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FDA Reconsiders Electronic Labeling for Certain Devices

The FDA has withdrawn a proposed rule that would have required manufacturers to submit labels and package inserts in electronic format for certain home-use medical devices.

The rule was intended to reduce the misuse of class II and class III devices. The agency had previously determined that this device group was at a higher risk of misuse due to misplaced labeling and operating instructions. Under the proposal, device information would have been uploaded to a database and made available to the public.

"It is FDA's hope that access to this information will contribute to improved medical outcomes and a reduction in adverse events," the agency said when it proposed the rule in October 2016.

There were more than 800,000 adverse events associated with medical devices in 2014, the agency noted and said it believed a labeling database could help prevent some of the events "when the labeling is lost or misplaced and the user is inexperienced with the

(See **Labeling**, *Page 2)*

Health Canada Makes Further Concessions to MDSAP Transition Plan

Health Canada said it wants to help devicemakers make the transition to the Medical Device Single Audit program and the agency has urged manufacturers to renew their licenses immediately, irrespective of their MDSAP status.

Canadian manufacturers need to renew annual licenses before Nov. 1, and Frederic Hamelin, manager of Quality Systems in Health Canada's Medical Devices Bureau, urged manufacturers to do this now as the MDSAP process is separate.

"If you don't have a MDSAP certificate, let us know you had your audit but don't yet have a certificate, and we will make an arrangement with you," he said during a webinar hosted by MEDEC.

(See **MDSAP**, *Page 4)*

FDA Warns Against Genetic Tests Predicting Medication Response

In an alert issued Thursday, the FDA warned against using unapproved genetic tests to predict patient responses to medications.

The agency made the move in response to reports of DNA tests and software programs claiming they could predict the effectiveness or side effects of drugs such as antidepressants, heart medications and acid reflux drugs in certain patients. The claims are not based on any currently existing sufficient clinical evidence, the FDA said.

For example, some tests claim results can be used by doctors to identify which antidepressant would be most effective. There is no established relationship between DNA variations and the effectiveness of antidepressants, the FDA said, expressing particular concern about reports that some healthcare providers have already changed prescriptions based on genetic test results, which could put patients at risk.

"It is important to note that there are some drugs whose use can be aided by the results of pharmacogenetic information. In those cases, there is scientific evidence to support relationships between the genetic variant and how a patient responds to a drug, which has been reviewed by the FDA," CDRH Director Jeffrey Shuren and CDER Director Janet Woodcock said in a joint statement.

The agency said it will continue to monitor such claims and take enforcement action for noncompliance. — Zack Budryk

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Labeling, *from Page 1*

home-use device, or when the labeling of the device has been updated with new information."

But the proposed database was immediately met with criticism by industry groups. "We support withdrawal of the rule, which raised concerns in terms of duplication of already available information, problematic implementation and the potential to confuse patients and caregivers," and AdvaMed spokesperson told *FDAnews.*

According to AdvaMed, an online medical device labeling database poses numerous problems, including risk to patient safety due to the frequency at which patient labeling may be updated. Customers might find different versions of their device's package insert in the proposed database and the manufacturer's website, which could result in confusion and "unintentional negative consequences," the group said.

In its withdrawal notice, the FDA explained that it had received several comments indicating the database as proposed would be "unduly burdensome… without efficiently enhancing public health." Concerns for the database's format and potential costs were also raised, ultimately leading to the FDA's decision to withdraw the proposed rule.

The matter isn't entirely closed, however. The agency said it plans to reconsider its approach and it will solicit further public input "at a future date."

In the same notice, the FDA withdrew a proposed amendment to the performance standard for laser products, indicating that the rule referenced an international performance standard that is currently being revised to reflect advancements in technology.

Read the *Federal Register* notice here: www.fdanews.com/11-01-18-Electronic.pdf.
—Tiffany Winters

FDA Asks Industry About Difference Between Servicing and Remanufacturing

The FDA is seeking feedback from device-makers to help craft guidance on the difference between servicing and remanufacturing devices.

The agency released a white paper outlining its initial thoughts about guiding principles and considerations for software and labeling, for discussion at a Dec. 10-11 public workshop.

Previous industry comments suggested that inadequate servicing of devices related to adverse events and deaths, but the agency maintains that they were a result of remanufacturing rather than servicing.

