International Devices & Diagnostics Monitor

Vol. 3, No. 47
Nov. 27, 2017

IN THIS ISSUE

India to Enforce New Code For Marketing Devices

As India gets ready to enforce its new medical device regulations in January, the government is gearing up to release a new uniform code for medical device marketing practices.

Previously, India's devices were regulated as pharmaceuticals, and the new regulations separate out devices for the first time from broader drug regulations.

Regulation of marketing practices for devices currently falls under the broader Uniform Code for Pharma Marketing Practices (UCPMP), which was introduced in 2011 and amended in 2015.

Under the UCPMP, drug and device companies cannot offer gifts or benefits to medical practitioners that would provide incentives to prescribe their products. The code, however, is voluntary and lacks any penal provisions to deter unethical practices.

The Department of Pharmaceuticals is in the process of upgrading its voluntary code to be mandatory.

(See **India***, Page 2)*

The EMA Gets a New Home: Amsterdam

The European Union landed on Amsterdam as the new home for the European Medicines Agency headquarters, following three rounds of voting and a tiebreaker against Milan. The agency hopes to keep a majority of its existing staff in the move.

The relocation presents an additional challenge for EMA as it implements the EU's new medical device and IVD regulations.

The decision leaves just 16 months for the EMA and its 900 staff to complete the move from its current location in London's Canary Wharf. Operations must be up and running in the capital of the Netherlands by March 30, 2019.

"Amsterdam ticks many of our boxes," said EMA Executive Director Guido Rasi after the vote. "It offers excellent connectivity

(See **Amsterdam***, Page 2)*

Amsterdam, *from Page 1*

and a building that can be shaped according to our needs." Internal surveys showed the agency would retain a large majority of its staff with such a choice, in comparison to the 18 other European locations that initially launched bids.

"However even in this case, our activities will be impacted and we need to plan for this now to avoid the creation of gaps in knowledge and expertise," Rasi said.

The EMA and the Netherlands plan to establish a joint governance structure to oversee the 220-mile relocation. During the move, the EMA will try to maintain "business as usual" for as long as possible, according to its continuity plan that includes a dedicated Brexit recruitment strategy for new hires. The agency also plans to bolster entitlements for current staff and families, and to provide other services to encourage retention (*IDDM*, Oct. 23). — Conor Hale

India, *from Page 1*

Following consultations with stakeholders, a separate new device code is also being finalized under the Department of Pharmaceuticals. The code discourages incentives that devicemakers can offer doctors for recommending certain devices. The code also would ban inducements such as foreign trips for enhanced training.

The Association of Indian Medical Device Manufacturers (AiMeD) said it welcomed a stricter and mandatory ethical marketing code for devicemakers.

"Many stakeholders like us wished this to be enforceable at times when self-regulation was not working," Rajiv Nath, forum coordinator for AiMeD, told FDAnews.

The association believes multinational companies currently have an unfair advantage in the market and are able to sway doctors' prescribing habits. This practice also keeps prices higher for medical devices.

"An enforceable Ethical Marketing Practices Code will help to address issues of exploitation of consumers with wayward runaway retail pricing, unfair anti-competitive trade practices and increasing corruption of the marketplace in healthcare where ethical manufacturers are finding it increasingly challenging to play fair," Nath said.

Currently, devicemakers often offer physicians free devices, such as glucose meters or glucose strips as an incentive to prescribe these products to their patients.

India has been taking steps to bring its regulations in line with international standards. For example, beginning Jan. 1, 2022, all medical devices sold in India will require a unique device identification, including a device identifier and a production identifier. A production identifier would include a serial number, lot or batch number, software version, and manufacturing and/or expiration date (*IDDM*, Feb. 20).

India has also implemented other measures to make India's device sector a more attractive place to invest. The government recently removed regulations that restricted foreign direct investment in the country.

Upcoming FDAnews Webinars and Conferences

Sharpen your understanding of regulatory compliance at these upcoming FDAnews events. Click on the links below for details.

