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Med Con 2013

FDA Safety and Innovation Act

Medical Device Pre-Market Requirements

Steven Niedelman
Lead Quality Systems & Compliance Consultant
King & Spalding LLP
1700 Pennsylvania Ave., N.W.
Washington, DC 20006
sniedelman@kslaw.com
(202(626-2942

FDASIA: Device User Fees

Types of Device User Fees remains unchanged:

- Baseline fees
  - Premarket Application Fee (PMA, PDP, PMR, BLA, 510(k))
  - Supplement and Submission Fee
  - Annual Fee (periodic reporting for Class III devices)
- Annual Establishment Registration Fees
  - FDASIA increases the number/types of establishments subject to fees to 22,000
- By sunset in 2017, will generate est. $595M

FDASIA: Establishments Subject to Fees

- Previously, establishment registration fees applied to manufacturers, single-use device reprocessors, and specification developers.
- FDASIA section 202 revises section 737(13) of the FDC Act to define "establishment subject to a registration fee" to mean an establishment that is "registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device." *See* FDC Act § 737(13)(A)-(C) (emphasis added).

FDA Performance Goals

- Original PMA, Panel track Supplements, Premarket Report Applications (including priority review):
  - Communicate with applicant regarding *acceptance for filing* within 15 calendar days of receipt of application.
  - Communicate the filing status within 45 calendar days for those applications *accepted for filing review* (will communicate the specific reasons for rejection where the application is not filed).

FDA Performance Goals (cont.)

- For applications that are filed, FDA will communicate with the applicant through a "Substantive Interaction" within 90 calendar days of the filing date for:
  - 65% of submissions received in FY 2013;
  - 75% of submissions received in FY 2014;
  - 85% of submissions received in FY 2015; and
  - 95% of submissions received in FY 2016-2017.

FDA Performance Goals (cont.)

- "Substantive Interaction" is:
  - An email, letter, teleconference, video conference, fax, or other form of communication such as a request for Additional Information or a Major Deficiency letter by FDA notifying the applicant of substantive deficiencies identified in initial submission review
  - A communication stating that FDA has not identified any deficiencies in the initial submission review and any further minor deficiencies will be communicated through interactive review, or
  - An approval or clearance letter issued prior to the Substantive Interaction goal date will qualify as a Substantive Interaction.

  (MDUFA Performance Goals and Procedures commitment letter, p. 18.)

FDA Performance Goals (cont.)

- Major Deficiency Letters
  - Will be issued based on a *complete review* of the application and will include *all deficiencies*. Any later identified deficiencies generally will be limited to issues raised in the applicant's response unless FDA determines the initial deficiencies do not adequately address important *new issues materially relevant* to a determination of safety and efficacy.

FDA Performance Goals (cont.)

- "MDUFA decisions" are:
  - Original PMAs: Decisions for Original PMAs are Approval, Approvable, Approvable Pending GMP Inspection, Not Approvable, Withdrawal, and Denial.
  - 180-Day PMA Supplements: Decisions for 180-Day PMA Supplements include Approval, Approvable, and Not Approvable.
  - Real-Time PMA Supplements: Decisions for Real-Time PMA supplements include Approval, Approvable, and not Approvable.
  - 510(k)s: Decisions for 510(k)s are substantially equivalent (SE) or not substantially equivalent (NSE).

Investigational Device Exemptions (§ 601)

- Amends FDCA § 520(g) to provide that the Secretary *shall not disapprove* an IDE application because:
  - The investigation may not support 510(k) clearance, a de novo classification determination, or PMA approval of the device;
  - The investigation may not meet a requirement, including a data requirement, relating to approval or clearance of the device; or
  - An additional or different investigation may be necessary to support clearance or approval of the device.

Documentation and Review of Significant Decisions (§ 603)

- Secretary shall provide a substantive summary of the scientific and regulatory rationale for any *significant CDRH decision* regarding submission or review of IDE applications, 510(k)s and PMA applications.

- Summary is to include "documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion." FDASIA § 603.

- Supervisory review of the significant decision may be requested, and may be conducted at the next supervisory level *or higher*.

- To request supervisory review, submit a request to the Secretary not later than 30 days after the decision, noting whether a teleconference or in-person meeting is sought. The Secretary shall schedule a meeting or teleconference review (if requested) within 30 days after the request. Secretary will issue a decision within 45 days of the request or within 30 days after a meeting or teleconference where one was requested.

Importantly, "significant decision" is not defined!

