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CDRH Releases List of Guidance Documents Expected for 2017

CDRH last week released a list of final and draft guidances it intends to issue in fiscal year 2017.

Its top tier, the "A" list, includes 12 final guidances, two of which have already been released, and four draft guidances. It also published a "B" list of five additional final guidances and eight draft guidances it intends to release if resources permit.

The 10 final guidances on the "A" list still to be released include two key topics: use of real-world evidence to support regulatory decision-making and determining substantial equivalence in premarket notifications. The two final guidances already released are Postmarket Management of Cybersecurity in Medical Device (see page 5) and Medical Device Accessories: Describing Accessories and Classification Pathway for New Accessory Types (see page 8).

(See **Guidance**, *Page 2)*

Cures Act Encourages Breakthrough Devices, Exempts Medical Software

Manufacturing-related provisions in the recently enacted 21st Century Cures Act establish a program for "breakthough" devices, exempt some categories of medical software from regulation as a medical device, and require the FDA to publish a list of reusable device types that must include usage instructions and cleaning data.

Section 3051 of the act requires the FDA to establish a program to speed up development of devices featuring breakthrough technologies that are designed to diagnose or treat serious conditions and have no approved or cleared alternatives. To participate in the program, a device must offer significant advantages over existing devices.

A sponsor may request priority review from the FDA at any time before submitting a device to the program, and the agency must respond within 60 days. The program builds on the FDA's Expedited Access Pathway, chiefly by permitting access to 510(k) devices.

(See **Cures**, *Page 4)*

Guidance, *from Page 1*

Other final guidance documents on the A-list include:

- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices;
- Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions;
- Suggested Format for Developing and Responding to Deficiencies;
- Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications with Different Technological Characteristics;
- Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS) - Based In Vitro Diagnostics Used for Diagnosing Germline Diseases;
- Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing – Based In Vitro Diagnostics;
- Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers;
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices;
- 510(k) Third Party Review Program; and
- New or revised procedural guidances for MDUFA IV implementation.

Draft guidance documents on the A-list include:

- IDE Submission, Content, Organization, Interactions;
- Update to Section V Demonstrating Insignificant Risk of an Erroneous Result in the Recommendations: Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices guidance;
- Dual 510(k) and CLIA Waiver; and
- New or revised procedural guidances for MDUFA IV implementation.

Final guidance documents that the FDA intends to release if resources allow (the "B" list) include:

- Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies
- Medical Device Development Tools;
- FDA Categorization of Investigational Device Exemption Devices to Assist the Centers for Medicare and Medicaid Services with Coverage Decisions;
- Unique Device Identification: Direct Marking of Devices; and
- Technical Considerations for Additive Manufactured Devices.

Draft guidance documents on the "B" list include:

- Standard Content and Format for Patient Labeling of Medical Devices;
- Standard Content and Format for Healthcare Provider Labeling of Medical Devices;
- Patient Matched Instrumentation for Orthopedic Devices;
- Utilizing Simulated Animal Transplant Models to Evaluate the Safety of Perfusion-based Organ Preservation Devices;
- Strategy to Assess the Credibility of Computational Modeling Studies;
- Related Replacement Reagent and Instrument Policy;
- Unique Device Identification System: Defining the Labeler; and
- Considerations to Support a Claim of Electromagnetic Compatibility for Medical Electrical Equipment and Medical Electrical Systems.

CDRH also released a list of 53 current final guidances from 1977, 1987, 1997 and 2007 that it would like to revise or withdraw.

Read the full announcement here: www.fdanews.com/12-28-16-Guidance.pdf.

FDA Settles Safety Report Rules for Combination Products after Seven Years

For products that include a device component, sponsors must submit five-day reports, with supplemental or follow-up reports; malfunction reports; and correction or removal reports, as well as comply with recordkeeping requirements.

The FDA said that correction and removal reporting requirements sometimes arise in relation to manufacturers' recalls after adverse events that may also trigger medical device reporting requirements. In such cases, a medical device report will suffice to comply with both sets of reporting requirements.

In a change from the 2009 proposed rule, the agency extended 15-day report requirements for products approved under device applications to 30 days.

Sponsors are not required to submit more than one report, the agency said, as long as a single document contains all required information and meets applicable deadlines.

