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IN THIS ISSUE

Gottlieb Reassures Staff as User Fee Deadline Approaches

FDA Commissioner Scott Gottlieb sought to assure agency staff last week that Congress will reauthorize its user fee programs before the Sept. 30 deadline, which promise to provide the agency more than $1.4 billion in funding for reviewing activities and staff salaries in the next fiscal year.

A finalized user fee reauthorization package — which passed the House July 12 — would leave the agency much more apt to hire rather than fire.

In an FDA-wide email, Gottlieb said he was confident the reauthorization bill would be considered in a timely manner — hopefully before the Senate adjourns for its summer recess, which has been delayed two weeks until mid-August.

Gottlieb said he would postpone sending out any "reductions in force" notices — legally required to be sent to federal employees 60 days ahead of potential layoffs — until after Sept. 30, the day the

(See **Gottlieb**, *Page 2)*

FDA Launches Device Software Pre-certification Pilot

The FDA's new pilot program for pre-certifying software for digital medical devices is up and running — and companies can apply to take part in the program on August 1.

FDA Commissioner Scott Gotlieb, who announced the pilot's formal launch last week, said the agency wants to lower regulatory hurdles and encourage innovations, noting healthcare has been slow to adopt disruptive technology tools like digital devices.

"We need a regulatory framework that accommodates the distinctive nature of digital health technology, its clinical promise, the unique user interface, and industry's compressed commercial cycle of new product introductions," he said.

The goal of the agency's new approach is to determine whether a company meets the necessary quality standard. Pre-certified

(See **Software**, *Page 2)*

Software, *from Page 1*

companies could submit less information than is currently required before marketing a new digital health tool. In some cases, pre-certified companies may not have to submit a premarket submission at all, Gottlieb said.

Rather than focusing on individual products, the pilot will take a company-based approach, so CDRH can "pre-certify" digital health developers with a culture of quality and organizational excellence.

The pre-certified firms could then qualify to market their lower-risk devices without additional FDA review or with a more streamlined premarket review.

The pilot program will include up to nine software firms of various sizes. The agency plans to include non-traditional software developers as well as medical product manufacturers. To qualify for the program, companies must have a track record in developing, testing, and maintaining software products and demonstrating a culture of quality and organizational excellence measures, the agency said. In addition, they must agree to collect real-world post-market data and provide it to the agency.

Read the *Federal Register* notice on the pre-certification pilot program here: www.fdanews.com/07-28-17-precertificationpilotprogram.pdf.

Read the Digital Health Innovation Act Plan here: www.fdanews.com/07-28-17-DigitalHealth.pdf.

Gottlieb, *from Page 1*

user fee programs expire, in the event that Congress does not act. The letters were previously anticipated in late July.

"My conversations with members of the Senate leave me with a high degree of confidence that the User Fee programs will be reauthorized before this September 30 deadline," Gottlieb wrote in the email.

It is unclear whether this means layoffs caused by a lack of user fee funding would then take effect around early December, and whether the agency alone would have the authority and funding necessary to cover the resulting 60-day gap.

Sen. Lamar Alexander (R-Tenn.), chairman of the HELP Committee, said that failing to pass the user fee bill would result in layoff notices being sent to more than 5,000 FDA employees, urging members to vote as soon as possible.

The user fee bills include provisions for the hiring of at least 230 additional full-time equivalents before 2022, to help the agency meet its goals of faster reviews and inspections. The next generation of user fees is expected to bring in a total of $1.42 billion in fiscal 2018, including a 45.2 percent increase over the $126 million expected from MDUFA this fiscal year (*IDDM*, July 17).

