INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 4, No. 6
Feb. 5, 2018

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Brazil Doubles License Registration Timeframe for High-Risk Devices, IVDs

Brazil's National Surveillance Agency has extended the registration period for high-risk Class III and Class IV devices and in vitro diagnostics from five years to 10 years.

Licenses already granted in Brazil will be automatically awarded the 10-year extension, which became effective Jan. 22.

ANVISA made the decision to extend the license period on Jan. 16 after consulting with the ANVISA board of directors and industry. The authority had announced in August 2017 that it was considering doubling the registration period for devices and IVDs, saying the move would cut costs for industry and reduce bureaucratic layers (*IDDM*, Aug. 14, 2017).

Extending the medical device registration period for higher-risk devices to 10 years will substantially improve market access, BMI Research Analyst Karen Simpkins told *FDAnews*.

"For comparison, medical device registrations are valid for five years in Argentina and Mexico. The extended validity timeframe, along with other recent regulatory developments, will further

(See **Brazil**, *Page 2)*

CDRH Clarifies Acceptance and Refusal Policies for 510(k)s and PMAs

CDRH updated its guidances on policies used for making determinations on accepting or refusing 510(k) submissions and premarket approval applications.

The guidance on 510(k)s and the one on PMAs supersede agency policies set forth in 2015 and 2012, respectively, prompted by commitments under the FDA Reauthorization Act of 2017 to base MDUFA IV performance goals on how long it takes to complete an application or submission review.

The guidances are intended to provide devicemakers a better understanding of the types of information required for a 510(k) to meet a "minimum threshold of acceptability" and for a PMA to be

(See **510(k)**, *Page 6)*

Gottlieb Calls for New Legislative Authority for Diagnostics

The FDA will be looking for new authority to regulate diagnostics, Commissioner Scott Gottlieb said in a session on precision medicines at the World Economic Forum in Davos, Switzerland.

"I think it's time that the agency needs to work with Congress and stakeholders to develop very specific targeted legislation that would give us a unique set of authorities to regulate diagnostics properly," Gottlieb said.

"My view is that the old 510(k), PMA pathway…the traditional pathway for approving medical devices, doesn't really fit well with modern diagnostics, and we need very well-fashioned authorities when it comes to diagnostics," he added.

The agency will issue guidance for the design of precision medicine clinical trials that are steered more towards safety, off-target effects and long-term implications and durability. It will seek accelerated approval for precision medicines, designed to optimize efficiency or therapeutic benefit for particular groups of patients, especially by using genetic or molecular profiling, according to Gottlieb. — James Miessler

Brazil, *from Page 1*

enhance the attractiveness of the Brazilian market, which already has one of the lowest regulatory risks in the Latin American region," Simpkins said.

Brazil has made a number of regulatory changes aimed at simplifying market entry for foreign devicemakers, such as getting rid of certain import requirements, including mandatory inspections at entry points. ANVISA will no longer require inspections of medical devices and IVDs at import locations after receiving product clearance, according to newly released guidelines (*IDDM*, Jan. 29).

AdvaMed said devicemakers reported long delays in clearing devices through customs in Brazil, largely due to bottlenecks in ANVISA's inspection procedures.

"In 2016, these delays increased to over 60 days versus the previous five-day average at a cost to the Brazilian health system of $196 million," AdvaMed said.

The industry group said it supported ANVISA measures to address the bottlenecks through streamlined procedures for low-risk devices and increasing funding to reduce the backlog.

Risk-based GMP Inspections

Brazil recently introduced a risk-based approach to good manufacturing inspections for manufacturers and distributors of medical devices to allow faster access to new technologies.

ANVISA will conduct risk assessments for international devices including reviews of technical documents rather than on-site GMP inspections, depending on the level of risk identified. The change will mean greater flexibility in determining risk for certain Class III or Class IV devices.

The agency plans to consider the manufacturing stage of the device, the technology involved, additional control factors, and how much value an on-site manufacturing inspection would add (*IDDM*, Oct. 9, 2017).

"Plans by ANVISA to streamline its GMP certification process will speed up market authorizations for moderate to high risk devices and improve access to new technologies, while reducing the burden of resource-intensive on-site inspections," said BMI in a recent report on Latin America.

