Quality System: Updates from FDARA and 21st Century Cures Act

FDA Small Business
Regulatory Education for Industry (REdI)
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FDARA
Accesorries
MDSAP
PatientPerspective
NEST
3rdParty
MDUFA
Inspections

Learning Objectives

Summarize the changes to postmarket requirements from:

- FDA Reauthorization Act (FDARA)
- 21st Century Cures Act
- Other Postmarket updates

FDARA

FDA Reauthorization Act

- Abbreviated as FDARA
- Enacted August 18, 2017
- Purpose
  - Reauthorize various FDA user fee programs- MDUFA, PDUFA, GDUFA, and BsUFA
  - Make policy and program changes
- CDRH Learn Module on MDUFA

FDARA 701: Authorizes…

Section 701 : Inspections

- Risk based inspection scheduling for device establishments
- Replaced previous biennial inspection requirement

FDARA 702: Authorizes…

Section 702: Improvements to Inspections

- Inspection announcement, timing, and communication
- FDA to provide nonbinding feedback within 45 calendar days of request
- Draft guidance issued by February 18, 2019 and finalize

FDARA: FDA Actions…

Section 702: Inspections

- FDA issued Draft Guidance for Nonbinding feedback after certain FDA Inspections of device establishments

- Issued on February 19, 2019

FDARA 703: Authorizes…

Section 703: Third Party Inspections

- Reauthorizes Third Party Inspections (Accredited Persons Program)
- Scheduled to expire October 01, 2017, extended to October 01, 2022

FDARA 704: Authorizes…

Section 704: Export certificates

- Provide reason to deny an export certificate
- When establishment agrees to a plan to correct 483 violations, FDA will not deny an export certificate
- Create a process for FDA to review denials
- Draft guidance issued by August 18, 2018 and finalize

FDARA 704: FDA Actions…

Section 704: Export certificates

- FDA issued a Draft Guidance "Process to request a review of the FDA's decision not to issue certain export certificates for devices"

- Issued on August 17, 2018

FDARA 705: Authorizes…

Section 705: Medical Device Single Audit Program (MDSAP)

- Authorizes FDA to recognize auditing organizations
- Facilitates harmonization of medical device inspections

FDARA 705: Actions….

Section 705: Medical Device Single Audit Program (MDSAP)

- MDSAP is no longer a pilot and is an active program

FDARA 707: Authorizes…

Section 707: Accessories

- Allows accessory classification to be distinct from classification of parent device

