BECKER & ASSOCIATES™
CONSULTING
An NSF International Company

FDASIA Impact on Medical Device

October 25, 2013

Elaine C. Messa, RAC, FRAPS
Executive Vice President

This document is intended to facilitate an oral briefing. It is not intended for use as a stand-alone report.

FDASIA 2012: Medical Device s

Brief Background

- User fees Reauthorization

- Medical Device Regulatory Improvements Introduction
- Comparison to Drug Provisions VII
  - Supply Chain
  - Inspections Delay Guidance
- Significant Device Provisions
  - Section 604 Device Modifications
  - Section 614 UDI (Unique Device Identifier
  - Section 607 de novo application process

FDASIA Overview Slide

- Signed into law July 9, 2012
- Gives the authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products
- Promotes innovation to speed patient access to safe and effective products
- Increases stakeholder involvement in FDA processes
- Enhances the safety of the drug supply chain

Reauthorizes User Fees

- 2013 – 2017
- Types of fees remained the same
- Fee amounts go up annually
- Companies Registered or required to register
  - Any facility "engaged in the manufacture, preparation, propagation, compounding, or processing of a device"
  - CMOs, Packagers, Sterilizers, sites that manage complaint files
- FDA performance goals increased with each year

Title VI – Medical Device Regulatory Improvements

- Sec. 601. Investigational device exemptions
- Sec. 602. Clarification of least burdensome standard
- Sec. 603. Agency documentation and review of significant decisions
- Sec. 604. Device modifications requiring premarket notification prior to marketing
- Sec. 605. Program to improve the device recall system
- Sec. 606. Clinical holds on investigational device exemptions
- Sec. 607. Modification of de novo application process
- Sec. 608. Reclassification procedures
- Sec. 609. Harmonization of device premarket review, inspection, and labeling symbols
- Sec. 610. Participation in international fora
- Sec. 611. Reauthorization of third-party review
- Sec. 612. Reauthorization of third-party inspection
- Sec. 613. Humanitarian device exemptions
- Sec. 614. Unique device identifier
- Sec. 615. Sentinel
- Sec. 616. Postmarket surveillance
- Sec. 617. Custom devices
- Sec. 618. Health information technology
- Sec. 619. Good guidance practices relating to devices
- Sec. 620. Pediatric device consortia.

FDASIA: Title 7 : Drug Supply Chain

Section 705 Risk Based Inspection Frequency

- Medical Devices implemented a Risk based Approach to Inspections
- Focus on Class II and III inspections
- 2 year inspection

Section 706 Records for Inspection

- Medical Device Initiative: Pre-Announced Inspection
  - Request for records **prior/ in advance** of the inspection
  - Voluntary

- Difference:
  - Regulatory Requirement for Drugs
  - Med Device is "For" an Inspection NOT "in Lieu" of inspection

Section 707 : Prohibition Against Delaying, Denying… Inspection

- Guidance Document: Reflects FDA current Thinking
- 501 (j)- Drugs maybe considered Adulterated for Delay, Denying …an inspection
- No such Medical Device regulation

Section 709 Administrative Detention

- Provision extends to Drugs FDA's current statutory authority to administratively detain for a reasonable period of time devices and tobacco products
  - Believed to be adulterated or Misbranded

Section 711: Enhancing the Safety and Quality of the Drug Supply

- Medical Device Quality System Regulation (1996)
  - Subpart E-Purchasing Controls 21 CFR820.50
    - (a) evaluation of suppliers : (including definition)

    (1) Evaluation of Suppliers

    (2) Extent of Control

    (3) Records of acceptable suppliers
- Preamble to the Regulation
- GHTF
  - FDA Participation
  - SG3/N17:2008 Guidance on the control of Products & Services obtained from Suppliers

21CFR 820.50:

- Subpart E--Purchasing Controls Sec. **820.50** Purchasing controls. Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

- (a) *Evaluation of suppliers, contractors, and consultants.* Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants.
  - Each manufacturer shall:
  - (1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
  - (2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
  - (3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

- (b) *Purchasing data.* Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with 820.40.

Sec. 604. Device Modifications Requiring Premarket Notification Prior to Marketing

- NLT 18 months after the date of enactment
- The Secretary shall submit a report regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device

The report shall include interpretation of the following terms:

'could significantly affect the safety or effectiveness

'a significant change or modification in design, material, chemical composition, energy source, or manufacturing process'

'major change or modification in the intended use of the device'.

- "(B) The Secretary shall withdraw the Food and Drug

Sec. 604. Device Modifications Requiring Premarket Notification Prior to Marketing

The report also shall discuss:

- processes for industry to use to determine whether a
- new submission under subsection (k) is required and shall
- analyze how to leverage existing quality system requirements
- to reduce premarket burden, facilitate continual device improvement,
- provide reasonable assurance of safety and effectiveness
- shall consider the input of interested stakeholders.

Sec. 604. Device Modifications Requiring Premarket Notification Prior to Marketing

- FDA shall withdraw the draft guidance entitled, "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device" (July 27, 2011)
- Not use this guidance as the basis of, any premarket review or any compliance or enforcement decisions or actions.
- Not issue any guidance or regulation:
  - before the receipt of the report
  - for one year after date of receipt of the report
- Revert to "When to Submit a 510(k) for a Change to an Existing Device" Guidance dated January 10, 1997 shall be in effect

Sec. 607. Modification *de novo* Application Process

- No more need for a 510(k) review to receive a "not substantially equivalent" decision
- *De novo* application can be submitted in lieu of a 510(k)
- FDA has 120 days following receipt of application to classify the device
- FDA can decline to classify if the agency identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence
- 31 Devices listed on FDA.gov as having been approved via the *de novo* pathway, with approval letters and decision summaries
- Awaiting guidance

Sec. 614. Unique Device Identifier

- FDA issued Final Unique Device Identifier (UDI) regulations on September 20, 2013
- Risk based timeframe for implementation
- www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

Thank You!
Questions?

Elaine C. Messa, RAC

Executive Vice President, Medical Device Practice

NSF Health Sciences-Becker Consulting

elaine.messa@becker-consult.com

202-822-1850