Brazil also participates in the Medical Device Single Audit Program (MDSAP), which is on track for full implementation in 2019. MDSAP was devised to leverage regulatory resources into a single audit program so manufacturers don't face multiple inspections. The regulatory authorities currently participating in the MDSAP program are: Australia's Therapeutic Good Administration; Brazil's ANVISA; Health Canada; Japan's Ministry of Health, Labor and Welfare; and the U.S. FDA (*IDDM*, June 26, 2017).

CDRH Plans to Complete Pre-Cert Program Design By Year's End

CDRH intends to complete the design of its digital health software pre-certification program by the end of this year, Associate Director Bakul Patel said during an FDA workshop on developing the Pre-Cert program.

The agency launched a pilot program last year, selecting nine digital health companies — Apple, Tidepool, Phosphorus, Fitbit, Alphabet's Verily, Johnson & Johnson, Roche, Pear Therapeutics, and Samsung — for their unique development approaches. At the Jan. 30-31 workshop, executives from the companies shared their stories about when FDA staff visited their facilities to begin collaborating on the program.

How is organizational excellence defined for the purposes of digital health development? We still do not know, but we are in the process of establishing this standard with the information gathered through the Pre-Cert program, Patel said.

'Paradigm Shift'

Under the current regulatory approach, premarket timelines are suited for hardware-based products and predetermined risks, Patel explained. But the "rapidly evolving nature of digital health is sparking a paradigm shift" adaptable to software development practices, rapid iterations, and evolving issues, such as cybersecurity, among other components, he said.

The FDA and the previously chosen participants have been seeking a consensus on what a standard of excellence means for digital health. But participation in the development process is not limited to the nine companies.

There is a 10th participant that was not included in the September 2017 announcement of the agency's picks — everyone else. Patel said. At the workshop, stakeholders were strongly encouraged to chime in with questions and tangible inputs. The 10th participant is needed to complete the development process — currently at the first of multiple stages — by the end of this year, and to increase the likelihood of the program being successful, Patel said.

From October through December 2017, the FDA Pre-Cert Core Team visited the companies to better understand the desired benefits of the program and to clarify questions. They also encountered some obstacles.

Challenges Ahead

One of the biggest takeaways from the initial site visits was realizing that there are countless different ways to design a quality management system, and the lack of common language to describe technology processes has been a major roadblock.

Yet another challenge, according to Adam Pellegrini, general manager at wellness company Fitbit, has been "suspending conceived notions" about how the Pre-Cert program will look like once it is fully developed.

The Pre-Cert program is not about products getting certified; it's about building a process with outcome-driven metrics and establishing long-lasting relationships with agency staff to encourage further innovation in digital health development, Pellegrini said.

Visits from the FDA Pre-Cert team allowed participating companies to be more engaged with agency staff, though they have pushed the companies to reevaluate established systems and to think more creatively about adapting their processes to keep pace with the iterative nature of digital health products while controlling design changes.

The time for revamping the regulatory approach on technologies has come, said CDRH Director Jeff Shuren at the workshop, adding current policies are outdated.

Digital health has underscored the need for the FDA to modernize regulations as these technologies are "characterized by highly iterative cycles of innovation" and "new software advances are introduced into products sometimes on a near-constant basis," the agency said in its

(See **Workshop***, Page 4)*

Jury Grants $26.7M in Patent Suit Against Ariosa Diagnostics

A jury in a Northern California District Court awarded biotechnology company Illumina $26.7 million in a patent suit against Ariosa Diagnostics, finding that Ariosa used patented prenatal testing technology without authorization.

Illumina accused Ariosa of infringing upon its patents by performing Illumina's Harmony Prenatal Test, alleging that the unauthorized use of the non-invasive DNA-based test caused the company irreparable damage.

The U.S. Patent and Trademark Office previously upheld the validity of the patents.

"This verdict again validates these patents, the hard work and ingenuity of the inventors, and their significant contribution" to noninvasive prenatal testing, said Charles Dadswell, Illumina's senior vice president and general counsel.

Arthrex's Plan to Resolve PTAB Challenge Backfires in Federal Circuit

The U.S. Court of Appeals for the Federal Circuit upheld a decision from the Patent and Trademark Office to bar devicemaker Arthrex from ever again patenting claims similar to those the company invalidated in an attempt to thwart infringement arguments.

The first nine claims in patent No. 8,821,541, describing a device for anchoring surgical suture to a patient's bone, were challenged by Smith & Nephew in 2016, and later disclaimed by Arthrex — a move patent owners can make if they come to realize that patented claims were too broad to be justifiably patentable in the first place.

