availability is in the patient's best interest (e.g., the device provides a specific public health benefit or addresses an unmet medical need of a well-defined patient population).

3. The sponsor submits an acceptable draft Data Development Plan approved by FDA. This requirement is a key EAP program feature and will include a description of the clinical and nonclinical data that the sponsor proposes to collect, as well as a timeline for the development and marketing of the device. FDA has indicated that the intent of the Data Development Plan is to foster predictable, efficient, transparent, and timely device

1 79 Fed. Reg. 22691 (Apr. 23, 2014). The draft guidance is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm393879.htm

assessment and review. Details on the information to be included in the draft Data Development Plan are outlined in an attachment to the draft guidance.

As part of the EAP program, FDA intends to work interactively with sponsors to determine whether certain data may be collected postmarket rather than premarket. In this regard, FDA notes that Section 513(a)(3)(C) of the Federal Food, Drug, and Cosmetic Act (FDCA) requires FDA to consider the use of postmarket controls in lieu of collecting and reviewing all effectiveness data prior to a PMA approval.[2] Getting the right balance between premarket and postmarket data collection, especially when it is appropriate to give greater reliance on postmarket collection, can reduce the extent of premarket data submission and will have a direct effect on when patients will have access to high quality, safe, and effective medical devices. An earlier guidance document, entitled, "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications, issued on March 28, 2012[3], is relevant to this part of the EAP program.

Other features of the EAP program worth noting are: (1) an explanation of the types of clinical evidence that may support PMA approval of EAP devices (e.g., intermediate and surrogate endpoints and two-phase studies); (2) alternative experimental designs for in vitro diagnostics devices (IVDs) that can generate the analytical and clinical validity of an IVD for premarket approval; (3) companion diagnostic considerations, and (4) an explanation of how, on a case-by-case basis, FDA may allow a sponsor to provide less manufacturing information in the PMA application for an EAP device (e.g., the sponsor has a good track record for quality systems and no new, unique manufacturing issues are present that could adversely impact the quality or performance of the EAP device).

In addition to the EAP draft guidance, FDA simultaneously released a separate draft guidance entitled "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval.[4] This draft guidance outlines the agency's current policy on when data can be collected after product approval and what enforcement actions are available to the FDA if approval conditions, such as postmarket data collection, are not met.

The FDA seeks public comment on both documents on or before July 22, 2014.

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2 Specifically, that section of the FDCA states:
In making a determination of a reasonable assurance of the effectiveness of a device for which [a premarket approval application] has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.
21 U.S.C. § 360c(a)(3)(C)

3 Available at: http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm267829.htm
4 Available at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm393882.htm

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