INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 3, No. 2
Jan. 9, 2017

IN THIS ISSUE

Bill With Bipartisan Support Would Repeal Device Tax

Rep. Erik Paulsen (R-Minn.) has reintroduced legislation that would permanently repeal the 2.3 percent medical device tax under the Affordable Care Act.

The bill, called the Protect Medical Innovation Act, which Paulsen originally introduced in 2013 and again in 2015, would make permanent a two-year suspension of the tax. It has bipartisan support with more than 200 cosponsors and has been praised by President Elect Donald Trump.

Paulsen said in a statement that the suspension already has created jobs and increased medical technology investment. He said a permanent repeal should be a "top priority" for Congress.

Advamed President Scott Whitaker said that repealing the tax will spur job growth, encourage medical technology companies to spend more on research and development, and help restart delayed projects.

In 2015, a Senate report found that the tax harms the domestic medical device industry — especially small businesses — and unfairly exempts exported devices.

Software Exclusions, Breakthrough Devices Featured in 21st Century Cures Act

Most of the provisions in the 21st Century Cures Act clarifying medical software regulation are straightforward and welcomed by industry, but it is unclear how the FDA will apply a provision on clinical decision support software.

Section 3060 of the Act exempts five categories of software from regulation as a medical device, including software used for administrative support, maintaining or encouraging a healthy lifestyle, electronic patient records, processing or displaying clinical data or related findings by a healthcare professional, and supporting or providing treatment recommendations (*IDDM*, Dec. 30, 2016).

(See **Cures**, *Page 2)*

Cures, *from Page 1*

The software exclusions "are welcome news to an industry that has been struggling with the question of whether its products are subject to FDA regulation," attorney Jeffrey Shapiro at Hyman, Phelps & McNamara said.

However, Shapiro said it remains uncertain how the FDA will apply the exclusion of software used for clinical decision support software (CDSS), which supports or provides recommendations regarding treatment decisions. Specifically, the provision excludes software that:

- Displays, analyzes, or prints medical information;
- Supports or provides recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and
- Enables 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.

The FDA has considered issuing CDSS guidance for the past few years. Although the exemption removes the need for guidance, it presents unresolved questions for manufacturers.

In particular, it is unclear what it means for a health care professional to "independently review" the basis for recommendations by software as opposed to "relying on" the software to make a decision — an issue that is ripe for future FDA guidance. Shapiro said that the relevant distinction arguably should be whether the basis of the software's recommendation is clear, and thus can be intelligently accepted or rejected similar to when talking with a colleague, or whether the health care professional blindly relies on the software's recommendations without knowing how they were reached.

A particular healthcare professional's training and expertise plays a role, because a primary benefit of CDSS is to encapsulate the expertise of the best-trained and most experienced doctors for the benefit of others who might rely more heavily on the software's recommendations. As a result, the FDA might make distinctions among health care professionals for whom the CDSS is intended when determining if it is regulated as a medical device.

By contrast, Shapiro said three of the excluded software categories are unsurprising and should not be controversial. Administrative support software such as Microsoft Word "is obviously not a medical device," he said. In addition, the FDA previously indicated it would not regulate lifestyle and patient record software even if it fell under the definition of a medical device. The Act simply clarifies that it does not.

Shapiro said the fourth category — software that processes or displays clinical data or related findings by a healthcare professional — appears to include products meeting the definition of either a medical device data system (MDDS) or a laboratory information system (LIS).

The FDA has previously announced it is exercising enforcement discretion not to regulate MDDS, and Section 3060 codifies that position. The agency currently regulates LIS as 510(k)-exempt Class I devices that are intended to store, retrieve, and process laboratory data. The FDA has continued to apply the quality system regulation to these devices, but under this exclusion, LIS products are no longer subject to the QSR or any other regulatory requirements.

Provision Offers Accountability

The provision on breakthrough devices in the 21st Century Cures Act will bring needed clarity for manufacturers and accountability for the FDA, according to one prominent regulatory consultant.

Section 3051 requires a new FDA program offering priority review of devices that provide more effective treatment or diagnosis of life threatening or irreversibly debilitating human disease or conditions. The program would also

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

Hong Kong Issues Alerts For Blade Impactor, Catheter

Hong Kong's Department of Health issued safety alerts for Synthes GmbH's PFNA Blade Impactor, Boston Scientific's Imager II Angiographic Catheter and Express LD Biliary Stent.