Smith & Nephew petitioned the PTO's Patent Trial and Appeal Board (PTAB) to consider Arthrex's disclaimer as a request for an adverse judgement in an inter partes review. The board decided in Smith & Nephew's favor and said "it would be unfair" for Arthrex to avoid the challenge and be able to pursue patentably indistinct claims in the future.

Mark Kachner, a partner at the intellectual property and technology law firm Knobbe Martens, told *FDAnews* Arthrex could have stood a better chance with presenting its argument in the appeals court if it had not waived the PTO's authority through its disclaimer.

The Arthrex patent has not been completely invalidated. A federal district court recently found the last two claims — challenged by a different competitor — to be valid, according to Kachner. — Ana Mulero

Workshop, *from Page 3*

2018 policy roadmap, outlining focus areas and goals for the fiscal year (*IDDM*, Jan. 15).

The shared vision for the Pre-Cert program includes getting the right digital health products to the right patients at the right time while providing reassurance of safety and effectiveness. Those that gain pre-certification could potentially bypass certain FDA requirements, such as submitting a product for premarket review, to reach the market at a faster pace (*IDDM*, Sept. 29, 2017).

The Pre-Cert workshop was designed for "setting the stage," Patel said, stressing that a successful paradigm shift focusing on software is heavily dependent on collaborative interactions. Future workshops will consider product-level risk categorization frameworks, as well as post-market surveillance and real-world evidence. — Ana Mulero

Medical Laser Manufacturer Draws Lengthy FDA Warning

Light Age, a New Jersey-based manufacturer of Class II medical lasers, drew an FDA warning letter for 12 different violations flagged during a fall 2017 site inspection.

The warning came after the FDA was not satisfied with the firm's December 2017 response to nonconformities listed in a Form 483. It reveals numerous GMP violations regarding the firm's procedures for handling complaints, and maintaining device history records (DHRs), among other issues.

Out of the 12 violations in the warning, three relate to customer complaints. At least three of the complaint cases evaluated by the FDA during the inspection lacked the required root cause investigations or rationale for not initiating investigations, and the firm was unable to provide or locate another three of the reviewed complaints.

DHRs and Complaints

Light Age had failed to adequately follow its complaint investigation procedure as it was lacking documentation on complaint trending and metrics reviews being performed. It was also unable to demonstrate during the FDA's visit that it had reviewed or investigated three complaints involving possible injuries — a Keloid scarring, a burn, and a rash.

In its response to these issues, the firm failed to ease the FDA's concerns due to a lack of written evidence of having conducted a retrospective review of all complaints and of having revised its complaint handling system. It also did not provide explanation for the missing complaints.

The firm's device master record (DMR) for its EpiCare Zenith device and several of its DHRs were found to be incomplete. The DMR lacked references to packaging, labeling, and installation specifications, among others, and DHRs for some of the identified distributed devices were missing critical manufacturing information, such as a justification for a previously set pulse rate.

The response to these nonconformities was inadequate in that completed DHRs were not provided for the identified examples, and it did not indicate whether the firm has "retrospectively reviewed all DHRs for devices which remain on the market to ensure they are complete and that nonconforming results have been adequately investigated," the agency said.

The investigator also observed the lack of calibration records for products used to manufacturer EpiCare Zenith devices during 2015, 2015, and 2016, as well as of design change validations. For example, the firm implemented an engineering change on its EpiCare portfolio in 2011 for safety reasons, but it failed to document whether the design change was verified or validated.

Additional Violations

Light Age's inadequate procedures for controlling nonconforming products, implementing CAPA actions, as well as conducting timely management reviews and internal quality audits were also found to be significant GMP violations.

The FDA found several CAPAs since January 2015 had been opened and then cancelled without rationales or actions taken, and nonconforming products that had been shipped without documented investigations or risk assessments. According to the firm's quality manager, nonconformities had not been documented since August 2016. Updated SOPs and associated personnel training records should have been included in the firm's response to these violations.

Lastly, the firm's processes, or lack thereof, for adverse event reporting were found to be in violation of the FDA's Medical Device Reporting requirements. Its MDR procedures were deficient as they did not establish internal systems or describe requirements to ensure adequate recordkeeping and complete event investigations, as well as timely submissions to the FDA.