The agency is aiming to fill several hundred long-unfilled vacancies using new hiring and negotiating authority granted in the 21st Century Cures Act, as well as its recently announced initiative to modernize the FDA's recruitment process. In addition, the FDA has been actively recruiting at meetings and trade shows.
— Conor Hale

Senate's 'Skinny' ACA Repeal Fails

The Republican effort to repeal the Affordable Care Act came to a halt in the Senate early Friday morning — with nays from Sens. Lisa Murkowski (R-Alaska), Susan Collins (R-Maine) and John McCain (R-Ariz.) — taking with it an extended moratorium on the device excise tax.

The "skinny repeal" plan represented a stripped-down version of the larger bills that had failed to pass over the past week. The final version of the repeal plan would have postponed the implementation of the medical device excise tax to January 2021. The excise tax is estimated to collect nearly $20 billion by 2026, starting January 2018.

Eyes now turn to the Senate's reauthorization of the FDA's user fees. Passed by the House earlier this month, its consideration was pushed until after the ACA repeal measures.

Whitehall Manufacturing Draws FDA Warning for Therapy Devices

Whitehall Manufacturing received a warning letter for multiple violations concerning its whirlpool immersion hydrotherapy and dry heat therapy devices.

Whitehall, a division of Acorn Engineering Company located in the City of Industry, Calif., produces healthcare and rehabilitation equipment, including physical therapy and sports medicine products.

An FDA investigator inspected the facility on March 6-23 and found numerous violations, including failure to establish a designated unit with formal procedures for receiving and evaluating consumer complaints; failure to investigate the possible failure of a device; and failure to establish a design history file or maintain a device history record.

The investigator also noted that Whitehall management executives had failed to conduct adequate and timely product quality reviews. Management also failed to identify training needs and provide appropriate training for their employees. The company failed to report problems with malfunctioning devices within 30 calendar days as required by CFR 803.50(a)(2) if the malfunction would be likely to cause or contribute to a death or serious injury.

Whitehall responded to the FDA notification of violations on April 13, submitting updated complaint handling procedures and other requested information, but the response was deemed inadequate by the agency.

Whitehall also submitted a medical device reporting procedure for their devices as required, but the FDA found the submitted procedure did not establish effective internal procedures for reporting problems.

The July 12 warning letter specifically addresses cases in which the dry heat therapy device and the hydrotherapy device failed and were replaced without documentation. In one case, the customer reported that a hydrotherapy device smelled like it was burning. In another case, a customer reported a defective turbine; the company replaced the turbine and brought the defective one back for testing, but did not document any subsequent test results. In yet another case, a defective splint pan therapy device, used to soften and custom shape splint material, caused the water temperature in the device to rise above the boiling point, but no investigation was documented.

Read the Whitehall Manufacturing warning letter here: www.fdanews.com/07-27-17-Whitehall.pdf. — Donna Scaramastra Gorman

National Biological Lands Warning For Nonconformance, Complaints

The FDA warned National Biological Corp. for failure to thoroughly investigate complaints and improper handling of out-of-spec products.

Following an inspection of the company's Beachwood, Ohio, facility, the agency issued a warning letter noting the company did not validate numerous pieces of equipment used to manufacture its phototherapy devices. The facility failed to validate its crimping machines, including the machine used to produce the devices.

Moreover, according to investigators, the facility had not validated the gluing/curing process it used to manufacture the devices.

The agency also took issue with the company's procedures for nonconforming materials. The procedures for such materials did not require evaluations, including determining the need for an evaluation, for all nonconformances, as required by 21 CFR 820.90.

The inspection further found that 500 nonconformances listed as scrap, return to vendor or "use as is" were not evaluated to determine if an investigation was needed, and 14 nonconformances in the facility log were not assigned an initial or final disposition.

(See **Biological***, Page 4)*

Malaysian Government Updates Requirements for Exempt Devices

Malaysia's Medical Device Authority updated its requirements for medical devices exempt from registration and is requiring notifications for demonstration models for marketing or education, models built for clinical research or performance evaluations, and custom-made or special access devices.

Importers or manufacturers of these devices are exempted from the requirement of an establishment license, but they must notify the agency using specific forms for each category of exempt product.