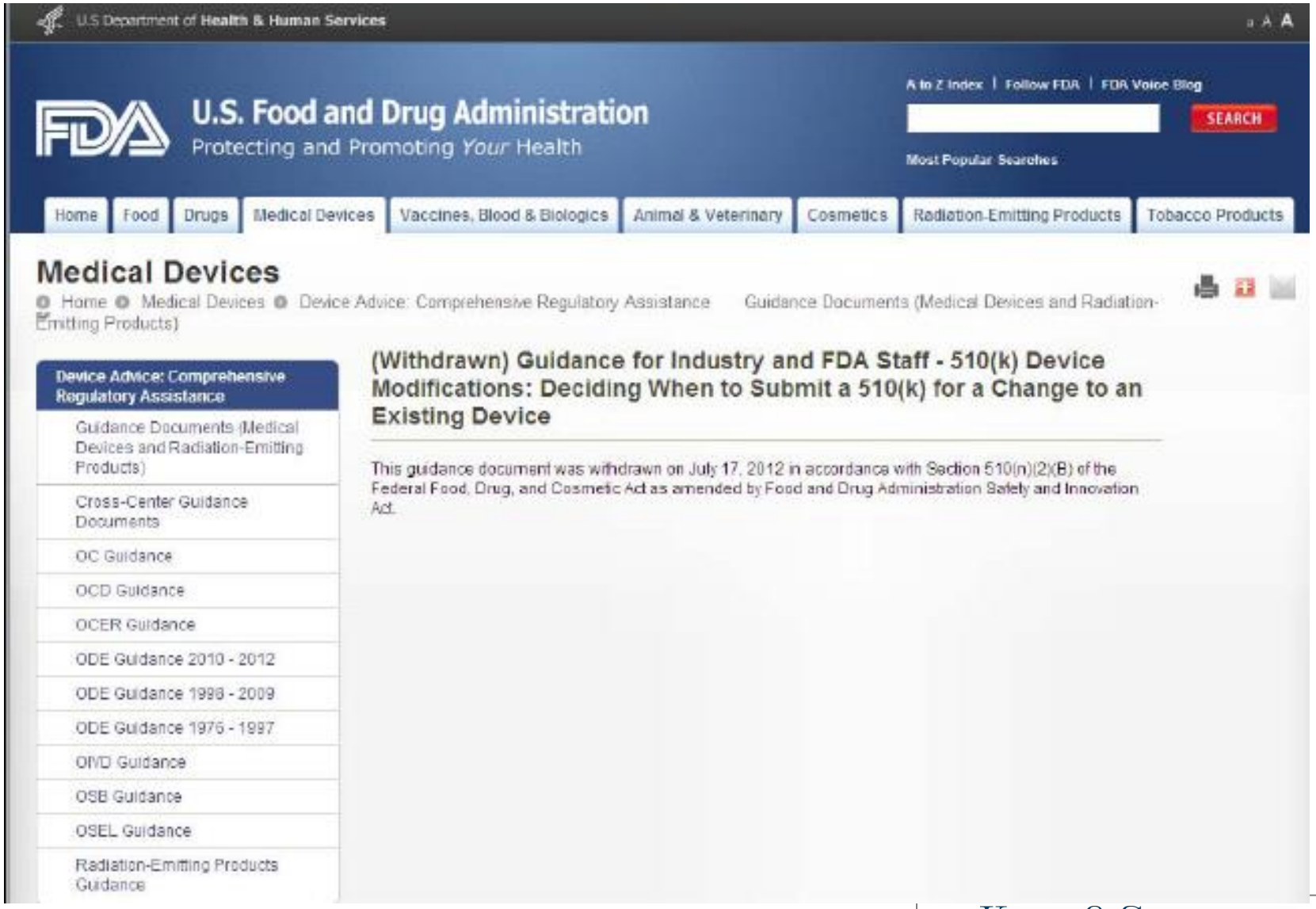
Device Modifications Requiring 510(k) Clearance Prior to Marketing (§ 604)

- Within 18 months after enactment (Jan. 9, 2014), FDA must submit to Congress a report regarding when a 510(k) should be submitted for a modification to a marketed device.
- Report must include FDA's interpretation of the terms:
  - "could significantly affect the safety or effectiveness of the device;"
  - "significant change or modification in design, material, chemical composition, energy source, or manufacturing process;" and
  - "major change or modification in the intended use of the device."

Device Modifications Requiring 510(k) (cont.)

- FDA's January 1997 guidance, "Deciding when to Submit a 510(k) for a Change to an Existing Device'" was revised in a draft guidance issued in July, 2011. The draft guidance was not well-received, and FDA announced it would issue a new draft guidance in light of the comments received.
- Instead, § 604 requires FDA to withdraw the July 2011 guidance and not issue similar draft guidance before Congress receives the report identified above; FDA may not issue any final guidance or regulation for one year after the date of receipt of the report by Congress.
- The 1997 guidance *will remain in effect* until a new regulation is promulgated or guidance is issued.

Device Modifications Requiring 510(k) (cont.)



Questions?

THANK YOU!