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IN THIS ISSUE

Editor's Note: Due to the holidays, *International Devices & Diagnostics Monitor* will not be published Dec. 26. The next issue will be published Jan. 2, 2017.

FDA Expected to Weather Major Changes During Presidential Transition

During the coming transfer of political power, the FDA will survive major changes despite strong rhetoric and vague promises for reform, said a long-time FDA insider.

Until a new commissioner is confirmed by the Senate, the agency will most likely defer or postpone large policy decisions or dramatic product approvals, said Steven Grossman, former deputy assistant secretary for health at HHS.

President-elect Donald Trump has not clearly outlined his policy for the FDA, but has made several campaign promises that could have a large effect — namely repealing two regulations across government for every one proposed — as well as freezing the hiring of new federal workers, which would leave the agency with hundreds of job vacancies in a workforce of about 15,000. Grossman spoke at an FDAnews webinar.

(See **Transition**, *Page 2)*

FDA, OHRP Publishes Joint Guidance On Electronic Informed Consent

The FDA and the HHS Office of Human Research Protections published a joint guidance on the use of electronic informed consent, containing recommendations for meeting both agency's regulations.

The guidance — presented in a question-and-answer format for sponsors, researchers and institutional review boards — finalizes a draft published in March 2015, with minor changes.

Information can be presented to the patient electronically through multiple media, including text, graphics, audio, video, podcasts and interactive websites, the guidance said. The information must contain all the informed consent elements required by HHS and the FDA. It should be easy to navigate or pause, and allow enough time for the subject to consider whether to participate. Subjects should also receive a copy of their consent agreement.

(See **eConsent**, *Page 2)*

Transition, *from Page 1*

Likewise, little is known of the stance of Trump's nominee for HHS Secretary, Rep. Tom Price (R-Ga.), whose candidacy has focused mainly on the fight to repeal the Affordable Care Act. However, Price would still have input on the selection of FDA commissioner, said Grossman, president of HPS Group, a consulting firm focused on FDA issues.

Meanwhile, Trump's transition team members working on FDA and HHS issues are much more knowledgeable when it comes to policy and government experience, in contrast with those tasked for more political-football agencies, such as the Environmental Protection Agency or financial watchdogs, Grossman said.

However, there is a conservative political view that the FDA is too broad in its reach, and that it malfunctions and hinders progress, and that while the next commissioner will have the power to steer the agency's regulations and approvals, Congress might be wary of seeing any stark changes.

Congress just finished passing its own multi-year, bipartisan reform package in the 21st Century Cures Act, and with user fee reauthorization due by next summer, Capitol Hill might be unwilling to spend time on further changes.

And while members of the pharmaceutical industry welcome reforms, they do not want to see major changes, said Grossman, who is also deputy executive director of the Alliance for a Stronger FDA.

Looking ahead, Price's upcoming Senate confirmation hearings, as well as those for the new FDA commissioner, will be illuminating not just in the candidate's positions, but also how members of Congress will try to force the nominees to commit to a course of action by putting them on the record. However, Grossman said, so far the Trump administration has not felt the need to fit into most traditional norms. — Conor Hale

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eConsent, *from Page 1*

Some subjects may prefer paper-based systems, or have difficulty using electronic systems due to poor eyesight or impaired motor skills — in these cases, electronic informed consent may not be appropriate, and a paper option should be provided. For pediatric studies, parental permission may be obtained through the same processes.

The process may take place in-person at a study site, or remotely — if any part of the process is to be completed remotely, sponsors must include methods to verify the subject's identity. Electronic signatures are acceptable under both FDA and HHS regulations, and the electronic system must ensure the subject's confidentiality and personal information. HIPAA authorizations may also be obtained electronically.

Investigational device exemption (IDE) applications must include copies of all forms and informational materials to be provided to subjects to obtain informed consent. When FDA approval of an IDE application is required, a sponsor must not begin an investigation until that approval is given.

Investigators should submit copies of all electronic and paper forms to their IRB, including any informational materials, websites or videos used during the informed consent process.

The investigator should also submit any written information related to the clinical investigation that is pro-vided to the subject on paper. Subsequent modifications to the study-related information must be approved. IRBs must maintain their own copies, either electronically or as a hard copy.