Examples

Parent device

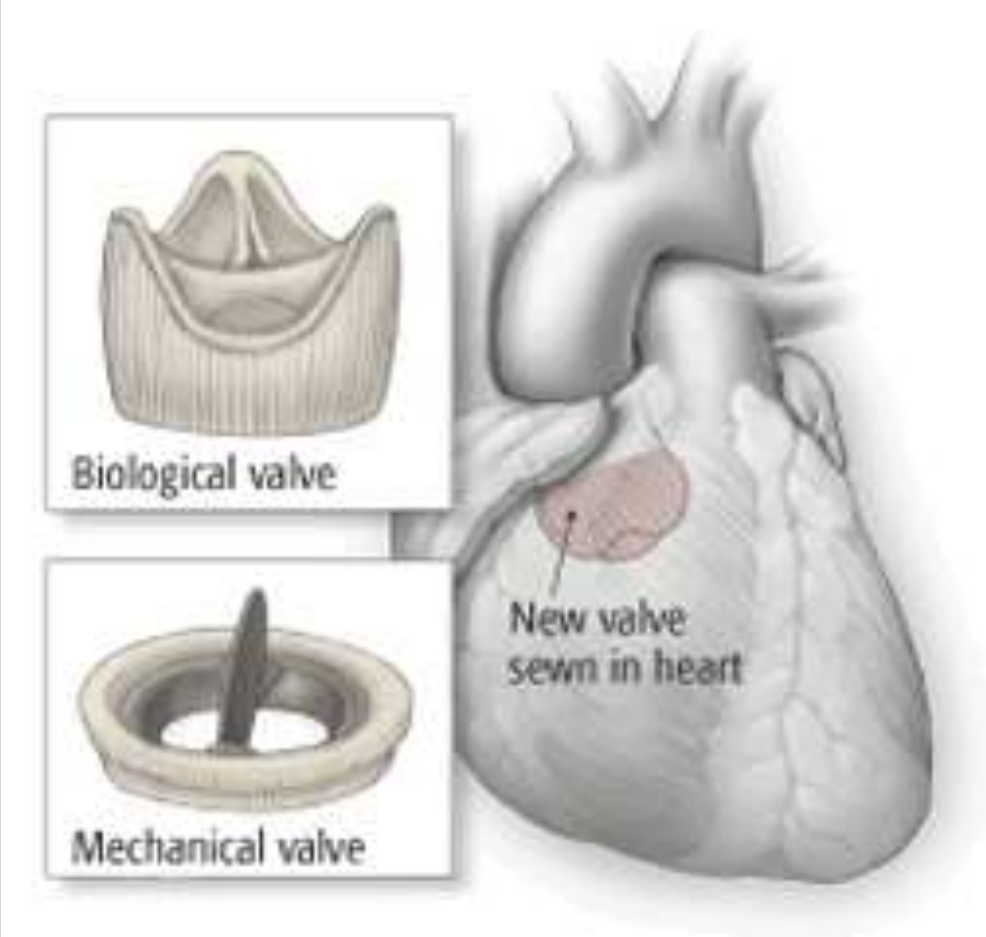


Photo credit – drugs.com

Accessory

Photo credit – ebay and Medtronic

FDARA 707: Authorizes…

Section 707: Accessories

- Classification is based on risk
- Requires FDA to respond to accessory classification requests within 85 calendar days
- Classify suitable accessories into Class I of the proposed list published on August 17, 2018

FDARA 707: FDA Actions…

Section 707 – Accessories

- FDA issued a final classification action Medical devices classification of accessories distinct from other devices finalized list of accessories suitable for Class I
- Issued on April 12, 2018

FDARA 707: FDA Actions…

Section 707 – Accessories

- FDA issued a guidance Medical Device Accessories – Describing Accessories and Classification Pathway for New Accessory Types
- Issued on December 20 , 2017

FDARA 707: FDA Actions…

- If accessory classification is distinct from another device prior to December 31, 2016:
  - Classification stands, unless reclassified
- If accessory is included in pending or future premarket submission:
  - Sponsor may include a request for the classification
  - FDA must include a grant or denial of the request for classification of the accessory

FDARA 707: FDA Actions…

- If accessory was included as part of a premarket submission:
  - Sponsor may include a request for the classification
  - FDA must respond by reclassifying or denying the request within 85 days.

FDARA 708: Authorizes…

Section 708: Postmarket Surveillance Pilots

- Designed to generate reliable and timely safety and surveillance data
- Inform development of methods, systems, criteria, and programs for devices
- May be designed and conducted in coordination with a comprehensive system for evaluating device technology

FDARA 708: Authorizes…

Section 708: Postmarket Surveillance Pilots

- Use electronic health data
- Prioritize devices and device types based on:
  1. The collection of real world evidence (RWE) is likely to advance public health
  2. Devices that are widely used
  3. Device failure with significant health consequences

FDARA 708: FDA Authorizes…

Section 708 - Postmarket Surveillance Pilots

- Report to Congress by February 18, 2019 and annually thereafter
- Independent review by January 31, 2021

FDARA 708: FDA Actions…

Section 708: Postmarket Surveillance Pilots

- Awarded funding to Medical Device Innovation Consortium (**MDIC**)
- To establish the National Evaluation System for Health Technology Coordinating Center (**NESTcc**)

www.meddeviceonline.com/doc/nestcc-at-two-progress-and-next-steps-for-real-world-evidence-for-medical-devices-0001