WEBINARS

Sensors and Wearables in Clinical Trials Critical Components for Success
Dec. 20, 2017, 1:30 p.m. - 3:00 p.m. ET
www.fdanews.com/sensorswearablesct

How to Build A World-Class Audit Team: *The Key to Avoiding FDA Enforcement*
Dec. 15, 2017, 1:30 p.m. - 3:00 p.m. ET
www.fdanews.com/auditteam

CONFERENCE

SOPs for the 21st Century: *Why Less Is More*
Dec. 7-8, 2017, Arlington, VA
www.fdanews.com/sops

Bill on Use of New Medical Devices For Soldiers Heads to White House

The Senate gave final congressional approval to a bill designed to resolve a dispute involving the FDA and the Department of Defense, preserving the FDA's authority over authorizing innovative medical devices for soldiers while streamlining the authorization process.

The measure, H.R. 4374, sponsored by Rep. Greg Walden (R-Ore.), was drafted because of a defense authorization bill working its way through Congress that contains a provision that would give the DoD authority to administer unapproved drugs and devices to soldiers.

FDA Commissioner Scott Gottlieb objected to the provision as a threat to the established process for approvals, with its attendant safeguards.

The Walden bill was drafted to address those concerns while providing for the faster approvals that the DoD wants. Congress adopted a rule requiring passage of the Walden legislation before final voting on the defense authorization bill.

Under existing regulations, the president can authorize military administration of unapproved devices through a different procedure.

Read the Walden bill here: www.fdanews.com/11-16-17-Waldenbill.pdf. — Gregory Roberts

House Sets Deadline for HHS To Develop Bill of Materials Action Plan

The House Energy and Commerce Committee is giving the Department of Health and Human Services until no later than Dec. 15 to come up with an action plan for creating "bills of materials" to enhance cybersecurity for healthcare technologies.

Creating a BOM for each component of a medical technology, including hardware and software, was among the six recommendations in the 2017 report from the Health Care Industry Cybersecurity Task Force established by HHS in 2016 per the Cybersecurity Act of 2015.

In a Nov. 16 letter to HHS, the lawmakers pointed to recent cyber attacks that highlighted the vulnerabilities and unpreparedness of the healthcare sector to "increasingly sophisticated and rapidly evolving cyber threats."

The lack of information about the various components of the technologies forced stakeholders to "take less targeted, and thus less effective, remediation steps, or to contact the manufacturers individually to try and obtain the missing information," the committee wrote.

As examples of known risks, they cited the vulnerabilities found in St. Jude Medical's (now Abbott's) implantable cardiac pacemakers and Merlin@home transmitter that were flagged by the FDA and the Department of Homeland Security earlier this year (*IDDM*, Jan. 16).

Read the full letter here: www.fdanews.com/11-22-17-ECCommBOMsRequest.pdf.

FDA Says Osteotech Must Improve Aseptic Processing, Investigations

The FDA cited Osteotech over inadequate sanitation and product deviation investigations.

The FDA issued a Form 483 to the firm following a July/August inspection of its Eatontown, New Jersey facility, where investigators found the facility's environmental controls did not ensure aseptic processing. As a result, gram-positive bacillus was identified in several product samples.

The agency also found that the material used to stopper bottles under vacuum and for lyophilization of soft tissue was not tested for microorganisms.

In addition, the FDA faulted the facility for its investigations of deviations related to current good tissue practice requirements. The company did not adequately review the causes of the deviations, the agency said. In four sterility failure investigations, the investigation did not consider all areas where contamination could have occurred, instead limiting them to the bottling room. Multiple clean corridors were omitted from the investigations.

Read the Osteotech Form 483 here: www.fdanews.com/11-22-17-osteotechinc483.pdf. — Zack Budryk

FDA Raps ADB Interests For Lack of CAPA, MDR Procedures

The FDA faulted ADB Interests for its MDR, complaint-handling and CAPA procedures.

The agency issued a Form 483 following a July/August inspection of the devicemaker's Pearland, Texas, facility. Investigators found the firm had no MDR procedures to ensure timely evaluation of events subject to MDR reporting requirements. The agency identified more than 70 MDR-reportable complaints and four consumer complaints filed between June 2016 and June 2017, but the company could not produce files to show the results of investigation.

The firm also lacked an adequate complaint procedure for its FasciaBlaster device, leaving customers to select "Other" on its "Contact Us" web page. Records documenting the procedure did not include the device name, unique device identifiers, the dates or results of investigations, or any corrective actions taken.