Notifications also are required for any changes in clinical trials, serious adverse events, progress reports on investigational devices, or export or disposal of devices upon completion of a clinical investigation.

Biological, *from Page 3*

The agency also took the company to task for its handling of complaints. Company procedures for complaints did not address whether an investigation was needed, and complaints were assigned a failure code rather than being evaluated and investigated. Furthermore, the facility's purchasing and vendor requirements did not list consultants and contractors or off-the-shelf components it uses.

The FDA also hit National Biological for violating risk analysis requirements. The company failed to incorporate several potential hazards from postmarket data into its risk analysis documents, such as complaints indicating potential risks from sharp edges and incorrect timer readings.

Investigators found the company did not properly calibrate the heat gun used for solder sleeve assembly for its phototherapy device, and the records listed no calibrations by personnel.

Lastly, the company maintained incomplete device history records that failed to properly document rework and reevaluation activities. Three of the six nonconformance reports documenting rework could not be tied to a device history record.

Read the National Biological Corp. warning letter here: www.fdanews.com/07-27-17-NatBio.pdf. — Zack Budryk

GAO Says Disposable Devices Should Be Covered by Medicare

The Government Accountability Office wants the Centers for Medicare & Medicaid Services to consider allowing the use of disposable medical devices in some situations where durable devices had only been covered by Medicare.

That's the thrust of GAO's new report, *Medicare: CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment*, published July 17.

Said the report's authors, Medicare spent $6.7 billion on durable medical equipment (DME) in 2015. Since companies have developed disposable versions of some of those devices, using those new products could reduce cost and provide better health outcomes. But Medicare generally does not cover disposable medical equipment.

GAO identified eight disposable devices that could potentially substitute for DME items that are covered. They fall into the Medicare DME categories of infusion pumps, including insulin pumps; blood glucose monitors; sleep apnea devices; and nebulizers.

Better Outcomes

The GAO researchers found that some of the disposable devices "could potentially save money or result in better health outcomes compared to the durable versions in some cases, but they are not covered by Medicare."

If Medicare starts allowing the use of disposable medical equipment in situations where it used to require durable medical equipment, how might that affect demand for non-disposable devices?

Martin Gahart, assistant director of healthcare for GAO said demand for both disposable and durable medical equipment "would in part depend on the method that Medicare pays for the devices. Currently, there are not a lot of disposable devices on the market, and they may not be appropriate substitutes in all cases."

Some stakeholders noted that CMS's DME definition is a disincentive to technological innovation, and the agency has already faced challenges making coverage decisions with some devices. Durable medical equipment is defined as equipment that lasts at least three years.

If Medicare coverage were expanded to include disposable DME substitutes, CMS would need to consider issues related to benefit category designation, said GAO. The agency identified three possible options for covering disposable DME substitutes: an expansion of the current DME benefit, an expansion of the current home health benefit, or establishment of a new benefit category.

Next Steps

The Congressional Appropriations Act, 2016, included a provision that GAO review the potential role of disposable medical devices as substitutes for durable medical equipment, Gahart said. Some of the language for the provision was first included in a bill proposed in the Senate in 2015. Even so, according to the report, HHS stated that such an evaluation was premature.

Now that this report is out, what are the next steps? "We recommended that the Centers for Medicare & Medicaid Services evaluate the potential costs and savings of using disposable devices as substitutes for durable medical equipment, and then—if deemed appropriate—seek the legislative authority to cover them," Gahart told *IDDM*.

"What happens next in part depends on what actions CMS and/or Congress decides to take. GAO's next steps are to follow-up with CMS periodically to ensure that the agency is conducting this evaluation and taking any action CMS deems appropriate based on the results of their efforts," he said.