Sponsors of different parts of a combination product must share safety information with each other within five calendar days, including events involving death, serious injury or other adverse events.

Overall, the rule applies only to combination product applicants and constituent part applicants. In response to several comments asking for clarification on the entities and products subject to the rule, the FDA provided an example of a prefilled syringe that received authorization via an NDA submitted by Company A, which purchases syringe components from Company B. Company A is the only entity applying for combination product approval; Company B would have no postmarket reporting duties under this rule.

The rule does not require blood fatality reporting for combination products that received marketing authorization under a device application.

Combination product applicants must maintain records relating to their postmarket safety reports for the longest required recordkeeping period applicable to the combination product: at this time, the recordkeeping period for combination product records would be at least 10 years, the FDA said.

The rule largely goes into effect Jan. 20, 2017, as many duties for both combination product and constituent part applicants are generally the same for any application holder already in compliance. However, the additional reporting requirements based on individual product components, as well as certain periodic reports and the requirements for related companies to share safety information will take effect 18 months later, in July 2018. The FDA said it intends to publish a guidance in the future providing recommendations on complying with this rule.

The final rule's notice in the Federal Register, including a summary of industry comments and FDA responses, is available here: www.fdanews.com/12-19-16-FDAFinalRule.pdf. — Conor Hale

New Zealand Proposes to Use Zimmer Biomet Implants

New Zealand's medical device and drug regulator is proposing to let hospitals purchase orthopedic implants and associated products made by Zimmer Biomet New Zealand.

The Pharmaceutical Management Agency's (PHARMAC) proposed national agreement would allow Zimmer Biomet to supply about 12,500 products, which are already supplied to District Health Board (DHB) hospitals by other manufacturers. In addition, Zimmer Biomet would provide educational services tailored to the needs of individual DHB Hospitals.

DHB's would save about $970,000 annually under the deal, based on current usage. Pricing for orthopedic implants and associated products would not be increased before March 1, 2020, subject to any prior termination of the agreement.

The agreement would supersede any existing DHB contracts with Zimmer Biomet for the devices listed.

Orthopaedic implants and associated products not listed on the Pharmaceutical Schedule could still be purchased by DHBs, and DHBs would be under no obligation to purchase devices from Zimmer Biomet.

Cures, *from Page 1*

Section 3059 requires the FDA within 180 days of the act's enactment to publish a list of reusable device types for which 510(k) submissions must include validated usage instructions and validation data for cleaning, disinfection, and sterilization.

This section also includes an unrelated requirement calling for final FDA guidance on when a new 510(k) is needed. Manufacturing groups have said in comments to the August draft guidance that the final guidance should clarify the test for a significant change.

Section 3060 identifies five categories of medical software that will not be regulated as a medical device. These include software that is used for:

- Administrative support of a health care facility, including processing and maintaining financial records, claims or billing information, appointment schedules, etc.;
- Maintaining or encouraging a healthy lifestyle, as long as the software is unrelated to diagnosing, curing, mitigating, preventing, or treating a disease or condition;
- Electronic patient records, including patient-provided information, to the extent the records are intended to transfer or store data, convert formats, or display the equivalent of a paper medical chart; and
- Transferring, storing, reformatting, or displaying clinical laboratory test or other device data, related findings by a health care professional, and other general information, as long as the software does not interpret or analyze the data.

With the exception of medical images, in vitro diagnostics, and signals or patterns from signal acquisition systems, Section 3060 also exempts software from being regulated as a medical device if it is used for:

- Enabling the health care professional to independently review the basis for — rather than rely primarily on — the software's recommendations when making diagnostic and treatment decisions;
- Displaying, analyzing, or printing medical information; and
- Supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition.

Not later than 120 days after the bill's enactment, and at least once every five years after, the HHS secretary must identify any type of Class I or II device determined to no longer require a report to provide reasonable assurance of safety and effectiveness.

Within a year of enactment, the FDA must:

- Issue draft guidance regarding the evaluation of devices used in regenerative therapies;
- Issue guidance on the implementation of the Act's program for the expedited review of breakthrough medical devices, including the criteria used for evaluation; and
- Revise a guidance published Jan. 30, 2008, on CLIA waiver applications for manufacturers of in vitro diagnostic devices.