Synthes GmbH is recalling its Impactor for PFNA Blade following complaints that the handle detached from the shaft of the device due to a weld failure.

The PFNA impactor is part of the PFNA and PFNA-II systems used for treating high energy fractures in younger patients and low energy fractures in older patients. It is used to insert the PFNA blade by applying gentle blows with a hammer to the distal end of the impactor.

Infection could result if the handle is loosened from the shaft and allows body fluids to get inside the handle. In addition, the hidden debris could enter the surgical site of subsequent patients during surgery. Irrigants used during surgery may also loosen or liquefy the debris and potentially contaminate the surgical site.

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

Angiographic Catheters

Boston Scientific is voluntarily recalling a single lot of its Imager II Angiographic Catheters due to packaging mislabeling. The affected lot was mislabeled as Imager II Contra 2 curve catheters when it actually contained Contra curve catheters.

Users can easily detect the problem and exchange the device, and there have been no reports of patient injuries. The affected products are not distributed in Hong Kong.

Read the notice here: www.fdanews.com/12-22-16-catheters.pdf.

Biliary Stent

Boston Scientific also issued a safety alert concerning its Express LD Biliary Stent, due to incorrect electronic instructions for use. The instructions included with the products refer to information on Boston Scientific's e-labeling website that is pertinent to the U.S., and which contains indications that are not approved by Health Canada.

Read the notice here: www.fdanews.com/12-22-16-stent.pdf.

Australia's TGA Issues Alerts for Medtronic Defibrillators, Other Devices

Australia's Therapeutic Goods Administration has issued safety alerts for Medtronic Australasia's cardiac resynchronisation therapy defibrillators (CRT-Ds), Fresenius Medical Care Australia's Seep-Safe tubing systems.

CRT-Ds are implantable medical devices that deliver electrical impulses to treat abnormal heart rhythms. They can be reprogrammed using external controllers. Medtronic said it has received two reports of patients outside of Australia losing therapy in their left ventricles following a particular sequence of reprogramming commands.

The issue has been confirmed in only 0.38 percent of patients implanted with the potentially affected CRT-D devices. Medtronic has contacted cardiologists treating patients with potentially affected devices.

Read the safety alert here: www.tga.gov.au/alert/medtronic-crt-ds-various-models.

Sleep-Safe Tubing Systems

Fresenius Medical Care Australia is recalling Sleep-Safe Set, Sleep-Safe Set Plus and Sleep-Safe Set Paed patient and drainage lines manufactured before September 2016 due to leakage problems.

Overwelded coils in these products may cause them to leak, which can make it difficult to unroll the tubing and create pinholes in the lines. This damage may not be visible, will not be detected by the device itself, and can lead to infection.

Read the notice here: www.fdanews.com/12-22-16-tubing.pdf.

Cures, *from Page 2*

deal with breakthrough technologies for which there are no approved alternatives, or that offer significant advantages over existing alternatives (*IDDM*, Dec. 30, 2016).

In the past, FDA decisions regarding which devices are innovative enough to warrant expedited approval have not been based on formal, well-understood criteria, and therefore may be "well-intentioned," but could be somewhat "arbitrary and inconsistent," according to Compliance Architects Founder Jack Garvey. By establishing formal criteria for a breakthrough device, Section 3051 will offer more certainty for manufacturers and make the FDA more accountable. "I don't think it will create more of a burden on industry, but it will force the FDA to up their game a little bit in terms of the rigor of their decisions," he said.

University of Cincinnati Professor Jim O'Reilly said although there are good rationales for the breakthrough device program, there is a chance that consumers could be hurt if devices are approved too quickly or with insufficient data. If that happens, the FDA will be able to use Section 3051 to justify its decision.

"Historically, we've driven our regulatory controls by a sense of fear that if we make a wrong decision, it will harm consumers," he said. As a result, the FDA has "tried to avoid risk at all costs" and required more and more data before approving medical devices. However, with the passage of the 21st Century Cures Act, "inaction is not going to be held against the FDA reviewers, and someday I suspect Congress will be held responsible for devices that cause harm," O'Reilly said.