The full guidance is available here: www.fdanews.com/12-14-16-FDAOHRPeConsentGuidance.pdf. — Conor Hale

New Zealand Proposes To List New Hip, Knee Implants

New Zealand's medical device and drug regulator is proposing to let hospitals purchase orthopedic hip and knee implants made by Stryker New Zealand Ltd.

The Pharmaceutical Management Agency's (PHARMAC) proposal would allow Stryker to supply about 3,700 orthopedic joint implants, additional craniomaxillofacial implants, cement and associated products to District Health Board (DHB) hospitals. DHBs could purchase Stryker's devices at PHARMAC-negotiated prices starting Feb. 1, 2017.

The agreement would not be a sole-supply agreement, and DHBs could continue to purchase other suppliers' brands of orthopaedic implants and associated products.

Final Guidance Calls for Public Notification of Emerging Signals

Almost a year after its draft guidance on communicating new information about medical device safety issues, the FDA has published final guidance that makes some relatively minor changes.

The eight-page final guidance highlights the FDA's need to disclose an emerging signal — new information that a marketed device may cause a problem that affects patient management decisions — at the same time it evaluates the information, rather than after completing its review.

The final guidance eliminates an appendix containing specific wording for public alerts on emerging signals (*IDDM*, Jan. 8). Instead, the final guidance states that the FDA typically will provide a description of the device, a summary of the emerging signal and the supporting evidence, and information on the device's benefits, risks, and use.

Also in contrast to the draft guidance, the final version: adds a new section on how the FDA evaluates emerging signals after they are identified; states that unconfirmed or unreliable information is not considered an emerging signal; adds two new factors for determining whether to issue an alert about an emerging signal, including data quality and the potential for patients not to receive needed treatments even in light of the new information; and states that FDA staff "intends to" (rather than "should") assess the need to issue an alert with 30 days of receiving an emerging signal.

Read the final guidance here: www.fdanews.com/12-14-16-emergingsignals.pdf. — Jeff Kinney

UK Issues Safety Notices For Suction Unit, Blood Analyzer

The UK's Medicines and Healthcare products Regulatory Agency released urgent field safety notices for a range of medical devices, including Laerdal's Medical's compact suction unit, Macopharma's LCRD2 blood filters and Ortho Clinical Diagnostic's Ortho Vision and Ortho Vision and Vision Max blood analyzers.

Laerdal's LCSU 4 compact suction units manufactured after May 2015 might not be able to be turned off without removing the power source, or might turn on by themselves.

Read the Laerdal notice here: www.fdanews.com/12-09-16-Laerdal.pdf.

Red Blood Cell Filters

Macopharma issued a field safety notice after being notified of a .01 percent increase in fast, and thus ineffective, filtrations for its LCRD2 red blood cell filter since June 2016. The company is investigating the cause of this "sporadic defect" and said that so far, tracing the defective filters has not highlighted a single batch, welding machine, or specific operator.

Read the notice here: www.fdanews.com/12-09-16-Macopharma.pdf.

Blood Analyzers

Ortho Clinical Diagnostics issued an urgent field safety notice for user-defined test templates on ORTHO VISION and VISION Max blood analyzers with software version 3.6.0 and below, due to a problem with the software.

Read the notice here: www.fdanews.com/12-09-16-Ortho.pdf.

Hong Kong Issues Warnings For Pacing Leads, Stents, Ventilators

Hong Kong's Department of Heath issued safety warnings for Boston Scientific Ingevity MRI endocardial pacing leads and Percuflex Urinary Diversion stents, Draeger Medical GmbH Oxylog 3000 and Oxylog 3000plus ventilators, and Brainlab radiation treatment software, all of which may have manufacturing or production defects.

Boston Scientific is implementing a voluntary field safety corrective action for 15 of the pacing leads, due to a possibility that the polyurethane boot at the terminal end of the lead was not securely connected.

In addition, Boston Scientific is recalling certain lots of Percuflex Urinary Diversion Stent Kits in Japan because the wrong size connectors were included with the stents, which could cause minimal delays in procedures.

Draeger Medical GmbH issued a medical device safety alert concerning its Oxylog 3000 and Oxylog 3000plus ventilators, due to a manufacturing defect in which the loss of contact of one of the control knobs generated an error message and caused the devices to stop working. The manufacturer has developed new software designed to fix the problem.