Investigators found the firm had not defined or implemented a CAPA procedure for processes, or returned products. Managers said 70 MDRs had been filed over the previous 12 months involving injuries related to the FasciaBlaster device, but no CAPAs had been initiated to address them.

The Form 483 can be read here: www.fdanews.com/11-22-17-ADBInterests483.pdf. — Zack Budryk

First Telehealth Feature for Cochlear Implants Snags FDA Approval

The FDA approved a remote programming feature for Cochlear Americas' Nucleus Cochlear Implant System — the first telehealth option for remote adjustments to cochlear implants.

Patients must have used their implant for at least six months and feel comfortable with the process to receive remote programming adjustments from specialized centers or clinics aimed at improving their quality of life, the FDA said.

Routine visits to an audiologist are required with standard cochlear implants — electronic hearing devices designed to stimulate nerves in the inner ear in order to provide hearing sensations — to receive adjustments to the stimulation electronic settings.

Being able to have a qualified audiologist program the device from a remote location "can greatly reduce the burden to patients and their families, especially those who must travel great distances or need frequent adjustments," said Malvina Eydelman, director of CDRH's Division of Ophthalmic, and Ear, Nose and Throat Devices.

Why Perform Root Cause Analysis?

Root cause analysis provides that systematic approach to problem-solving, allowing companies to dig into a problem and analyze it rationally, to clearly identify the problem and then separate the root causes from secondary causes or symptoms.

Take the following example of a problem that at first glance may seem relatively simple to address. An internal audit reveals that a manufacturing group has consistently failed to follow the proper assembly procedure, which in turn has caused deviations and nonconformances in the end product. Many managers would look at this problem and jump to an immediate conclusion: the employees are simply not following instructions and need to be reprimanded or retrained.

However, digging down further, you might find a number of other issues at play:

- The written procedures in the device master record may be unclear or outdated;
- The work instructions were not written by or reviewed by the machine operators;
- Training wasn't adequate.

Further investigation in this case could reveal a problem much deeper and more complex than initially believed.

Excerpted from the FDAnews management report: ***Root Cause Analysis for Drugs and Devices.***

Jury Returns Verdict in Defective J&J Hip Implants Case

A federal court jury in Texas returned a $247 million verdict on behalf of six individuals who said they suffered serious medical complications from metal-on-metal Pinnacle Acetabular Cup System hip implants made by the Johnson & Johnson subsidiary DePuy Orthopaedics.

The jury awarded more than $78 million in compensatory damages for the six plaintiffs and more than $168 million in punitive damages against Johnson & Johnson and DePuy.

J&J, which faces more than 9,700 lawsuits over Pinnacle implants in state and federal courts across the country, said it would immediately begin the appeal process.

The implants were most commonly used to treat joint failure caused by osteoarthritis. DePuy stopped selling the metal-on-metal Pinnacle implants in 2013 after the FDA strengthened regulations on artificial hip devices.

Claims

Lead attorney for the plaintiffs, Mark Lanier of the Lanier Law Firm in Houston, did not mince words about the jury's decision.

"Hopefully medical device manufacturers will learn that safety must truly come first — it isn't just a mantra to be said at the right times in the right places," he said. "It must be an actual practice, even in the marketing department."

The Nov. 16 verdict followed claims filed by six New York residents who received the implant and alleged that the devices had unreasonably high failure rates that lead to severe pain and inflammation, bone erosion and tissue loss.

The plaintiffs claimed that DePuy officials knew about the dangers of the Pinnacle hip implants but failed to warn doctors or patients. They also claimed that the companies falsely promoted the device, saying it lasted longer than similar implants that feature ceramic or plastic materials.

Lanier said he thanks the jury for sending a very strong message about the responsibility the defendants have to take care of their consumers, but added that it took the defendants putting the plaintiffs through burdensome litigation before justice could be served.

"The companies should have done the right thing when these serious medical concerns became known many years ago," he said.

The trial was the fourth "bellwether" in the multidistrict litigation consolidating more than 9,000 similar lawsuits nationwide. Bellwether trials are set to establish evidence and evaluate witness testimony that is representative of the issues involved in mass litigation.

Trials

J&J won the first Pinnacle trial it faced in 2014, but subsequent juries have found the companies liable. Two trials involving plaintiffs from California and Texas resulted in verdicts of $502 million (an award that was later cut to $150 million), and $1.04 billion (which was later dropped to $543 million).