Another unresolved issue stems from the fact that Section 3051 opens priority review to device types subject to 510(k) clearances and not just PMA approval or de novo requests. Jay Crowley, vice president of UDI Services and Solutions at USDM Life Sciences, questioned the usefulness of this provision.

"A 510K device by definition is substantially equivalent to a currently marketed device, so it's a little hard to understand how you could have a novel device that is also a 510(k) product," he said. "When you think about unmet needs, you typically think about new products."

However, he agreed that the expedited pathway for breakthrough devices is helpful overall. "Everyone has to agree — which is a bit of a challenge — that a device meets an unmet need, but it's a useful tool from a social perspective," Crowley said. "It allows the FDA to do the right thing when the right thing is put before them."

FDA Reclassifies Surgical Mesh to Class II

The FDA issued a final order reclassifying specialized surgical instrumentation for use with urogynecologic surgical mesh from Class I to Class II with special controls based on new information regarding adverse events.

In May 2014, the FDA published a proposed order to reclassify these devices from Class I to Class II. In the order, the agency said it would convene a panel to discuss the reclassification before finalizing it.

The panel found that these devices are associated with various complications, including damage to blood vessels, nerves, and connective tissue, as well as irritation and infection.

The final order revises the proposed order to require proof that the device, if reusable, can be adequately reprocessed to remove contaminants and to require non-clinical performance testing to show that the device meets all design specifications and performance requirements.

In addition, the final order reiterates other special controls in the proposed order. These include requirements that the devices be biocompatible, have a proven shelf life, and include specific labeling elements.

Read the notice here: www.fdanews.com/01-05-17-surgicalmesh.pdf.

Malaysia MDA Issues Guidance On Changing Registration Ownership

New guidance from Malaysia's Medical Device Authority (MDA) describes procedures for changing ownership of a medical device registration.

In Malaysia, a local manufacturer or its local authorized representative is responsible for registering a medical device with the government. The new guidance says that a change of ownership of a medical device registration is required if:

- A manufacturer outside Malaysia has set up a company in Malaysia and intends to obtain ownership of a medical device registration from an authorized representative;
- A manufacturer replaces an existing authorized representative with a new authorized representative for purposes of marketing the device;
- Two medical device companies merge; or
- An existing authorized representative ceases operation.

An application to change the ownership of a medical device registration can only be made for completed, not pending, registrations. An application must be made by the new owner through an online portal, following steps laid out in the guidance, and the MDA will need about 30 working days to process it. Both the old and new owners will be notified of the outcome, and the effective date of the change is the date the application is approved.

Read the guidance here: www.fdanews.com/12-30-16-registrations.pdf.

India's NPPA Places Price Controls on Coronary Stents

Five months after deciding that coronary stents should appear on the National List of Essential Medicines (NLEM), India's National Pharmaceutical Price Authority (NPPA) has imposed price controls on the devices.

The government placed stents on the NLEM in July after numerous meetings with stent manufacturers, cardiologists and NGOs. At the time, experts concluded that the government should carefully consider price controls (*IDDM*, July 26, 2016).

The Medical Technology Association of India (MTaI), an industry group, said in a statement that it was "surprised" and "disappointed" by the decision, which it said will limit doctors' ability to provide patients with innovative stents that they might need, but that cost more than the price controls allow.

MTaI also said that India's medical device industry tried to avoid mandatory price controls by voluntarily offering to provide a particular type of FDA-approved stent at a specific price. In addition, manufacturers have partnered with a number of state government reimbursement programs to offer quality stents at the lowest possible prices, MTaI said.

As a result, to improve patient access to coronary stents and avoid compromising health outcomes, the group urged the NPPA to reconsider its decision and involve manufacturers, health care providers, and other stakeholders in all future discussions of price regulations.

CFDA Releases Draft Classification Catalog

The China Food and Drug Administration (CFDA) has released a long-anticipated draft Classification Catalog of Medical Devices that contains more specific categories and provides clearer guidance to manufacturers.