Read the Light Age warning letter here: www.fdanews.com/02-01-18-LightAgeWL.pdf.
— Ana Mulero

510(k), *from Page 1*

considered complete. Updates reflect a continued effort to make better use of FDA resources allocated for product reviews.

Both guidances are applicable to all medical devices reviewed either through a 510(k) submission or a PMA application, and new details for combination products are included.

510(k) Submissions

The 510(k) refuse to accept (RTA) policy is separated into two stages, quantity vs. quality. The first — acceptance review — allows agency review staff to determine whether the submission is complete, meaning that it includes all the elements identified in the guidance, before conducting a substantive review, during which the actual quality of the submitted data is assessed.

Past guidances on the policy focused on defining broad issues or principles and the checklists "dealt largely with administrative elements but did not address specific content that is essential for 510(k) review," which in turn led to an "inefficient use of resources and frequently lengthened review times," the agency said.

The FDA added it "had accepted many inadequate submissions for review, and FDA staff invested significant time in constructing extensive letters requesting all of the additional information needed to conduct a substantive review."

An initial review of completeness enables early interactions as submitters can be informed of missing elements in a 510(k) deemed incomplete within the first 15 days after FDA receipt.

PMA Applications

The PMA guidance provides details of the elements required for FDA review staff to accept an application, or refuse to file it if the applicant does not meet the outlined criteria, which were separated into two categories — acceptance criteria and filing criteria.

It is not "significantly different" from past guidances, CDRH noted. The included PMA filing criteria, as well as the preliminary and filing review questions all remain the same as in the past.

But there is a notable change to the recommendation on submitting the manufacturing section. Previously, a delayed submission of this section would not result in a refuse-to-file decision, and it could be submitted up to 90 days after the original application.

Delayed submission of the manufacturing section has "rarely occurred in recent years, and in many cases this section is submitted prior to other sections of the PMA, as part of a modular PMA submission," the FDA said. "Therefore, we are now including the manufacturing section in the checklist for a complete PMA application for an original PMA or a panel-track supplement."

Providing an electronic copy "in place of one of the six hard copies of the PMA" is encouraged.

Read the 510(k) guidance here: www.fdanews.com/02-01-18-510ks.pdf.

Read the PMA guidance here: www.fdanews.com/02-01-18-PMAs.pdf. — Ana Mulero

Brexit Health Alliance: A 'No Deal' Could Impact Device Supply Chains

The Brexit Health Alliance called for post-Brexit cooperation between the European Union and the United Kingdom on medical device regulations to avoid disruption of international supply chains.

Brexit "could have serious implications for patients' access to medicines and medical technologies," according the alliance, whose members include the Academy of Medical Royal Colleges, the Association of British Healthcare Industries, the NHS Confederation, and other stakeholders.

The call comes as the U.K. and the EU negotiate over continuing relations post-Brexit. Regardless of whether they reach a "deal" or "no deal" on continuing relations, a lack of EU-U.K. cooperation on medical devices "could put public health at risk," the alliance said.

BHA pointed to one reason a "no deal" could have a detrimental impact on supply chains — an estimated 50 percent of the assessment work for authorizing products to reach the EU market is done in the U.K. "There is already limited capacity in this area across Europe and any possible loss of capacity could clearly impact the availability of medical devices," the alliance said.

The alliance also called for "aligning the U.K. as much as possible with the EU's regulation of medicines and medical devices" in the interest of patient safety and public health.

With the EU's new medical device and in vitro diagnostic regulations — being phased-in over the course of three and five years, respectively — there are unique challenges because of Brexit as it is unclear how they will be implemented in the U.K., especially if there is "no deal."

The U.K. parliament's European Union Committee issued a report in December stating, the closer the U.K. and the EU get to the deadline of March 29, 2019, "the more damaging a breakdown of negotiations, and a 'no deal' outcome, would be."

Citing evidence submitted by devicemaker giant Johnson & Johnson, the committee said a "no deal" scenario "could potentially disrupt the supply of medicines, medical devices and other healthcare products from the EU to the U.K."

BHA is not the only group expressing concerns over Brexit's potential impacts. MedTech Europe issued a position paper in November recommending actions to mitigate harmful effects, which include recognizing U.K.-issued CE Marks until they expire, and avoiding lengthy delays for cross-border product supplies (*IDDM*, Nov. 20, 2017). — Ana Mulero

APPROVALS

FDA Grants EAP Designation To AngioDynamics Cancer Treatment System

New York-based devicemaker AngioDynamics obtained the FDA's expedited access pathway designation for its NanoKnife ablation system for treatment of Stage III pancreatic cancer.