The FDA considers servicing as the repair or preventative maintenance on a finished device after distribution to return it to the specifications established by the original equipment manufacturer to meet its original intended use. Remanufacturing is processing, conditioning, renovating, repacking, restoring or any act done to a finished device that significantly changes the device's performance or safety specifications or intended use.

There is an overlap between the regulatory definition of remanufacturing and the standard for when a 510(k) is required for a change to a legally marketed device, which could change safety or effectiveness in the intended use, the FDA said.

The agency is seeking comment on the following proposed guiding principles:

- Servicing does not significantly change the safety or performance specifications of a device;
- Evaluate whether any changes to a device require a new 510(k);
- Assess component/part/material dimensional and performance specifications. Assessment of changes to dimensional specifications can inform whether the activity performed is servicing or manufacturing;
- Employ a risk-based approach when assessing whether an activity is servicing or remanufacturing. An activity performed on a device is likely remanufacturing when a risk-based assessment identified any new risks or significantly increases known risks, and thus significantly changes performance or safety specifications or intended use; and
- Adequately document decision-making to explain why a determination is made. Documentation should specify why activities performed don't significantly change the performance or safety specifications or intended use of a marketed device.

The white paper also discusses includes an appendix of definitions. Comments on the paper may be submitted until Jan. 25, 2019.

Read the white paper here: www.fdanews.com/11-01-18-WhitePaper.pdf.

Office of Inspector General Prods FDA To Improve Postmarket Cybersecurity

The FDA needs to do more to reduce postmarket cybersecurity risks to medical devices, according to the HHS Office of the Inspector General.

OIG researchers conducted an audit and found the FDA's policies and procedures "insufficient" for handling postmarket medical device cybersecurity events.

The OIG acknowledged that the agency had implemented some recommendations from a draft version of its audit report, but it called on the agency to:

- Continually assess cybersecurity risks to medical devices and update its plans and strategies as needed;
- Establish written procedures for securely sharing sensitive information about cybersecurity events with key stakeholders who have a "need to know";
- Enter into a formal agreement with the Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team; and
- Ensure the establishment and maintenance of procedures for handling recalls of medical devices vulnerable to cybersecurity threats.

Read the full report OIG here: www.fdanews.com/11-01-18-OIGreport.pdf.

Judge Shoots Down PBM Call For Dismissal of EpiPen Pricing Suit

A proposed class action suit alleging that multiple pharmacy benefit managers are responsible for Mylan's price hike of EpiPen will move forward, after a Minnesota federal judge denied requests to have the case thrown out.

Participants in ERISA-governed health plans that used EpiPens for severe allergies filed the class action in Minnesota District Court against Prime Therapeutics, Express Scripts, CVS Health and other PBMs, alleging that their negotiations caused Mylan to raise EpiPen prices while they collected millions of dollars in rebates and other payments.

Specifically, the plaintiffs said the benefit managers violated sections of ERISA because they failed to meet their fiduciary obligations to their clients and engaged in fiduciary self-dealing by pocketing rebates. Their actions led to huge out-of-pocket costs for EpiPen, they said.

The defendants breached their duty of loyalty under ERISA and caused EpiPen benchmark price inflation through "solicitation and receipt of increasing rebates from Mylan for EpiPen" and kept a significant portion of the rebates as profit, the plaintiffs claimed.

The PBMs argued that the plaintiffs couldn't establish a link between their injuries and the PBMs' alleged actions. But Judge Paul A. Magnuson shot down the down their calls for dismissal, saying they could reimburse plaintiffs by paying them back for overcharges or lowering EpiPen prices. — James Miessler

MDSAP, *from Page 1*

"We won't willy-nilly cancel your licenses on the spot," he said.

Hamelin noted the agency has made a number of concessions to allow devicemakers more time to comply during the MDSAP transition. In May, the agency reduced audit requirements for smaller companies with lower-risk products, because they "were telling us the process was expensive," he said. As a result, the agency talked to regulatory partners and adjusted the program to reduce the audits, since costs are tied to the duration of the audit (*IDDM*, May 14).

"This was one of the bigger changes we made this year to help them manage the costs," he said, clarifying that companies with up to 100 employees with a good compliance history would qualify for the shorter audit.

The consortium also addressed surveillance audits and standardized audit requirements for auditing organizations to make the process more uniform because many AOs were doing audits differently, "which we believed was a reflection of us as regulators not providing clear enough guidance," he said.

