IMDRF International Medical Device Regulators Forum

U.S. FDA Center for Devices and Radiological Health Update

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General Wellness: Policy for Low-Risk Devices – Final Guidance

- *General Wellness: Policy for Low-Risk Devices* issued July 28, 2016
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf

- The FDA encourages the development of general wellness technologies, such as fitness trackers, which can empower individuals to manage and take a more active role in their health.

- This guidance takes a hands-off approach to the regulation of low risk general wellness products that only promote a healthy lifestyle or that promote a well-known association between a healthy lifestyle and a certain disease or condition.

- The FDA will continue to focus its oversight on products that are invasive, implanted or pose greater risks to patients, even if they are intended for general wellness purposes.

FACTORS TO CONSIDER REGARDING BENEFIT-RISK IN MEDICAL DEVICE PRODUCT AVAILABILITY, COMPLIANCE, AND ENFORCEMENT DECISIONS DRAFT GUIDANCE

- *Draft Guidance – Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions* issued June 15, 2016.
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm506679.pdf
- To help maximize patient safety and medical device quality this draft guidance clarifies how the agency may assess the benefits and risks of medical devices when making product availability, compliance, and enforcement decisions.
- When determining whether to take a compliance or enforcement action that could directly affect a medical device's availability, FDA may consider relevant, reliable information relating to patient perspective(s) and real-world data, in addition to traditional scientific and clinical data.
- The draft guidance may also help medical device companies in conducting their own benefit-risk assessments when evaluating the appropriate response to certain issues, such as determining whether to initiate a recall to correct a defective product or remove it from the market.

Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices – Final Guidance

- *Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices – Final Guidance* issued June 21, 2016.
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM444591.pdf
- Despite a recognized need, relatively few medical devices have pediatric specific indications and labeling.
- This guidance includes a framework to consider leveraging existing data to augment what is known about a device's performance in pediatric patients, in order to minimize risk and maximize patient access to pediatric devices.
- The extrapolation of data to support pediatric indications may benefit pediatric patients by increasing the availability of medical devices with appropriate labeling to support safe and effective pediatric use.

USE OF SYMBOLS IN LABELING – FINAL RULE

- *Use of Symbols in Labeling Final Rule* issued June 14, 2016.
  - https://www.gpo.gov/fdsys/pkg/FR-2016-06-15/pdf/2016-13989.pdf

- FDA revised its labeling regulations to allow manufacturers to use more symbols to replace text. The use of certain standardized symbols is voluntary, and may not need adjacent explanatory text.

- Part of the regulations outline that labeling using symbols without adjacent text must include a glossary so that users have a reference for symbols they do not recognize.

- The final rule will help to harmonize the labeling requirements of U.S. and international regulatory bodies.

- The FDA is also modifying the current list of FDA-recognized standards that have stand-alone symbols.

Dissemination of Patient-Specific Information from Devices by Device Manufacturers – Draft Guidance

- *Dissemination of Patient-Specific Information from Devices by Device Manufacturers - Draft Guidance* issued June 9, 2016.
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm505756.pdf

- FDA issued this guidance to clarify that FDA requirements do not prohibit manufacturers from sharing patient-specific information recorded, stored, processed, retrieved and/or derived from a medical device with the patient who is either treated or diagnosed with that device.

- Providing patients with access to accurate, useable information about their health care when they request it (including the medical products they use and patient-specific information these products generate) may empower patients to be more engaged with their health care providers in making sound medical decisions.

- FDA believes that device manufacturers should take certain considerations into account when sharing patient-specific information to help to ensure that the information is useable to patients and to avoid the disclosure of confusing or unclear information.

Postmarket Surveillance Under Section 522 of the Food, Drug, and Cosmetic Act – Final Guidance

- *Postmarket Surveillance Under Section 522 of the Food, Drug, and Cosmetic Act Final Guidance* issued May 16, 2016.
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM268141.pdf

- Section 522 of the Federal Food, Drug, and Cosmetic Act provides FDA with the authority to require device manufacturers to conduct postmarket surveillance of certain class II or class III devices.

- This guidance document clarifies the 522 postmarket surveillance process and provides manufacturers with information on how to fulfill section 522 obligations, and recommendations on the format, content, and review of postmarket surveillance plan submissions.

USE OF REAL-WORLD EVIDENCE TO SUPPORT REGULATORY DECISION-MAKING FOR MEDICAL DEVICES – DRAFT GUIDANCE

- On July 26, 2016 , FDA issued the *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices - Draft Guidance*
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf

- Real-world data, which are collected from sources outside of traditional clinical trials, can provide powerful insight into the benefits and risks of medical devices, including how they are used by health care providers and patients.

- This new draft guidance clarifies how we determine that real-world data may be sufficient for use in premarket and postmarket regulatory decisions, without changing the evidentiary standards we use to make those decisions.

- Creating a national evaluation system for medical devices is a top priority to help ensure the quality and reliability of real-world data.

Deciding When to Submit a 510(k) for a Change to an Existing Device – Draft Guidance
Deciding When to Submit a 510(k) for a Software Change to an Existing Device – Draft Guidance

- On August 5, 2016, FDA issued the draft guidance documents: *Deciding When to Submit a 510(k) for a Change to an Existing Device*, which applies to medical device changes broadly, and *Deciding When to Submit a 510(k) for a Software Change to an Existing Device,* which focuses on software-specific changes.
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514771.pdf
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737.pdf
- At a time where medical technology is rapidly evolving, the FDA must ensure the continued safety and effectiveness of modified medical devices while also facilitating timely access to the latest beneficial technologies.
- Not all device modifications require FDA review. These draft guidances aim to strike the right balance by clarifying the changes that trigger the requirements for FDA review including major modifications to changes to the intended use that could significantly impact safety and effectiveness.
- The guidances will improve clarity regarding minor changes that do not require FDA review and help ensure we receive appropriate submissions for modifications that do require FDA's premarket review.

Patient Preference Information – Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling Final Guidance

- On August 23, 2016, FDA issued the final guidance *Patient Preference Information – Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling*.
  - Patient Preference Information – Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling
- Patient preference information can provide a unique and important perspective that can help the FDA evaluate the benefits and risks of certain medical devices in support of device approval decisions.
- The guidance is intended to encourage medical device manufacturers to voluntarily include in their premarket submissions information about the tradeoffs patients may consider when evaluating the benefits and risks of a treatment option.
- In considering the patient perspective, the FDA remains committed to assuring that devices meet the requisite standards. This guidance does not change the review standards for PMAs, HDE applications, or *de novo* requests.

510(k) Third Party Review Program Draft Guidance

- On September 9, 2016, FDA issued the Draft Guidance – *510(k) Third Party Review Program.*
- The draft guidance implements Section 523 of the Federal Food, Drug, and Cosmetic Act by providing a process of recognition for qualified third parties to conduct the initial premarket review of premarket notification (510k)) submissions for certain low-to-moderate risks devices as well as review 510(k) submissions for modifications made to previously cleared devices.
- The Third Party review program would provide manufacturers of eligible devices an alternative review process that may yield more rapid 510(k) decisions.
- The objective of this guidance is to ensure a harmonized quality of work among third party review organizations based on the IMDRF regulatory assessment program Medical Device Single Audit Program (MDSAP).
- This guidance describes criteria the FDA's third party premarket review program will consider to recognize, rerecognize, deny recognition, and deny rerecognition to third party review organizations for the purpose of conducting the initial review of premarket notification (510(k)) submissions for certain low-to-moderate risk devices.

THANK YOU