Other device-related deadlines in the Act include:

- Within 18 months, the FDA must publish a draft guidance defining the criteria for establishing "probable benefit" for humanitarian device exemptions;
- Within two years, the FDA must published a report examining risks and benefits associated to regulated medical software, summarizing impacts on patient safety; and
- Before January 2019, the HHS secretary must present to Congress a report on the progress of the expedited device pathway.

Present Barack Obama signed the bill into law on Dec. 13. While parts of the final measure include funding, most of the FDA's activities included in the measure would have to be funded by a separate appropriations bill.

Congress recently passed a temporary measure to fund the FDA and other government agencies through April 28. That continuing resolution contains the first round of appropriations for the 21st Century Cures Act, with the FDA receiving an additional $20 million for the 2017 fiscal year.

Final Guidance Addresses Medical Device Cybersecurity Reports

Almost a year after releasing draft guidance on how manufacturers should deal with postmarket cybersecurity vulnerabilities in medical devices, the FDA issued final guidance that clarifies requirements for reporting an uncontrolled cyber vulnerability.

Such an uncontrolled risk must be reported to the FDA unless:

- There are no known serious adverse events or deaths associated with the vulnerability;
- No later than 30 days after learning of the vulnerability, the manufacturer tells its customers and users about it, identifies interim compensating controls, and develops a remediation plan; and
- No later than 60 days after learning of the vulnerability, the manufacturer eliminates it, validates the change, and distributes an adequate solution to end users. Additionally, the manufacturer should follow up with end users as needed beyond the initial 60 day period.

The 30-page final guidance makes several more changes to the January 2016 draft guidance, including:

- Recommending that manufacturers' cybersecurity risk management programs include procedures for monitoring third-party software components for new vulnerabilities throughout a device's life cycle and provide software updates that address vulnerabilities;
- Listing resources to help manufacturers prioritize vulnerabilities;
- Recommending that manufacturers adopt a vulnerability disclosure policy that includes telling the person who submitted the initial vulnerability report that the report was received;
- Advising that some changes made to strengthen device security might affect other device functionality, potentially requiring additional premarket or postmarket regulatory actions;
- Adding additional examples of cybersecurity vulnerabilities and how manufacturers should deal with them; and
- Encouraging manufacturers to participate in information sharing analysis organizations to address cybersecurity vulnerabilities and develop risk control measures.

Read the final guidance here: www.fdanews.com/12-28-16-CybersecurityGuidance.pdf.

Nomax Lands Warning Letter for Documentation, Other Violations

Nomax Inc. received a warning letter for failing to evaluate complaints, document corrective and preventive actions, and committing other violations.

The St. Louis, Mo.-based company manufactures and repacks contact lens cases and other products.

During an inspection of Nomax's facility in October, the FDA discovered that the company failed to review, evaluate, and investigate quality complaints involving a container for soft, gas-permeable, and hard contact lenses. Nomax also failed to verify or validate corrective and preventive actions taken to address this complaint.

In addition, the FDA said Nomax did not review and document the suitability and effectiveness of its quality system at defined intervals. Specifically, the dates and results of management review meetings, including a list of attendees and review of quality trend analyses, were not documented from January 2015 to September 2016.

The agency also cited Nomax for not documenting acceptance activities for the contact lens container, including that the device conformed to width, depth, and other specifications.

The company additionally failed to maintain a device history record for the contact lens container and properly evaluate potential suppliers.

The FDA also expressed concerns about the timeliness of training of key personnel and an audit that Nomax conducted of its products.

Read the warning letter here: www.fdanews.com/12-28-16-Nomax.pdf.

Best Medical Canada Lands Form 483 for Complaint Procedures

Best Medical Canada landed a Form 483 for not establishing adequate complaint procedures or ensuring that its devices conformed to specifications.

According to an October inspection of its Silver Spring, Md., facilities, procedures for receiving, reviewing, and evaluating complaints by a formally designated unit were not adequately established. Specifically, Best Medical did not identify repair work orders as complaints in accordance with its procedures. As a result, there was no documentation showing that these incidents were reviewed for MDR reportability.

In addition, production processes were not monitored to ensure that a device conformed to its specifications. The company failed to document various steps in the manufacturing process for its BMC Dosimeters.

The company promised to correct both violations.

Read the Form 483 here: www.fdanews.com/12-22-16-BestMedical.pdf.