The draft catalog is not yet available in English, but according to attorney Anna Zhao at Covington & Burling the document:

- Reduces the number of sub-catalogs to 22 from the original 43 in accordance with the functions and clinical uses of medical devices;
- Reclassifies the current 265 entries of products into 205 primary categories, and further subdivides the 205 primary categories into 1,136 sub-categories of products;

(See **CFDA**, *Page 6)*

Panoramic Corp. Gets Form 483 For Reporting Failures

Panoramic Corp. received a Form 483 for not reporting a correction and removal to the FDA and failing to submit medical device reports (MDRs).

During an April 2015 visit to the company's Fort Wayne, Ind., facility, inspectors reported that the company had failed to report a correction or removal conducted to reduce a health risk posed by one of the firm's dental x-ray machines.

Specifically, Panoramic issued a letter to customers with PC-1 OOO dental panoramic x-ray machines alerting them of a problem that might cause the machines' rotating arm or chassis to collapse. After receiving additional complaints, it issued a second letter alerting customers to the same issue and providing a warning label for the machine. After it sent the second letter, Panoramic received 18 additional complaints about the problem. The company did not report sending either of the letters or the warning label to the FDA.

Inspectors also found that since 2009, Panoramic had received 2,490 service requests and 19 complaints about the flaw in the PC-1000 dental panoramic x-ray machines that caused the upper rotating arm/chassis to collapse. The Form 483 said at least 17 complaints included reports of a patient or healthcare professional being struck. Nevertheless, Panoramic determined no MDR was necessary.

Read the Form 483 here: www.fdanews.com/01-03-17-Panoramic.pdf.

CFDA, *from Page 5*

- For each sub-category, adds a detailed description of the product features and intended uses for those products. It also includes a product example column with 4,500 example products for each sub-category of devices; and
- Places 19 sub-categories of products into a lower classification — for example, x-ray image processing systems and nuclear magnetic resonance imaging systems have been classified from Class III to Class II.

The draft catalog also contains a new medical software section with five primary categories for treatment planning, image processing, data processing, IVD, and decision support, as well as a catch-all entry.

Zhao said the current catalog, which was issued in 2002, has been criticized for not providing clear guidance to manufacturers seeking a classification decision. In particular, it does not include product descriptions and intended uses for some categories of products. The categories also overlap, which can lead to inconsistent determinations. By contrast, the new draft catalog is a lot more concrete and granular, she said.

The 2002 catalog is outdated and "fails to keep up with the rapid proliferation of medical devices and the growth of complex technologies that have taken place in China," said Grace Fu Palma, founder and CEO of China Med Device, a Boston-based consulting firm that helps U.S. medtech companies expand into the Chinese market.

The draft catalog has significant implications for medical devices registrations and renewals, Fu Palma said. In particular, if a device is not included in the draft catalog, a manufacturer must go through an expert panel forum to get it listed, which is time-consuming and costly, she added.

The draft catalog does not cover in vitro diagnostic devices other than software, because IVD devices have a separate sub-catalog issued in 2013.

Release of the draft catalog is one of the final changes stemming from a 2014 revision of China's primary vehicle for regulating medical devices, the Medical Device Supervision and Administration Regulations. The draft is expected to be finalized quickly, perhaps early this year.

BRIEFS

Nurse Assist Recalls Saline Flush Syringes

Nurse Assist Inc. is recalling its normal saline flush syringes due to incidents of Burkholderia cepacia (B. cepacia) contamination. B. cepacia is a bacterium that can cause bloodstream infections, particularly in patients with weak immune systems.

According to the U.S. Centers for Disease Control and Prevention, the effects of Burkholderia cepacia on people vary widely but can include serious respiratory infections, especially in patients with cystic fibrosis.

FDA Will Post Faster Recall Information

The FDA announced that it will post information in the searchable Medical Device Recalls Database and the OpenFDA Device Recalls API much earlier than previously — at the time a firm takes a correction or removal action and notifies the agency, rather than at the time of the FDA's recall classification.

This change will help minimize confusion among patients and health care providers from a delay between when a firm initiates a correction or removal action and when the FDA announces the recall classification. It should also assist firms that are seeking information about legally marketed medical devices.

FDA Renews Technical Electronic Product Radiation Safety Standards Committee

The FDA announced the renewal of the Technical Electronic Product Radiation Safety Standards Committee for an additional two years beyond the charter expiration date. The committee provides advice to the FDA for setting standards for radiation emissions from electronic products. The new charter will be in effect until December 24, 2018.