FDARA 708 Pilot Examples

First round of NESTcc Test Cases

Total Product Life Cycle (TPLC) Alignment	Project Title	Regulatory Pathway	Technology of Interest	Disease Area
Pre-market Submission	Comparative Effectiveness of Alternative Approaches for Wound Closure	510(k)	Wound Closure	Dermatology
Label Expansion	Testing the Use of Real-World Data from Three Unique Sources to Expand Indications	PMA	Endovascular Therapies	Vascular
Label Expansion	The Feasibility of Using Real-World Data in the Evaluation of Cardiac Ablation Catheters	PMA	Ablation Catheters	Cardiology

FDARA 710: Authorizes…

Section 710: Third Party Servicers

By May 15, 2018, post a report that includes:

- Information from 2016 FR notice and public workshop
- Authorities FDA has to regulate servicers and actions FDA can take
- Information about regulation of servicing by states, the Joint Commission, and other regulatory authorities

FDARA 710: FDA Actions…

Section 710: Third Party Servicers

FDA posted the report

- Issued May 2018
- This report was informed by feedback from all stakeholder groups

FDARA 710: FDA Actions…

Section 710: Third Party Servicers

Intended FDA actions:

- Promote adoption of Quality Management principles
- Clarify difference between Servicing and Remanufacturing
- Strengthen Cybersecurity practices associated with servicing
- Foster evidence development

FDARA 902: Authorizes…

Section 902: Annual report of inspections

- Requires FDA to post information related to inspections for the approval of medical devices.
- Post by March 1 of each year

FDARA 902: FDA Actions…

Section 902: Annual report of inspections

- The FDA has posted the FDARA reports

FDARA 903: Authorizes…

Section 903: Real time quarterly reports

- Requires FDA to provide Real Time reporting related to the process for the review of FDA regulated products.

FDARA 902: FDA Actions…

Section 903: Real time quarterly reports

- The FDA has posted the FDARA reports

21st Century Cures Act

21st Century Cures Act

- Abbreviated as **Cures**
- Enacted December 13, 2016
- Implemented in 2017
- Amended the Federal Food, Drug, and Cosmetic Act (FD&C Act)

21st Century Cures Act

- Designed to expedite medical device development
- Bring new innovations to the market sooner
- Incorporate patient perspective into decision making process

21st Century Cures Act

- Section 510(o) revised definition of device in Section 201(h) of FD&C Act

- Does not include certain software that:
  - Supports administrative functions
  - Encourages healthy lifestyle
  - Serves Electronic health records (EHR)
  - Displays and sorts records
  - Provides limited clinical decision support