Final Guidance Describes Risk-Benefit Factors for FDA Enforcement Actions

The FDA has provided new clarity for industry regarding the risk-benefit factors the agency may consider in prioritizing resources for medical device compliance and enforcement.

Manufacturers can use the same risk-benefit factors when choosing their responses to nonconforming product or compliance issues, the final guidance says.

When the FDA assesses device benefits, it considers the type of benefit; likelihood of patients experiencing benefits; duration of effects; patient preference; benefits for healthcare professionals or caregivers; and medical necessity.

Risk considerations include severity, categorized into three levels: deaths or serious injuries, non-serious events or events without reported harm; likelihood of risk; nonconforming product risks, such as how many nonconforming devices are on the market; duration of exposure; false-positive or false-negative results; patient tolerance of risk; and risk factors for healthcare professionals.

The final guidance clarifies some of the examples in the draft guidance (*IDDM*, June 17) and provides additional examples to show how the FDA considers risk-benefit factors affecting product availability decisions. The new examples include a malfunction of a pregnancy test with low benefit and moderate additional risk, and a recall of a radiation therapy device with high benefit and increased risk for some patients.

The final guidance also encourages manufacturers that wish to provide information on benefits and risks to do so through the designated FDA point of contact for the issue being assessed, spokeswoman Deborah Kotz said. For example, a district recall coordinator would be the appropriate point of contact in the context of a potential recall.

Read the final guidance here: www.fdanews.com/12-29-16-Benefit-RiskGuidance.pdf.

BRIEFS

FDA Issues Bone Anchor Draft Guidance for Marketing Submissions

The FDA has published a draft guidance document providing recommendations for marketing submissions of bone anchor devices.

This publication is updating the 1996 guidance to clarify and provide current thinking on the recommended content for a bone anchor marketing submission, including performance testing recommendations and device description.

These devices are indicated for attachment of soft tissue to bone.

This guidance is issued for comment purposes only.

FDA Classifies Ischemic Stroke Treatment Device as Class II

The FDA issued a final order classifying neurovascular mechanical thrombectomy devices for acute ischemic stroke treatment as Class II devices with special controls.

This type of device mechanically removes blood clots to restore blood flow in the neurovasculature.

Firms that intend to market this type of device must submit a premarket notification and comply with the special controls listed in the final order.

A public workshop will be held on Feb. 2, 2017, from 8 a.m. to 5 p.m. EST, to obtain stakeholders' input on the coordination of registries for these devices.

FDA Announces Changes To Consensus Standards

The FDA announced additions, withdrawals, corrections, and revisions of certain consensus standards the agency recognizes for premarket submissions and other requirements for medical devices.

The announcement describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

The announcement also lists additional standards not previously recognized by FDA.

FDA Reclassifies Pedicle Screw Systems

The FDA has issued a final order to reclassify pedicle screw systems, from a Class III device to Class II.

The agency has also renamed the device to thoracolumbosacral pedicle screw systems. This order is effective on December 30, 2016.

Medical Carts Have Potential Fire Risk

The FDA has issued a letter warning health care facilities of potential safety risks associated with battery-powered mobile medical carts.

The FDA has received medical device reports of hospital fires and other health hazards associated with batteries used in mobile medical carts and their chargers. In these events, a range from smoke production and overheating to equipment fires and explosion can occur with lithium, lead acid and other types of batteries.

HAS Grants Reimbursement to Theraclion

The French's National Health Authority has given a favorable opinion for reimbursement to Theraclion's Echopulse for the treatment of non-malignant breast tumors.

The two main objectives of this system are to accelerate patient access to medical innovations and support business development. The study has been approved to commence in 12 hospitals across France.

EU Grants Marketing Approval to HiberGene

Dublin, Ireland-based HiberGene Diagnostics has earned CE Mark approval for its HG C. difficile test.

HG C. difficile enables the detection of the bacterium, Clostridium difficile (C. difficile), from stool samples in under 60 minutes. The launch of HG C. difficile is the third in HiberGene's.

Audifon Hit with Form 483 For Complaint Evaluations

Audifon-USA established inadequate procedures for complaint reviews, corrective and preventive actions, equipment calibration, and other activities, according to a Form 483.

During a July inspection of the company's Debary, Fla., facility, the FDA found several defects in Audifon's complaint handling procedures.