Read the 39-page GAO report here: www.fdanews.com/07-27-17-GAO.pdf. — Suz Redfearn

India Releases Guidance on Safety And Performance Principles

India's Ministry of Health and Family Welfare released draft guidance on essential principles for safety and performance of medical devices marketed in India.

The country recently finalized new medical device regulations and the regulators worked with device and diagnostics stakeholders to develop principles for compliance with the new rules.

Effective Jan. 1, 2018, device manufacturers will no longer be required to comply with regulations written for pharmaceuticals. For example, the drug regulations mandate four-phase clinical trials, whereas the new device regulations require two-phase trials (*IDDM*, Feb. 17).

The draft guidance "does not dictate how a manufacturer should prove that their medical devices have met the essential principles," the Drugs Controller General said, noting the document provides flexibility so manufacturers can continually use the most advanced technologies to develop new devices.

The guidance lays out the following requirements of safety and performance that apply to all medical devices and IVDs:

- Devices are to be designed and manufactured so that they perform as intended and don't compromise the clinical condition or safety of patients;
- Solutions adopted by the devicemaker should confirm to safety principles and take into account state-of-the-art technology. Risk should be controlled to an acceptable level. To minimize risk, the devicemaker should first identify foreseeable hazards and estimate the associated risks. Then it should eliminate as much risk as possible, reduce remaining risk, take adequate protection measures and inform users of any residual risk;
- Devices need to be designed, manufactured and packaged so that under normal conditions, they are suitable for their intended purpose;
- The characteristics and performance of the device should not adversely affect the health or safety of the patient or user when the "device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions;"
- Devices should be designed, manufactured and packaged so that their characteristics and performance are not adversely affected by transport and storage conditions;
- All known and foreseeable risks "and any undesirable effects" should be minimized and be acceptable when weighed against the benefits of the device under normal conditions; and
- Every device requires clinical evidence appropriate for its intended use and it must be classified to demonstrate that it complies with provisions of the essential principles.

Clinical evaluation should include clinical investigation reports, literature reviews or clinical experience to establish a favorable benefit-risk ratio – and clinical studies must be carried out according to the new Medical Device Rules.

For diagnostic devices with a measuring function, the emphasis is placed on accuracy, precision and stability based on appropriate scientific design to address sensitivity, specificity, and reproducibility. The guidance stresses traceability and quality control measures.

The 27-page guidance also covers risks associated with medical devices incorporating biologic materials, including those incorporating cells, tissues and derivatives of microbial recombinant origin. It covers infection and microbial contamination, manufacturing and environment properties, combination devices, devices that incorporate software, protection against mechanical risks and radiation, performance evaluation and labeling requirements.

Definitions for analytical performance, clinical data and evaluation; harm, risk and hazards; are also included.

Read the draft guidance document here: www.fdanews.com/07-27-17-EssentialPrinciplesSafety.pdf.

483 Roundup: Device Firms Flagged For Quality, Complaint Procedures

The FDA cited three devicemakers for a variety of deficiencies including quality and complaint procedures and equipment problems.

Trinity Sterile: Trinity Sterile was cited for lack of quality audits, equipment maintenance, and incomplete device history records.

The agency issued a Form 483 after a February-March inspection of the firm's Salisbury, Md., facility. Investigators found the company did not sufficiently detail the maintenance process for several pieces of equipment and machinery, including sealing machines, HVACs and air compressors, boilers and sterilizers.

The agency also found 18 of 40 2015 audit "elements" where the audit was left incomplete, and none of the 2016/2017 audits were closed.

The company's machine validation protocols lacked clearly-defined acceptance criteria for validating all five machines in manufacturing, and test failures occurred in three of the five without justification. In its CAPAs for nonconforming products, the company failed to create a noncomformance form or determine the root cause, which the agency noted as a repeat observation.

The devicemaker had no design control procedures for its convenience kit products relating to expiration dates, defined user needs and intended uses, or risk analysis for packing or life expectancy. Eleven of 15 CAPAs did not identify a root cause, check for effectiveness or perform corrective actions.

