FDA-CMS Parallel Review

U.S. Food & Drug Administration

The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) (the Agencies) have established a pilot program for concurrent review of certain FDA premarket review submissions for medical devices and CMS national coverage determinations. By reducing the interval between FDA marketing approval and Medical coverage, this process will facilitate the development of innovative products and shorten the time it takes to bring these important products to patients.

During its pilot phase, the agencies will offer to perform parallel review for up to five innovative devices per year. Appropriate candidates for the parallel review pilot are medical devices that meet one of the following criteria:

1. New technologies for which the sponsor/requester has a pre-investigational device exemption (IDE) or an approved IDE application designation.
2. New technologies that would require an original or supplemental application for premarket approval (PMA) or a petition for de novo review.
3. New technologies that fall within the scope of a Part A or Part B Medicare benefit category and are not subject to a national coverage decision (NCD).

The pilot program is voluntary and will not change the existing separate and distinct review standards for FDA device approval and CMS coverage determination. It is only available for medical device technologies that meet the above criteria.

CMS and FDA encourage any interested sponsors who believe their devices are appropriate candidates and would like to explore the use of the pilot program to contact FDA via email at parallel-review@fda.gov [1].

SOURCE [2]

Source URL (retrieved on *03/09/2014 - 10:22am*):
http://www.mdtmag.com/news/2011/10/fda-cms-parallel-review

Links:
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/mailto:parallel-review@fda.gov
[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm255678.htm