NanoKnife is designed to permanently open pores in targeted cell membranes via low energy direct current electrical pulses, resulting in cell death, and the patient's body naturally removes the treated tissue "in a matter of weeks," the company said.

The system previously received 510(k) clearance for surgical ablation of soft tissue.

Bio-Rad Gains Additional FDA Clearances for Blood Typing Products

Bio-Rad Laboratories received 510(k) clearance from the FDA for its IH-Incubator L and IH-Centrifuge L instruments for use with the full range of Bio-Rad's IH-system gel reagents for manual blood typing methods.

The instruments maximize efficiency and space in the laboratory by accommodating both conventional tube and gel blood typing.

"This addition rounds out our offering, specifically benefitting smaller laboratories that use manual methods to test blood," said John Hertia,

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

Approvals, *from Page 7*

Bio-Rad's executive vice president and president of the company's clinical diagnostics group.

electroCore Snags New Use Indication For Portable Migraine Therapy Technology

Bioelectronic medicine company electroCore achieved FDA 510(k) clearance for a new use indication on its gammaCore therapy technology.

The new clearance allows for the noninvasive neuromodulation treatment to be used for treating acute migraine-associated pain in adult patients. The FDA previously cleared gammaCore for treating pain associated with adult episodic cluster headache.

Self-administered treatment, using gammaCore, can be delivered through a hand-held unit designed to provide mild electric stimulations to the vagus nerves through a patient's skin.

FDA Clears Masimo Brain Function Monitoring Device

The FDA cleared the Next Generation SedLine brain function monitoring device from Masimo.

"SedLine helps clinicians monitor the state of the brain under anesthesia with bilateral acquisition and processing of four lead of electroencephalogram (ECG) signals," Masimo said.

The device uses a signal processing engine for providing clinicians with a complete picture of a patient's brain representing activity in both sides.

Meso Scale Diagnostics Wins FDA Nod for IVD Assay

Maryland-based immunoassay developer Meso Scale Diagnostics received FDA clearance for its conventional C-reactive protein assay for in vitro diagnostic use.

The assay features the company's proprietary multi-array technology and its MESO SECTOR S 700 for the detection of analytes in bodily fluids.

Multi Radiance Medical Pain Relief Laser Technology Achieves FDA Clearance

Multi Radiance Medical achieved FDA clearance for its MR4 Laser technology indicated for neck and shoulder pain relief.

The technology was cleared under the Product Classification NHN.

The new classification "gives clinicians and patients a clinically proven safe and effective alternative to opioids and other drugs for managing this common pain," the company said.

FDA Clears Campylobacter Assays

The FDA cleared two diagnostic tests manufactured by TECHLAB for diagnosing campylobacteriosis, a foodborne illness that causes diarrhea, cramps, fever, and vomiting.

The CAMPYLOBACTER QUIK CHECK can detect Campylobacter jejuni and Campylobacter coli in less than 30 minutes, the company said.

The CAMPYLOBACTER CHECK is designed to aid diagnostic laboratories in testing large numbers of human fecal specimens.

Visioneering Technologies Suite Of Contact Lenses Gets CE Mark

Atlanta-based devicemaker Visioneering Technologies received a CE Mark for its suite of proprietary NaturalVue contact lenses.

The lenses use Visioneering's Neurofocus optics technology for an "extended depth-of-focus design to address known optical risk factors associated with myopia progression."

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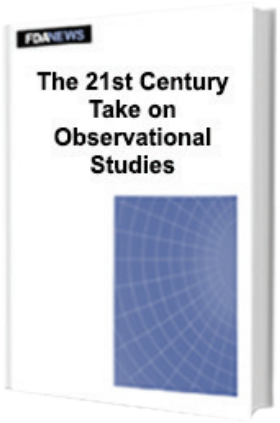

The 21st Century Take on Observational Studies: *Using Real-World Evidence in the New Millennium*

Passage of the 21st Century Cures Act reaffirmed Congress's and the FDA's commitment to using real-world evidence to supplement or even replace traditional clinical trials.

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- New data sources that make observational studies a viable alternative to clinical trials
- How drug- and devicemakers view observational research and how they are using it

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