Saginaw Medical Services: Saginaw Medical Services drew a Form 483 for the absence of quality and acceptance procedures as well as its failure to maintain device records.

The agency issued the form after a May inspection of the firm's Saginaw, Mich., facility. According to investigators, the facility had no procedures or directions in place regarding its quality policy, management reviews or audits, and did not conduct regular audits. The company had completed several made-to-order wheelchair cushion jobs since the beginning of 2015, but had no documentation describing the production procedures.

The firm also failed to produce documentation of the acceptance activity for the cushions' final fitting process or procedures for this activity, the agency said. Investigators found the firm's complaint procedures did not include an evaluation process for whether a complaint is reportable as an MDR. It also lacked device master records or device history records for the cushions.

Lantz Medical: The FDA put Lantz Medical on notice for issues ranging from undefined complaint procedures to a lack of procedures for device history records.

The agency issued a Form 483 following a May inspection of the firm's Indianapolis facility. Inspectors found the company had no requirements for analyzing whether complaints warrant investigations. Lantz also lacked procedures for evaluating complaints to determine whether they must be reported to the FDA as an MDR, and it had no procedures for MDR submissions.

Investigators also highlighted Lantz's CAPA procedures, noting they did not require analysis of quality data for the company's Vector I Hand Rehabilitation System. The company also had insufficient procedures for ensuring conformance and design control, receiving or inspecting components, or maintaining device history records.

Lantz lacked procedures for selecting suppliers or for performing quality audits. The company also failed to document management reviews from June of 2014 to May 2017. The facility's document control procedures did not require changes to be approved before implementation.

Read the Trinity Sterile Form 483 here: www.fdanews.com/07-27-17-trinitysterileinc483.pdf.

Read the Saginaw Medical Services Form 483 here: www.fdanews.com/07-27-17-saginawmedicalserviceinc483.pdf.

Read the Lantz Medical Form 483 here: www.fdanews.com/07-27-17-lantzmedicalinc483.pdf.

— Zack Budryk

APPROVALS

FDA Clears First Neonatal MRI Device

The FDA cleared Aspect Imaging's Embrace Neonatal MRI System as the first MRI device specifically for neonatal brain and head imaging in neonatal intensive care units.

The system includes a temperature-controlled incubator that minimizes movement of the baby. The device can be used on neonates with a head circumference up to 38 centimeters and weight between 1 and 4.5 kilograms.

The unit does not require a safety zone or a radiofrequency shielded room. It is fully enclosed, so medical device implants in close proximity to the system are not required to be "MR Conditional" or "MR Safe."

Royal Philips' Psoriasis Treatment Device Cleared

Royal Philips received 510(k) clearance from the FDA for its BlueControl light therapy device for treating milk psoriasis.

A Class II, home-use prescription product, the wearable device obtained CE Mark approval in 2015 and has been rolled out in select European countries, including the U.K. and Germany.

The company hopes to launch the device in the U.S. market in early 2018, in collaboration with dermatologists and patient support groups.

FDA Clears Saebo's Virtual Reality Rehab System

Medical virtual reality device manufacturer Saebo received FDA clearance for its *Saebo*VR rehab system.

The proprietary platform engages clients in physical and cognitive challenges involving daily functional activities, using a virtual assistant that appears on the screen to provide real-time feedback.

The Charlotte, NC, company's system exercises injured or impaired limbs in simulations of daily activities including grocery shopping and preparing meals.

The device can be personalized to alter coordination, timing, speed, endurance and range of motion, and the software issues graphical reports after each session.

CFDA Approves Gilupi CTC Device

The China Food and Drug Administration approved the Gilupi CellCollector, a circulating tumor cell isolation device.

The firm credited its strategic partner and largest shareholder Hebei Viroad Biotechnology for assistance with the CFDA approval. Gilupi plans to launch the product in China using Viroad's experience with the Chinese market.

