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August 2010

LIFE SCIENCES PRACTICE

ALERT

If You're Disappointed with the 510(k) Process, Here Is Your Chance to Actually Influence the Process

By Anton P. Ness, Christian Moffitt and Alfred J. Monte, Jr.

On **Tuesday, August 31, 2010**, the Center for Devices and Radiological Health (CDRH) will host a **live webinar** to discuss the details of both reports and respond to any questions and concerns raised by the medical device community. To participate in the webinar, visit:

http://fda.yorkcast.com/webcast/Viewer/?peid=8fed89730ec045e9add6b222f8686a45

The FDA is now seeking additional public comments and input on the reports, especially on implementation feasibility and on potential alternatives.

Before You Can Help Yourself, You Must Know the Subject Well

The 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act formally established jurisdiction by the FDA over medical devices, requiring premarket review and approval by the FDA by means of a 510(k) submission prior to any marketing of new products. Such review is for the purposes of making available to consumers devices that are safe and effective and fostering innovation in the medical device industry. "The 510(k) process was originally intended to ensure economic parity between post-enactment and pre-enactment devices." *Riegel v. Medtronic*, 451 F.3d 104 (2d Cir. 2006).

Thirty-three years after the Amendments and the birth of the 510(k), in September 2009, CDRH convened an internal 510(k) Working Group that began a comprehensive assessment of the 510(k) process, being charged with evaluating the 510(k) program and exploring actions CDRH could take to strengthen the program and improve the constancy of its decision making, with a principal focus on actions the Center could take in the short term under its existing statutory authority. Another and independent assessment by the Institute of Medicine is expected to conclude in the summer of 2011. (Another recent CDRH Report is titled "Volume II: Task Force Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations.")

Two open meetings earlier in 2010, plus comments entered into the dockets of each group, provided significant input for the reports.

What FDA Says It Is Trying to Achieve By the Review Process

- A rational, well-defined, and consistently interpreted review standard
- Well-informed decision making
- Continuous quality assurance

What You Should Do Now

- Prepare for the August 31, 2010, webinar by reading and understanding our recent blog entry and the report.
- Immediately determine your company's position on the issues to be discussed during the webinar.
- Be prepared to ask specific questions of the presenters.
- Gather and submit your company's feedback regarding the draft reports to the FDA, by no later than October 4, 2010.

The Report, **Volume I** may be obtained at:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf

The Report, **Volume II** may be obtained at:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220783.pdf

Further information from the CDRH on the Reports, Basic Questions and Answers," may be found at:
http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm221069.htm

Visit our blog posting on this webinar at
http://lifesciences.foxrothschild.com/2010/08/articles/medical-devices/if-youre-as-disappointed-with-the-510k-process-as-everyone-else-who-manufactures-medical-devices-here-is-your-chance-to-actually-influence-the-process/

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