All class II, III and IV device manufacturers are required to comply with the program requirements by Jan. 1, 2019. Manufacturers need to provide evidence by the end of the year, he said, adding that manufacturers that have had an audit performed need to submit their MDSAP certificates before the end of the year.

Manufacturers that intend to complete the transition but can't get the audit completed by the end of the year need to submit:

- Their existing Canadian Medical Devices Conformity Assessment System (CMDCAS) certificate;
- A copy of the ISO 13485 certificate issued by a MDSAP auditing organization; and
- Documented evidence that an audit is scheduled (even a letter confirming the audit will take place).

"This is not a free pass; we will find out if you don't get the audit done," he warned.

Manufacturers that have been audited but are waiting for certificates, should submit their CMDCAS certificate, with the ISO 13485 certificate and a Form G00026.1 indicating the MDSAP surveillance audit has been conducted.

The agency is hosting a MDSAP consortium meeting in Washington, D.C. on Dec. 5.

Complaint Procedures Lacking at Beijing Polycon

Procedures for submitting medical device reports to the FDA, as well as inadequate CAPA procedures were among the numerous quality system failures uncovered during a Jan. 29 to Feb. 1 inspection of Beijing Polycon Medical Engineering's plant in Beijing.

The Chinese firm had not established a link to an electronic portal for submitting electronic medical device reports, and the firm's procedures didn't define timelines for submitting MDRs.

Procedures for receiving, reviewing and evaluating complaints by a designated unit had not been established, the FDA investigators found, and there were no procedures for processing complaints outside of China.

Investigators noted that none of the complaints reviewed that occurred outside of the U.S. — for devices similar to those marketed in the U.S. — included documentation of the MDR evaluation, and when investigations were conducted, critical data were missing.

Design review procedures were also missing critical information such as when formal design reviews were held and who attended them. Results of design reviews were also not documented and retained in the design history file.

Design validation activities and design verification results also fell short, according to the Form 483. For example, design validation procedures didn't ensure that validation was performed under defined operating conditions such as

(See **483***, Page 6)*

Installation: Phase 1 of QSR-Compliant Equipment Control

The FDA expects devicemakers to follow Quality Systems Regulation-compliant procedures for installing equipment used in the course of device manufacture, including any ancillary equipment that affects production, such as environmental systems and contamination controls.

Installation could be as simple as plugging in a piece of equipment. On the other hand, it could be a complicated endeavor. Regardless of the complexity of the exercise, the FDA expects to see evidence that a devicemaker performed installation qualification, defined in Global Harmonization Taskforce (GHTF) guidance on the topic as establishing via objective evidence that all key aspects of the installation — including installation of ancillary equipment — meet approved specifications and that recommendations from the equipment supplier are suitably considered.

However, following the GHTF guidance will not ensure QSR compliance, says Dan O'Leary, president of Ombu Enterprises, noting that "QSR has got a lot more issues involved in it."

Installation qualification is considered part of process validation, but it's important to remember that it also stands alone for production equipment. Many qualification issues are going to be critical to the basic installation of equipment, O'Leary says.

Devicemakers must establish what characteristics are necessary for a piece of equipment to perform its intended task; these characteristics comprise the requirements, or specifications. For equipment purchased from an outside vendor, this information is included in the purchasing data. For equipment made in-house, the requirements are addressed in the design and construction parameters. O'Leary points out that this applies to test equipment as well as production equipment.

Ancillary systems that must be considered could include, depending on the specific production equipment, electric power or air systems, along with systems to manage discharges from the equipment in question. Installation covers physically placing the manufacturing equipment in a manufacturing environment and connecting to any ancillary equipment.

So devicemakers need to have clear procedures for how to hook up equipment to power, for instance. Other questions to answer regarding installation include whether the equipment will require air cooling or hook-up to water and whether it discharges a material or substance that will have to be routed somewhere and handled appropriately.

Excerpted from the FDAnews management report: *Three Phases of QSR-Compliant Equipment Control*.

483, *from Page 5*

simulated-use conditions. Inspectors also noted that validation tests didn't identify the unit under testing, the acceptance criteria, the dates of the testing or the test results.

"It was noted the testing was conducted prior to the start of the design project and no raw data was available for review," the agency said.