Finally, Brainlab issued a medical device safety alert concerning its iPlan RT, iPlan RT Dose (all versions) and BrainSCAN (discontinued) radiation treatment software when using the pencil beam algorithm for dose calculation of small MLC-shaped fields.

In these devices, the pencil beam algorithm refers to beam data that is acquired by performing dose measurements for Multileaf Collimator fields at predefined field sizes and that are stored using the iPlan RT Physics Administration /BrainSCAN Beam Profile Editor. For each beam contained in a radiation treatment plan, dose calculation is performed based on these tabulated measurement values. If a beam's equivalent field size does not correspond to the measured field size, the measured values are interpolated accordingly.

Due to an inaccurate implementation in the software, this interpolation between two measured values is less accurate. For certain treatment setups, this leads to an insufficient amount of Monitor Units being calculated and the delivered dose being lower than the planned dose.

China's NDRC Fines Medtronic $17M for Price Fixing

China's National Development and Reform Commission fined Medtronic's Shanghai enterprise $17 million for price fixing.

The NDRC took issue with Medtronic for setting minimum wholesale prices for its cardiovascular and diabetes products with its distributors in China, violating Article 14 of China's antimonopoly law.

China's NDRC took the position that Medtronic, the country's leading medical device maker with about $1.5 billion in China sales in 2015, was using contracts with distributors to tighten its control on the market and drive up prices.

Medtronic Spokesman Fernando Vivanco confirmed that Medtronic was investigated by China's NDRC related to the country's antimonopoly law and he said in an interview that the company accepts the NDRC's decision.

An attorney in Shanghai said that the practice of setting a minimum price is considered one of five types of price manipulation in China. She said that the practice "deprives sub-tier distributors from setting their own prices" and that the government is trying to reduce the price of high-value consumables such as medical devices.

Device makers in China can supply directly to hospitals or go through distributors, but the more common practice is to sell directly to hospitals via collective tendering. — Tamra Sami

United Contact Lens Cited For Testing, Complaint Procedures

United Contact Lens received a warning letter for failing to test finished products and establish written customer complaint procedures.

The FDA inspected United's Arlington, Wash., facility in October and discovered that the firm failed to establish and maintain procedures to ensure that all purchased products and services conformed to specified requirements.

In particular, United did not establish purchasing control procedures for evaluating suppliers, contractors, and consultants. This is a repeat observation from a 2013 inspection.

Inspectors also revealed that the firm did not establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit.

United's customer complaint procedure states that a determination will be made as to whether a Medical Device Report must be filed and a customer complaint form completed. However, this determination reportedly was not documented for 15 complaints received since January of 2015.

Other observations include a failure to establish procedures for quality audits, establish and maintain corrective and preventive action (CAPA) procedures, and establish and maintain equipment maintenance procedures.

Separately, United Contact Lens received a Form 483 after an inspection revealed CAPA violations and inadequate written procedures.

Investigators recorded nine observations during the October inspection, including insufficient CAPA procedures. For example, the procedures did not include quality system deficiencies.

Other issues included unestablished or inadequate quality audit procedures, procedures for finished devices, and equipment calibration procedures.

The warning letter is here: www.fdanews.com/12-13-16-UnitedContactLens.pdf

The Form 483 is here: www.fdanews.com/12-09-16-unitedcontactlens.pdf. — Derek Major

Orchid Orthopedics Gets Form 483 for Software Validation

Orchid Orthopedics Solutions received a Form 483 after inspectors found that the company failed to validate computer software and properly document rework and re-evaluation activities.

After an inspection of the medical device development and manufacturing company's Memphis, Tenn., Facility in March, it was discovered that Orchid failed to validate computer software used as part of production.

The FDA also found that device history records showing rework and reevaluation activities did not include a determination of whether there had been any adverse effects from these activities on the devices. In addition, rework procedures did not require an adverse effect determination to be made.

Read the Form 483 here: www.fdanews.com/12-09-16-Orchid.pdf.

Ultroid Technologies Receives Form 483 for Lack of CAPA Procedures

The FDA handed Ultroid Technologies a Form 483 after an inspection revealed inadequate corrective and preventive action (CAPA) procedures.