Said Lanier, this case marks the first time a jury has assessed three consecutive nine-figure punitive awards against a company for fraud on the consumer and medical communities. But will this bring on a sea change in the medical device industry?

Lanier is skeptical. "I am not sure Johnson & Johnson gets the message yet," he said.

"They still talk like their economic power and position will trump the legal system and allow them the ability to do as they please without accountability in the courts."

Lanier said he hopes a plan can now be put into place to begin moving through hundreds of these claims each year.

How to Avoid Common CAPA Pitfalls

FDA inspection reports consistently show that the corrective and preventive action process is the biggest inspection problem for medical device facilities. And those who have to implement CAPAs have plenty of questions about how best to manage them.

Quality management expert Jon Speer, founder and vice president of QA/RA at Greenlight Guru, addressed some of the main issues that plague those who work with CAPAs in the device industry, in a recent FDAnews webinar "How to Implement and Maintain a Modern CAPA System While Avoiding Common Pitfalls and Mistakes."

For example, device companies may not be clear on whether it's advantageous to keep their CAPA system separate from other systems like those used for training and complaints — or integrated with them. Speer advises keeping all the information together in one integrated system.

Informed Decisions

"You need a system where all of these disparate parts of your quality system are connected together in one single source so that you can use the information, that data, to make informed decisions that impact the quality of your products and processes," he said.

"Audits, CAPAs, complaints, non-conformances, all of these records that we're generating — these are the proof, the evidence that we did what we said we were going to do, the evidence that things are documented in a way that shows that our products are safe and effective."

Another common concern: What is a good balance between corrective to preventative CAPAs? Speer said there is no magic ratio, though in general it's much preferred that most of the energy spent goes toward prevention. Unfortunately, however, that's not the current state of affairs.

"It's overwhelmingly skewed toward being greater than 80 percent corrective in nature now," he said. "The first step is for us to get our ratio of corrective to preventative more in a one-to-one relationship rather than a four-to-one type of relationship. Try to shift in that direction."

But what if company leadership doesn't see the value of robust CAPA processes that are preventive in nature? Speer said he's worked in that culture before, and it's frustrating, adding it's sometimes fear works best in one's effort to wake up management about the importance of CAPAs.

"There's plenty of data from FDA inspections year after year that consistently show that the CAPA process is statistically the biggest problem of the medical device industry," said Speer. He added that sometimes grassroots efforts within the company can work to press those in the C-suite to adopt a mindset change. — Suz Redfearn

Building a World-Class Advertising and Promotion Review Program

An FDANEWS Conference

Dec. 14-15, 2017 • Raleigh, NC

FDA marketing scrutiny no longer is limited to magazine and TV ads. Now the agency is poking around, checking signage in tradeshow booths ... checking in on Twitter, YouTube and Facebook ... and listening to the physicians and other healthcare professionals you've paid to speak or train.

In 2016 the Office of Prescription Drug Promotion issued 11 enforcement letters. A 20 percent increase from 2015. Six of those 2016 letters were issued in December alone. What is the meaning of OPDP's recent upswing in enforcement?

Face it: You need help. Not with creating better ads and promotions — you already know how to do that — but for making sure your promotional activities aren't magnets for warning letters.

Come to Raleigh in December for two days of intense learning. You'll arrive back home with a bag full of tricks and tips to keep all your marketing efforts squeaky-clean.

Register online at:
www.fdanews.com/advertisingpromotion
Or call toll free: (888) 838-5578 (inside the U.S.)
or +1 (703) 538-7600

IV Bag Shortage Continues After Hurricane Maria Damage

The FDA continues to grapple with shortages of saline intravenous injection bags that were worsened when Hurricane Maria devastated Puerto Rico, and the agency is temporarily allowing the importation of bags to boost the supply, Commissioner Scott Gottlieb said.

Shortages of the bags have been reported intermittently since 2014, but the hurricane exacerbated them significantly when it struck Puerto Rican manufacturers, he said. The FDA has been working with Baxter, owner of a storm-damaged bag factory in Puerto Rico, to restore its production.

The FDA recently has approved saline bags for import from Fresenius Kabi, a German producer, and from Grifols, headquartered in Spain, Gottlieb said.