Specifically, there was no requirement that all complaints be evaluated to determine if they involved reportable events; the procedure and work instructions did not define "complaint" to help identify complaints; there were no provisions to ensure that returned devices handled as repairs were evaluated to see if they should be classified as complaints; and there were no provisions to describe requirements for a complaint investigation, including identification of the most likely underlying cause.

Investigators also observed that Audifon's corrective and preventive action procedures were not verified or validated prior to implementation.

In addition, the company was observed not to have maintained procedures for calibrating and maintaining some of its hearing aid components.

Investigators also reported that Audifon had not established procedures that described how non-conforming products were documented, including use of the firm's rejection tickets. These procedures also did not include provisions for rework.

Finally, the company's written MDR procedures did not include provisions to identify and report serious injuries and malfunctions, and they did not address eMDR reporting requirements.

Read the Form 483 here: www.fdanews.com/12-22-16-Audifon.pdf.

Final Guidance Clarifies Regulation Of Accessory Devices

Almost two years after issuing draft guidance on how it classifies accessory devices, the FDA has released the final guidance that also clarifies when software as a medical device is an accessory.

The final guidance defines "accessory" as "a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices." The guidance also encourages manufacturers to use the *de novo* classification process to request classification of accessories that have not been previously classified, cleared or approved.

The final guidance updates the Jan. 20, 2015 draft guidance to apply it to all software products that meet the definition of an accessory, including software as a medical device (SaMD).

SaMD that uses data from a medical device does not automatically become an accessory. For example, a stand-alone software program intended to analyze radiological images or data generated by a device is considered SaMD but not an accessory.

Read the final guidance here: www.fdanews.com/12-29-16-Accessories.pdf.

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Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editor: Jeff Kinney
+1 (703) 538-7634
jkinney@fdanews.com

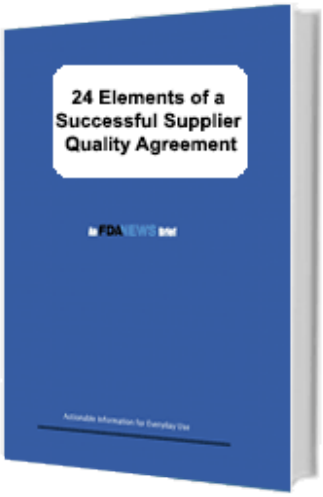
Ad Sales: Jim Desborough
+1 (703) 538-7647
jdesborough@fdanews.com

Multi-User Sales: Jeff Grizzel
+1 (703) 538-7669
jgrizzel@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • www.fdanews.com

Reporters: José Vasquez, Cynthia Jessup, Derek Major, Conor Hale

President: Cynthia Carter



24 Elements of a Successful Supplier Quality Agreement

Supplier quality is a fundamental topic of perennial importance.

Your agreements with suppliers must be written and executed to cover every possible contingency and ensure that the materials that go into your products are exactly what you require and are available when you need them.

Today's minor mistake by your supplier could easily turn into tomorrow's major recall. And if you don't catch all the oversights in your quality agreement, odds are the FDA will.

In this FDANews Brief, 20-year industry veteran Steven Sharf, explains the elements that need to go into your quality agreement:

1. Calibration and Maintenance
2. Batch Documentation
3. Change Control
4. Deviations / OOSs
5. Field Alerts / Recalls
6. Material Inspection / Testing / Release
7. Labeling Controls
8. Rejected Materials
9. Complaint Handling
10. APR / PQR Inputs
11. Audits / Inspections
12. Specifications
13. Subcontracting
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GCP Questions, FDA Answers

What subject information are you allowed to collect under HIPAAA? Which members of the study's staff are allowed to dispense the investigational product to subjects? What do you do if your principal investigator resigns? What constitutes a "certified copy" of an electronic record?

The FDA's Office of Good Clinical Practices (OGCP) fields questions like these from clinical research professionals just like you every day.

FDAnews' staff has culled through hundreds of questions submitted to OGCP and curated more than 175 of the most relevant responses for you — segmented by category — saving you the time and frustration of sifting through the questions and responses.

Some of these may be questions you've asked yourself and others you may not have even thought of. But all of them get straight to the heart of your role as a clinical trial professional — how to conduct safe, effective, compliant trials that can win FDA approval.

This collection sheds light on some of the most difficult and important topics in clinical trial research, including:

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