Anika Therapeutics Scores CE Mark For Tendon-Injury Treatment

Bedford, Massachusetts-based Anika Therapeutics, Inc. has won CE Mark for its Orthovisc-T, indicated to relieve pain and restore function of tendons damaged by chronic injury and overuse.

Orthovisc-T is designed to provide lubrication and encourage tendon gliding. It is administered via injection into the site of injury.

FDA and Health Canada Approve OneTouch Vibe Plus Insulin Pump

Animas Corporation, a division of the Johnson & Johnson Diabetes Care Companies, has gained FDA Clearance and Health Canada's authorization for its OneTouch Vibe plus insulin pump and continuous glucose monitoring system for the treatment of patients age two and older living with diabetes.

The transmitter collects blood glucose readings from the sensor and sends them to the patient's insulin pump screen and compatible mobile device systems and app.

FDA Grants Marketing Clearance to Cepheid's Next-Generation Test for MRSA Colonization

Sunnyvale, California-based Cepheid received clearance from the FDA for Xpert MRSA NxG methicillin-resistant Staphylococcus aureus (MRSA) infection control test.

Xpert MRSA NxG is a molecular test that delivers results in about an hour. The test has been validated for use with both ESwab (Copan) and rayon swabs.

Iradimed Corporation Scores FDA Clearance For MRI Compatible IV Infusion Pump

Winter Springs, Florida- based Iradimed Corporation received FDA clearance for its MRidium 3860+ magnetic resonance imaging (MRI) compatible IV infusion pump system, including its dose error reduction system software feature.

The compatible IV infusion pump system has been designed with a non-magnetic motor and other feature in order to deliver anesthesia and other IV fluids during MRI procedures.

FDA Grants Marketing Clearance To SalutarisMD's RBS System

Tucson, Arizona-based Salutaris Medical Devices, Inc. has received marketing clearance for its SMD-Sr90-DA Radionuclide Brachytherapy Source (RBS), which is used within a manual brachytherapy applicator system.

The SMD-Sr90-DA RBS device is indicated for episcleral brachytherapy. The patented technology delivers a single-use brachytherapy procedure.

Precision Interconnect Cited For Poor Documentation

Precision Interconnect was hit with a Form 483 for poor corrective and preventive action (CAPA) procedures and failing to ensure that products conformed to requirements.

During a September 2016 inspection of the company's Wilsonville, Ore., facility, inspectors found that certain CAPA records were opened to address a customer audit finding that Precision's supplier management system did not ensure requirements for supplier evaluations were consistently met. Although several corrective actions were specified in the CAPA file, there was no documentation that they were completed.

The Form 483 also said that Precision failed to ensure that all received products and services conformed to specified requirements. In particular, the firm's procedure governing supplier evaluation and monitoring activities required that supplier be evaluated, and that review results be reported on a scorecard. According to the inspectors, not all suppliers were scored in the evaluations, and supplier scoring was conducted with inconsistent parameters.

Read the Form 483 here: www.fdanews.com/01-03-17-Precision.pdf.

Clement Clarke Gets Form 483 For Validation Procedures

Clement Clarke International Ltd. was cited for problems with its validation and acceptance procedures, supplier evaluations, and controls for nonconforming products.

According to a Form 483, inspectors who visited the company's Harlow, UK, facility in October found that Clement had not conducted various processes used to manufacture its Class II Peak Flow Meters in contravention of the firm's procedures.

Inspectors also reported that software used as part of production and in the company's quality system had not been validated for its intended use according to an established protocol.

Clement also did not follow its inspection and sampling procedures for certain incoming goods, including components of its Peak Flow Meter. In particular, the firm did not document any inspections of these components.

The FDA also said Clement failed to document the evaluation and selection of suppliers on the proper forms or evaluate production errors during weekly meetings to see if an investigation was needed.

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

White Square Chemical Gets Form 483 for Poor Procedures

White Square Chemical failed to establish a design history file, complete a risk analysis, and committed other violations, according to investigators who handed the company a Form 483.

After visiting the company's Tavernier, Fla., facility in July, inspectors reported that White Square had not established a design history file for its Novus or NovusBond devices. It had not established design inputs, design outputs, design review, design verification, design validation, and design transfer.