The agency also is working with federal and local officials to move medical-products factories to the head of the line for regaining access to the damaged Puerto Rican power grid as it is repaired, he said. That collaboration also includes efforts to clear roads for deliveries of supplies and to provide fuel and electrical generators for the companies, Gottlieb said. — Gregory Roberts

ANSM Sees Uptick in Adverse Event Reports for Bayer IUD

France's National Agency for the Safety of Medicines reported a major uptick in adverse advents associated with Bayer's Mirena intrauterine device.

More than 2,700 adverse events reported were associated with the IUD between May 15 and Aug. 4, 2017, including 870 with anxiety symptoms, ANSM said. The number of adverse event reports for the device totaled 510 from its marketing launch in 1997 to May 15, 2017.

The European Medicines Agency said earlier this month there is insufficient data to establish a direct connection between the occurrence of the reported adverse effects, including anxiety, and the IUDs, which are indicated to prevent pregnancy or to treat abnormal menstrual bleeding.

But ANSM said it will launch a pharmacoepidemiology study to assess the frequency of certain adverse effects because its survey results echoed the findings of an analysis based on health insurance data. The analysis assessed how frequently certain undesirable effects occurred with levonorgestrel IUDs compared to those with copper and revealed "a low but increased risk" of anti-anxiety drug use in women with Mirena.

APPROVALS

EMD Serono Wins FDA Nod For Redesigned Pen Injector

EMD Serono received the FDA's approval for a redesigned version of its Gonal-f RFF Redi-ject pen injector.

First approved in 2013, the device is designed to inject follitropin alfra to induce ovulation and pregnancy in oligo-anovulatory women.

The redesigned pen was evaluated in a simulated-use study involving 86 women with infertility and 30 fertility nurses.

Cianna Medical Gets FDA Clearance For Breast Tumor Localization System

The FDA cleared Cianna Medical's nonradioactive breast tumor localization system for long-term implant.

Smaller than a grain of rice, the SAVI SCOUT implant allows physicians to pinpoint a location for a biopsy or a lumpectomy without time restrictions or interfering with magnetic resonance imaging studies.

FDA Clears Clinical Genomics-Quest Diagnostics Fecal Test

Clinical Genomics and Quest Diagnostics received FDA-clearance for InSure One, an at-home fecal immunochemical test (FIT).

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

Approvals, *from Page 7*

The test uses a single sample of toilet bowl water to detect human hemoglobin in the user's blood with the goal of detecting lower gastrointestinal bleeding, which may be associated with health conditions such as colorectal cancer and anemia.

Varian Medical Wins Shonin Approval For Cancer Treatment Device

Varian Medical Systems has obtained Shonin approval to introduce its cancer treatment device for commercial distribution in Japan.

The system enhances image-guided volumetric intensity modulated radiotherapy and shortens the time from installation to first treatment, the company said. The device uses a nine-step workflow process compared to the 30-step standard for other technologies.

Alcyone Lifesciences Scores FDA Clearance For Ventricular Catheter and Flusher System

Alcyone Lifesciences announced it has received FDA clearance for its Alivio ventricular catheter and flusher system for treating neurological condition called hydrocephalus, which can be life-threatening.

The Alivio System consists of a flusher and a ventricular catheter with a unique relief membrane. It is designed for non-invasive retrograde flushing the ventricular catheter with the goal of restoring or increasing cerebrospinal fluid.

FDA Clears Drug Coated Catheter for Marketing

The FDA has approved the Lutonix 035 drug coated balloon percutaneous transluminal angioplasty catheter, Model 9010 for commercial distribution with certain restrictions.

The device is a thin tube with an inflatable balloon at the tip used to treat narrowed or blocked blood vessels. It is used as an access site for dialysis in patients with chronic kidney failure.

The balloon is coated on its outer surface with the drug paclitaxel to help prevent the vessels from narrowing again.

FDA Clears First Device for Reduction Of Opioid Withdrawal Symptoms

The FDA has cleared a new indication for Innovative Health Solutions' electric nerve stimulation device for use in reducing opioid withdrawal symptoms as part of the agency's continued efforts to address the U.S. opioid epidemic.