21st Century Cures Act

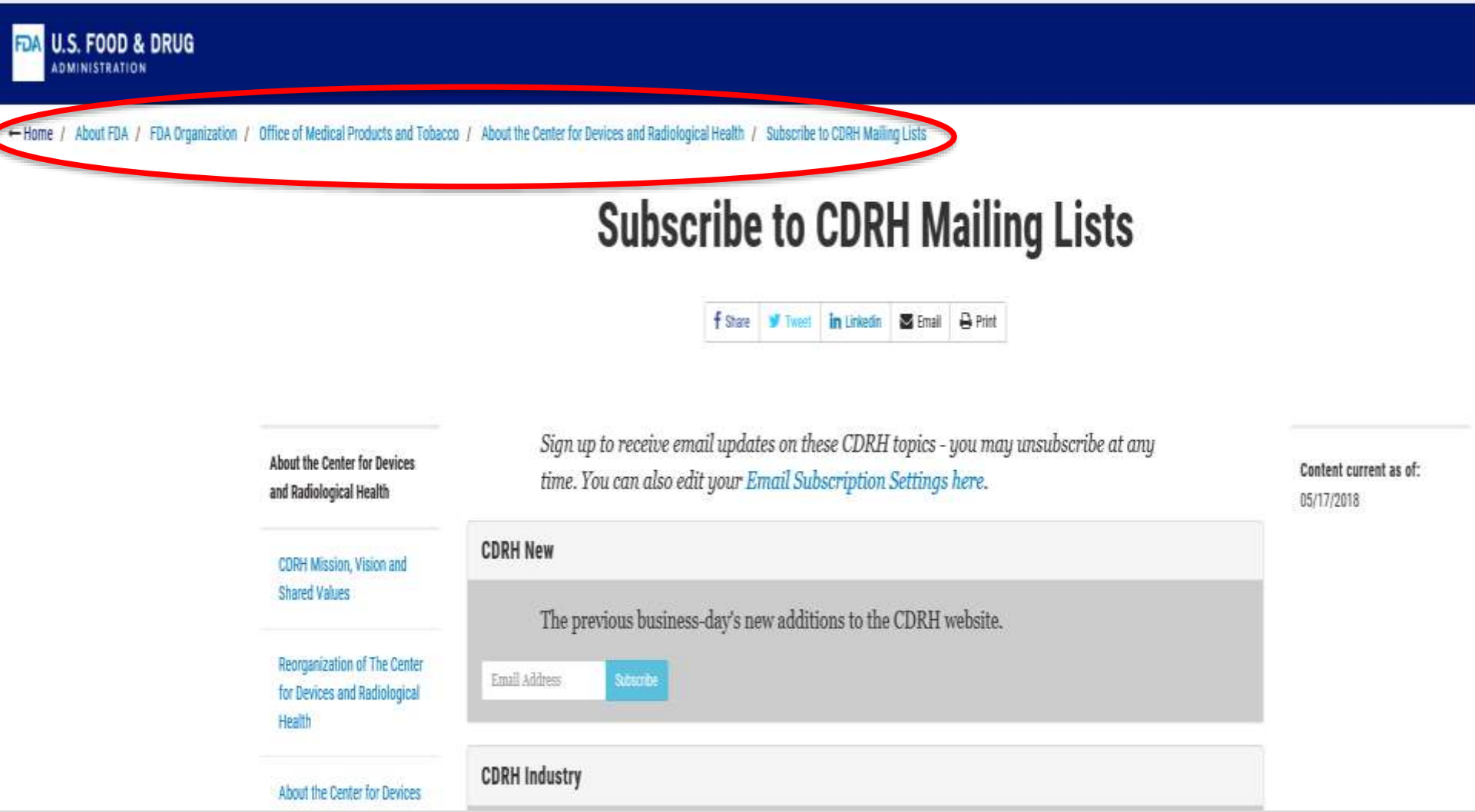
- FDA published a draft guidance Changes to Existing Medical Software Policies resulting from 21st century cures act
- Issued on December 08, 2017
- The concepts will be made throughout:
  - General wellness
  - Mobile medical application
  - Off the Shelf Software
  - Medical Device Data Systems (MDDS)

Other Postmarket updates

Recent Postmarket Updates

- FDA issued a guidance document Manufacturing site change supplements: content and submission
- Issued on December 17, 2018

To Subscribe



www.fda.gov/about-fda/about-center-devices-and-radiological-health/subscribe-cdrh-mailing-lists

Resources

- Email subscriptions
- FDARA
- Nonbinding feedback after certain FDA Inspections of device establishments
- Process to request a review of the FDA's decision not to issue certain export certificates for devices
- Medical devices classification of accessories distinct from other devices finalized list of accessories suitable for Class I
- Medical Device Accessories – Describing Accessories and Classification Pathway for New Accessory Types
- www.meddeviceonline.com/doc/nestcc-at-two-progress-and-next-steps-for-real-world-evidence-for-medical-devices-0001

Resources

- Third Party Servicing Report
- FDARA reports
- 21st Century Cures Act
- Changes to Existing Medical Software Policies resulting from 21st century cures act
- Manufacturing site change Supplements: content and submission

Summary

- The FDA Reauthorization Act incorporated a number of changes that impacted devices in the postmarket setting.

- The 21st Century Cures Act is intended to help advance getting innovative products to market.

Questions?

Your Call to Action

- Keep current with regulatory changes being made by the U.S. Food and Drug Administration (FDA)
- Subscribe to the FDA email list to receive important information coming directly from FDA (as mentioned in slide 35)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