The August inspection noted ten observations, including that Ultroid's CAPA records did not identify why seals were broken in a kit used with a hemorrhoid management system. CAPA records also did not clearly show that user errors caused problems with the system's cable connections.

In addition, Ultroid's records did not cover review, verification, or validation of a change to a sterile barrier for the probe used with the Hemorrhoid Management System. There also were no records covering verification or validation of a change to the cable for the system's hand piece.

Ultroid also did not fully implement its internal quality audit procedures or make available for copying the production and labeling records for its Hemorrhoid Management System.

The full form can be seen here: www.fdanews.com/12-09-16-UltroidTechnologies.pdf. — Derek Major

Inservco Inc. Receives Form 483 Citing Procedures, Device History

Inservco Inc. received a Form 483 for not establishing a complaint handling procedure, failing to properly maintain device history records, and other violations.

During an inspection of the quality assembly and test services company's Lagrange, Ohio facility in late February and early March, inspectors determined that company procedures did not state how all complaints were processed in a uniform and timely manner, how oral complaints were documented, or that complaints would be evaluated for investigation and that the evaluation would be documented.

The FDA also found that Inservco did not establish adequate procedures that defined the responsibility for review and disposal of nonconforming products. The procedures it had failed to capture all nonconformance data for evaluation, or address how nonconformance material reports should be voided or deleted.

In addition, the manufacture of about 85 devices was not properly documented in device history records. Required documents included a certificate of compliance, finished product device release, and final acceptance inspection report form, none of which were included in the device history records for these products.

Lastly, procedures for accepting incoming products and calibrating equipment were not followed, and personnel training was not properly documented. With regard to personnel training, the company did not maintain training records for any personnel related to its quality policy, quality procedures, or quality system regulations, including but not limited to complaint handling, nonconformance and CAPA management and medical device reporting. Inservco also failed to follow its resource management procedure which states that the quality policy, quality system regulations, and applicable quality procedures are formal training requirements that require formal training records to be maintained for all personnel completing them.

Read the Form 483 here: www.fdanews.com/12-09-16-Inservco.pdf.

CryoSurgery Hit With Form 493 For Acceptance, Quality Procedures

CryoSurgery Inc. landed a Form 493 for poorly documented acceptance activities and inadequate procedures for ensuring the quality of received products.

During an inspection of the refrigerated gases company's Nashville, Tenn. facility, the FDA found that acceptance activities were not adequately documented and maintained as part of device history records for cryotherapy canisters following their distribution. Specifically, checks of boxes of the canisters were documented on the outside of each box. However, when the boxes were discarded, the acceptance activity record was not maintained.

Inspectors also reported that CryoSurgery failed to establish procedures to ensure that all purchased or otherwise received products and services conformed to specified requirements. In particular, the company did not establish requirements for evaluating and controlling suppliers of services and consultants, and a vender providing calibration services was not evaluated based on its ability to meet requirements.

Read the Form 483 here: www.fdanews.com/12-09-16-CryoSurgery.pdf.

FDA Reaches Agreements To Use Device Registries

The FDA recently reached agreements to use 14 device registries as part of its ongoing effort to harness real-world evidence to evaluate the performance of medical devices.

CDRH Director Jeffrey Shuren last week reiterated in an interview with *IDDM* that using real-world evidence, including data gathered by the National Evaluation System for health Technology (NEST), is one of his top priorities in 2017.

The FDA has also awarded $3 million in seed funding to the Medical Device Innovation Consortium (MDIC) to establish NEST to collect and analyze data from clinical registries, electronic health records, medical billing claims, data transmitted from devices and other sources throughout the medical device life cycle.

Currently, NEST is seeking nominations and applications for inaugural members of its governing committee. The governing committee will provide strategic oversight and leadership, and will be supported by an executive director who will provide operational leadership to staff and ongoing working groups. Committee members will serve up to 3-year terms.

Applications and nominations for NEST Governing Committee positions must be submitted by Jan. 16, 2017.

More information on the governing committee is here: www.fdanews.com/12-12-16-governingcommittee.pdf.

BRIEFS

FDA Finalizes Ban On Powdered Gloves

The FDA has finalized a ban on most powdered gloves in the U.S., as the agency says they pose unreasonable and substantial risks that cannot be corrected through new or updated labeling.