During a review of CAPA activities, inspectors noted that not all sources of potential nonconformities were identified to detect recurring quality problems.

In addition, design verification results, including the identification of the design, were not properly documented in the design history file. Procedures for design change were not approved before changes were made to device designs, and document control procedures were not established to ensure that when changes were made, the revision numbers were updated, the agency said.

Read the Beijing Polycon Form 483 here: www.fdanews.com/10-30-18-beijingpolyconmedicalengineeringltd483.pdf.

LSVT Global Receives 10-Item 483 for QS Deficiencies

Failure to establish a design history file or to put procedures in place to control device history records, in addition to failure to conduct quality reviews, landed devicemaker LSVT Global a 10-item Form 483 following a July 16 to July 17 inspection of is plant in Tucson, Arizona.

The firm's companion diagnostic software device with a microphone for evaluating patients with Parkinson's disease for loudness and communication that has been on the market since September 2009, but it had not established a design history file, the FDA said.

The device software, which was developed by a third party software developer, was not validated, and LSVT lacked a device master record and a documented risk analysis plan for its unclassified companion device.

The firm failed to put procedures in place for controlling device history records, nor did it maintain or document device history records for batch/unit release of the device.

Potential suppliers of the software, microphone and USB used in manufacturing the companion device were not evaluated, the 483 says, and procedures for acceptance of incoming products were not established.

The FDA said the firm had not conducted any quality system management reviews since the business began in 2003, and management with executive responsibility had not reviewed the suitability of the quality system. Not surprisingly, no quality audits had been conducted since the firm was established, and there was no documentation for personnel training.

Read the LSVT Global Form 483 here: www.fdanews.com/10-30-18-lsvtglobalIllc483.pdf.

CDRH Posts Update on Medical Device Testing Accreditation Pilot

The FDA posted an update on its Accreditation Scheme for Conformity Assessment (ASCA) pilot, which aims to streamline conformity assessments for medical device submissions that meet yet-to-be-announced standards.

The pilot will include "a minimum of five appropriate FDA-recognized consensus standards, at least one of which will be device-specific," according to a new ASCA Q&A web page. The standards could include biological evaluation of medical devices and basic safety and essential performance of medical electrical equipment, medical electrical systems and laboratory equipment, according to the document.

During negotiations with industry stakeholders, a consensus emerged that an accreditation program could improve device premarket review, especially standards conformity assessment activities, the agency said.

Under the program, the FDA will define a conformity assessment scheme describing the interactions between and specifications for accreditation bodies and testing labs. The scheme will outline a process for participation by accreditation bodies and testing labs and for the suspension or withdrawal of poorly performing participants.

The agency also said it plans to post public information about ASCA testing labs, including the FDA-recognized consensus standards for which they are accredited, on its website.

In a video released at an ASCA workshop earlier this year, CDRH standards management staff member Scott Colburn said that many testing labs weren't part of the standards development process—but now they can be. That way, "when we receive that test report, we have greater confidence in knowing that what the design of that standard was for can be met with what our perspective was when developing it," he said.

As plans for the ASCA pilot move forward, stakeholders will have more opportunities to provide feedback. The agency says it will publish and seek comments on draft guidance by the end of FY 2019.

That guidance will include more specific information about participation in and operation of the program, which is slated to go into effect by September 30, 2020 — although in the new Q&A the agency says it's "working to do so as soon as possible and before that date."

Read the agency's update here: www.fdanews.com/11-01-18-ASCA.pdf. — Gienna Shaw

APPROVALS

Acandis Gains CE Mark for Accero Stent

German devicemaker Acandis has received a CE Mark for its Accero stent, a smooth-surfaced implant for treating intracranial aneurysms that is now available for sale in Europe.

Accero is a self-expanding braided stent that is designed to exhibit reliable coil retention. It can be delivered through double lumen balloon guide catheters and 0.0165 to 0.0170" microcatheters.

The stent's titanium oxide/oxynitride protective film is designed with high oxygen and nitrogen intensities to improve vessel healing.

FDA OK's Philips' IntelliVue Mobile App

The FDA granted 510(k) clearance for Philips' Intellivue GuardianSoftware mobile application, which allows clinicians to see a patients' vital signs and early warning signs through a mobile device.

The app provides clinicians with real-time data so that they can receive warning of patient deterioration before adverse events occur.

The mobile app is designed to be compatible with certain wearable devices, such as biosensors.