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

FDANEWS

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

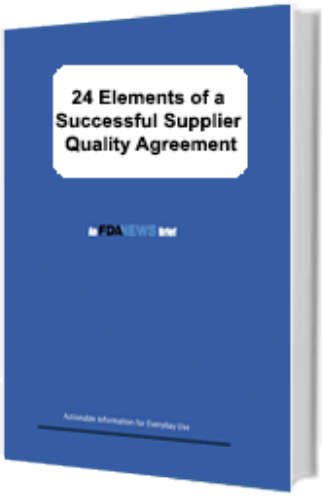
Editor: Jeff Kinney
+1 (703) 538-7634
jkinney@fdanews.com

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 **Managing Editor:** Declan Conroy **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
14. Dispute Resolution
15. Warehousing and Distribution
16. Technical Transfer
17. Validation / Qualification
18. Record Retention
19. Sample Retention
20. Reprocessing / Reworking
21. Supplier Qualification
22. Stability Programs
23. Contact List
24. Responsibility Matrix

Use this 24-point plan to make sure you've covered all your bases and keep your suppliers well in hand. Order your copy today.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/52994
3. **FAX:** +1 (703) 538-7676
4. **MAIL:** FDAnews 300 N. Washington St., Suite 200 Falls Church, VA 22046-3431

☑**Yes!** Please send me ____ copy(ies) of ***24 Elements of a Successful Supplier Quality Agreement*** at the price of $177 for each PDF.

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

Email _____

METHOD OF PAYMENT

❑ Check enclosed (payable to FDAnews)

❑ Bill me/my company. Our P.O.# _____

❑ Charge my credit card:
❑ Visa ❑ MasterCard ❑ American Express

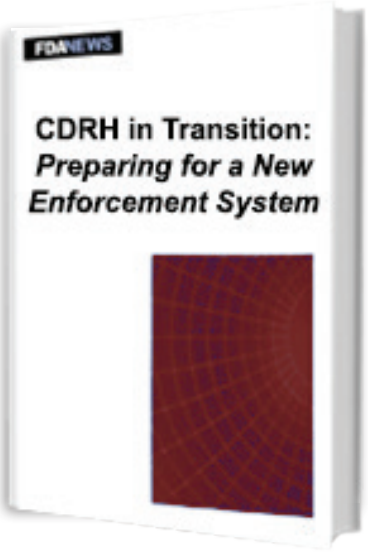
Credit card no. _____

Expiration date _____

Signature _____
(Signature required on credit card and bill-me orders)

Virginia customers add 6% sales tax.

16FLYR-N



CDRH in Transition: *Preparing for a New Enforcement System*

The looming realignment of CDRH's programs and retooling of inspection procedures have raised many questions among devicemakers trying to prepare for future inspections.

Currently, devicemakers are used to seeing one "generic" investigator at their inspections and they are used to investigators following the approach set out in the FDA's Investigations Manual and Quality Systems Inspection Technique.

But that's all about to change, creating a "perfect storm" that will leave devicemakers drowning in unfamiliar waters. Now is the time to make preparations to weather that storm, and **CDRH in Transition: *Preparing for a New Enforcement System*** is the place to start. In this report, noted industry expert John Avellanet gives his well-informed perspective on where CDRH enforcement is headed and what adjustments devicemakers will need to survive.

CDRH in Transition: *Preparing for a New Enforcement System* outlines how — and when — CDRH plans to update its programs in the coming years and how devicemakers should respond. Think of it as your to-do list for the next 18 months.

Order your copy today!

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/52247
3. **FAX:** +1 (703) 538-7676
4. **MAIL:** FDAnews 300 N. Washington St., Suite 200 Falls Church, VA 22046-3431

☑**Yes!** Please send me ____ copy(ies) of ***CDRH in Transition*** at the price of $397 for each PDF.

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

Email _____

METHOD OF PAYMENT

❑ Check enclosed (payable to FDAnews)

❑ Bill me/my company. Our P.O.# _____

❑ Charge my credit card:
❑ Visa ❑ MasterCard ❑ American Express

Credit card no. _____

Expiration date _____

Signature _____
(Signature required on credit card and bill-me orders)

16FLYR-N