The final rule is substantively identical to a proposed rule issued in March (*IDDM*, March 25), except for clarifying that the ban applies to all powdered patient examination gloves and powder surgical gloves, regardless of the material from which they are made. According to the FDA, language in the proposed rule could have been interpreted to mean that only powdered natural rubber latex and powdered synthetic latex gloves were banned, which was not the agency's intent.

Read the final rule here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-30382.pdf.

FDA Finalizes Rule On Pediatric Hospital Beds

A FDA final rule renames pediatric hospital beds as pediatric medical cribs and establishes special controls for these devices.

(See **Briefs**, *Page 8)*

Briefs, *from Page 7*

The rule also creates a separate regulation that places medical bassinets in Class II and establishes special controls.

The rule stems from reports of malfunctions in medical cribs such as drop-sided rails not latching, and reports of medical bassinet tipping or not being cleaned properly.

Read the final rule here: www.fdanews.com/12-16-16-cribs.pdf.

Gordian Surgical Gets FDA Clearance for TroClose1200

Gordian received FDA clearance for TroClose1200, a trocar with a combination closure system for the binding of abdominal wall incisions during minimally invasive surgical procedures.

The device is a 2-in-1. It serves as a trocar, which opens the abdomen and closes internal incisions made during surgery.

Gordian received a CE Mark in September.

FDA Expands Clearances For AMI's TubeClear System

Actuated Medical has received additional FDA clearances for TubeClear therapy system.

This clearance allows the device system to be utilized in feeding tubes as narrow as 2mm and decompression tubes 2mm to 3mm in adult patients.

The device is also cleared to not only be cleaned by other health professionals whose patients have clogged feeding tubes, but also while the tube is implanted in the patient.

Provision Healthcare Obtains FDA Clearance for SC360 Therapy System

ProNova Solutions gained FDA clearance for SC360 proton therapy system.

The device is a patient-bed scanning radiation system that treats cancer patients at all angles without moving the patient.

Centurion Issues Recall On Multi-Med Single Lumen Catheters

Centurion Corp. has recalled convenience kits that have multi-med single lumen catheters due to potential excess material that remains at the tip of the catheter from the manufacturing process.

The catheter is used to sample blood and administer drugs or fluids. This manufacturing error can lead to separation during use and cause blood clots, embolisms and even death.

FDA Awards Lumendi Marketing Clearance for DiLumen

Lumendi has received FDA marketing clearance for DiLumen, an endoscopic device used in the surgical treatment of colon lesions.

DiLumen is a flexible single-use sheath component that attaches to the end of a colonoscope. During surgery, the sheath expands its two balloons to widen the stomach tubes to create an operable area to treat stomach lesions.

FDA Grants ISO 13485:2003 Certification to Eclipse Aesthetics

Eclipse Aesthetics achieved ISO 13485:2003 certification and the total use of their quality management systems.This certification allows the company to continue manufacturing its platelet-rich plasma kit, Eclipse PRP.

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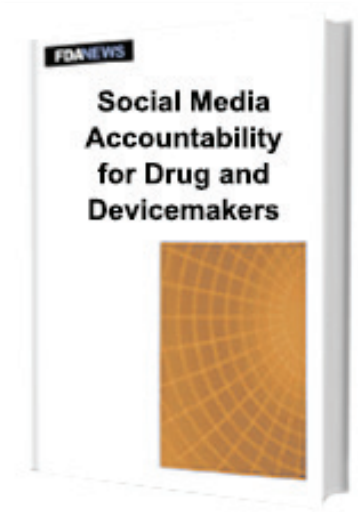

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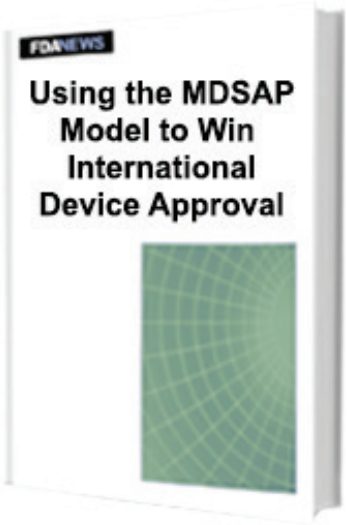

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