QT Ultrasound's QTviewer Gets FDA's Green Light

The FDA has given QT Ultrasound 510(k) clearance for its QTviewer, the latest addition to its QT Ultrasound breast scanner.

(See **Approvals**, *Page 8)*

Approvals, *from Page 7*

The viewer stores images of the breast for viewing on a radiologist workstation, and has tools for additional image analysis, such as correlate, probe and region of interest.

The QTviewer generates coronal, axial and sagittal images that are used for review of the breast.

FDA Clears Microsoft's HoloLens For Pre-Operative Surgical Planning

The FDA has granted 510(k) clearance for Microsoft's HoloLens, allowing it to be used with the OpenSight Augmented Reality System for planning surgeries.

The OpenSight AR system overlaps 2D, 3D and 4D images on patient's bodies to visualize what doctors may see internally during surgery.

A head-mounted smart glasses device, HoloLens is a self-contained holographic computer.

Baxter's Renal Replacement System And Blood Warmer Cleared in EU

Baxter's PrisMax renal replacement system and TherMax blood warmer both received the CE Mark allowing them to be marketed in the European Union.

The devices are cleared to be used in conjunction with one another. The PrisMax system is used for removing waste products, excessive fluids and inflammatory mediators, while the TherMax device maintains blood temperature while it is purified outside the body.

The two devices also assist in the management of sepsis and kidney injury.

Bio-Rad's Blood Typing Device Receives FDA Clearance

The blood typing results are automatically transferred to Bio-Rad's IH-Com patient data management software.

The FDA has granted 510(k) approval to Bio-Rad's blood typing instrument, which is meant to be used in small to medium-sized laboratories.

The IH-Reader 24 device combines a reader with a centrifuge to read blood type and antibody screening results.

RPS Diagnostics Gains Updated CE Mark for RPC Test

RPS Diagnostics' FebriDx, a rapid point-of-care test, has received an updated CE Mark, clearing it for launch in the EU.

The diagnostic test allows for a 10-minute assessment of the patient's immune response to an acute respiratory infection by analyzing a fingerstick blood sample.

The single-use device points out underlying, clinically significant infections in patients and determines if they are bacterial or viral.

Concepta's MyLotus Brand Receives CE Mark

Concepta's MyLotus products, used to self-measure hormone levels, received the CE Mark.

The devices can be used at home to test a woman's fertility levels to identify optimal fertility and increase the chance of pregnancy.

The products, which are expected to launch in the UK in the coming months via a new online platform, can be used as a low-cost alternative or prior to in vitro fertilization.

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FDANEWS

EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements*

The new EU Medical Device Regulation is massive… complex… and confusing… and you must be ready to comply by May 26, 2020.

When the European Union revised its system of rules for medical device manufacturers in 2017, it replaced a longstanding set of directives on specific topics with one large document that covers all aspects of making devices in EU countries.

Not only did they consolidate all the rules, they gave them greater weight. Previously, medical device directives provided guidance but did not have the force of law. The new MDR, however, contains mandates that are legally enforceable by EU member countries.

The FDAnews report **EU MDR Compliance** can help. Our editors have combed through the regulations, picking out the most minute compliance points and building them into a checklist of 200+ requirements you can use to confirm that you are satisfying all the EU mandates for device manufacturing. The report provides:

- Definitions of key terms in the EU MDR
- Knowing where to find specific requirements in the 150+ page regulation
- Checklists that walk you through every aspect of manufacturing, safety and performance requirements
- A training tool for employees new to the regulations

EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements* is the tool that collects all the requirements, explains them and itemized them in an easy-to-use form to ensure compliance.

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Complaint Management for Devicemakers: *From Receiving and Investigating to Analyzing Trends*

Complaint management is essential to a functioning quality management system.

Understanding the FDA's Quality System Regulation isn't enough — you must also master ISO 13485:2016 and the new EU MDR. They all require devicemakers to conduct trending in some form or another. But none of them tell you HOW.

This new edition of the best-selling **Medical Device Complaint Management** fills in that gap for you.

In addition to teaching the principles of successful complaint management …

- Receiving, documenting and investigating complaints
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It's certain that your complaint management system will come under intense scrutiny in your next GMP inspection. Make sure you can show investigators not only how you have reacted to problems but also how you learn from them and use that information to drive continual improvement.

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