MedicalXpress

FDA proposes accelerated medical device approval plan

April 23 2014

(HealthDay)—The U.S. Food and Drug Administration has proposed a new program that would provide expedited access to high-risk medical devices intended for patients with serious conditions whose medical needs are not met by current technology.

The proposed Expedited Access Premarket Approval Application for Unmet Medical Needs for Life Threatening or Irreversibly Debilitating Diseases or Conditions ("Expedited Access PMA" or "EAP") program features earlier and more interactive engagement with staff from the FDA. This will include the involvement of senior management and a collaboratively developed plan for collecting the data to support approval.

According to the FDA, EAP is not a new pathway to market, but rather an approach where all parties work together to facilitate product development under the agency's existing regulatory authorities. EAP

seeks to reduce the time associated with product development, not just reduce the time for the premarket review. In addition to the program, the FDA has published a separate draft guidance outlining the agency's current policy on the timeline for data to be collected after product approval and what actions are available to the agency if approval conditions, such as postmarket data collection, are not met. Advice on the use of surrogate or independent markers to support approval, similar to those seen for accelerated approval of prescription drugs, is included in the guidance.

"We are excited to offer a proposed program for expedited access for certain high-risk medical devices," Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health, said in a statement. "The program allows manufacturers to engage early and often with the agency. We expect most devices that enter this program will be in the pre-clinical trial phase."

More information: More Information