The CellCollector was the first in vivo CTC isolation device to secure the CE-mark.

CSA Medical's trueFreeze Catheter Tech Wins Expanded 510(k) Approval

The FDA awarded 510(k) clearance for an expansion of CSA Medical's trueFreeze catheter device.

The new approval covers a third spray kit that allows the user to cut the time of liquid nitrogen spray in half, which shortens treatment time. The system is indicated for cryosurgery in dermatological, gynecological and general surgery procedures.

The expansion re-establishes trueFreeze's approval to treat Barrett's Esophagus and malignant lesions. The system allows users to deliver liquid nitrogen to destroy cancerous tissues in the esophagus.

FDA Approves EIT's 3D-Printed Spinal Support Implants

The FDA issued marketing clearance for Emerging Implant Technologies' 3D-printed titanium spinal support implants.

The German company's titanium implants are already approved in more than 15 countries. The device is made 80 percent porous, using a selective laser melting process.

(See **Approvals***, Page 9)*

Approvals, *from Page 8*

The device will enter the market along with competitors. Virginia-based K2M has already secured the FDA's clearance for its 3D printed lumbar support cage, as has a Stryker 3D spinal implant.

Cardiac Troponin Test Receives CE Mark

Singulex has received the CE Mark for its Singulex Sgx Clarity cTnl assay for the biomarker troponin. The assay is indicated for use in conjunction with a clinical evaluation for ruling out cardiac ischemia in patients suspected of having coronary artery disease.

The company plans to submit data for FDA clearance of the assay in 2018.

Voluntis Secures FDA Clearance, CE Mark For Digital Diabetes Management System

Voluntis received FDA clearance and CE Mark approval to integrate Insulia, its digital diabetes management system, with Sanofi's Toujeo insulin glargine.

The system uses a patient mobile app and web portal to provide real time insulin dosage recommendations and information.

Voluntis plans to launch the system in the European market in the near future. It is currently working on an extension for the app to include basal insulins and GLP-1 basal insulin combos.

Biotronik Atrial Leadless ICD Line Scores FDA Approval

The FDA approved Biotronik's Intica DX and Intica CRT-DX implantable defibrillator systems.

The Intica device line is the first that does not require an atrial lead because it provides atrial signal information. The systems remove several of the risks and complications associated with implanting cardiac resynchronization therapy devices.

The new device also incorporates the German company's MultiPole Pacing technology, which allows two pacings per cardiac cycle for the left ventricle.

Masimo Scores CE Mark for RPVi Device

Masimo was granted CE Mark approval for its multi-wavelength version of the Pleth Variability Index for monitoring changes in fluid volume.

The approved device, the RPVi, is a noninvasive continuous measurement device that monitors changes in the perfusion index during respiratory cycles. The changes can reflect physiologic factors ranging from vascular tone to circulating blood volume.

The company recently received CE Mark approval for its Rainbow Super DCI-mini sensor, a reusable spot-check sensor with multiple physiologic measurements.

FDA Clears DarioHealth's Glucose Meter and App

DarioHealth secured 510(k) clearance from the FDA for its combination glucose meter and app for Android devices.

The pocket-sized meter device syncs with a companion app, available on Android and iOS devices, which includes a nutrition guide and log. Users can view the raw data as well as patterns and trends.

Since receiving FDA clearance in December 2015, DarioHealth has marketed the product in the U.S. exclusively for the Apple iOS 6.1 platform and higher.

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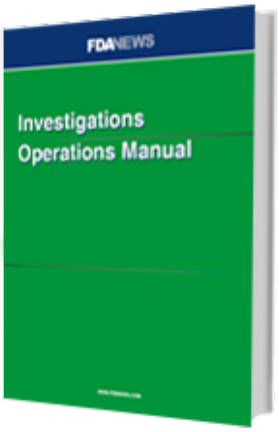

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