A chip contained in the NSS-2 Bridge device stimulates certain cranial nerves via electrical pulses to relieve acute physical withdrawal symptoms such as sweating, gastrointestinal upset, agitation, insomnia and joint pain.

The device can remain behind a patient's ear for up to five days during the withdrawal phase.

Second Sight Receives EAP Designation For Visual Prosthesis System

Second Sight Medical Products received FDA expedited access pathway designation for the Orion Cortical visual prosthesis system.

The Orion is designed to transmit electrical pulses wirelessly to an array of electrodes implanted on the surface of the visual cortex, intended to result in the perception of patterns of light.

By bypassing the retina and optic nerve and directly stimulating the visual cortex, a cortical prosthesis system has the potential to restore vision to blind patients.

FDANEWS

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

Editor: Ana Mulero
+1 (703) 538-7634
amulero@fdanews.com

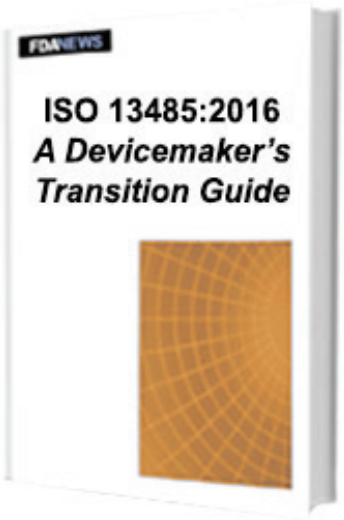
Ad Sales: Jim Desborough
+1 (703) 538-7647
jdesborough@fdanews.com

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: Conor Hale, Zack Budryk, Josephine Hill **Managing Editor:** Declan Conroy **President:** Cynthia Carter

Copyright © 2017 by Washington Business Information Inc. All rights reserved. ***International Devices & Diagnostics Monitor*** (ISSN 2376-7537), is published weekly, 50 issues, for $1,247. Photocopying or reproducing in any form, including electronic or facsimile transmission, scanning or electronic storage is a violation of federal copyright law and is strictly prohibited without the publisher's express written permission. Subscribers registered with the Copyright Clearance Center (CCC) may reproduce articles for internal use only. For more information, contact CCC at www.copyright.com or call (978) 750-8400.



ISO 13485:2016
A Devicemaker's Transition Guide

The ISO 13485 have rules changed — and you need to know how.

Our team of experts have spent hours parsing out every clause in the new version of the rules and compared them to ISO 13485:2003.

ISO 13485:2016 — *A Devicemaker's Transition Guide* saves you valuable time. It has a clause-by-clause, line-by-line, 46-page comparison of the old and new versions of 13485 that shows you exactly what and where the new requirements are.

In this management report you will also learn:

- The major differences between ISO 13485:2003 and ISO 13485:2016
- The role of ISO 13485:2016 in the MDSAP and Canada's plan to adopt it
- The status of EN ISO 13485:2016 and issues related to the product directives
- Some potential concerns related to ISO 13485:2016 and FDA's QSR
- How recent revisions to ISO 9001 compare to the new 13485

The report interprets the four key areas in the 2016 version — risk management, design control, supplier management and corrective and preventive action — and explains what kind of changes the new standard will require.

Based on the insight of one of the world's foremost ISO experts, this report is essential for any devicemaker that hopes to survive the coming transitions. Order your copy of **ISO 13485:2016 — *A Devicemaker's Transition Guide*** today.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/53254
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 **ISO 13485:2016 — *A Devicemaker's Transition Guide*** 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

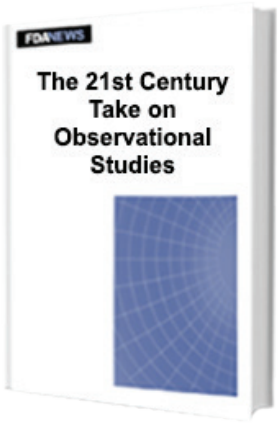
Credit card no. _____

Expiration date _____

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

Virginia customers add 6% sales tax.

17FLYR-N



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.

More flexible, faster and cheaper research methods, including observational studies, are now acceptable in the FDA's approval process.

Observational research requires an entirely different set of procedures and careful planning to ensure the real-world evidence collected is valid and reliable.

The 21st Century Take on Observational Studies walks you through everything you need to know about the opportunities and pitfalls observational studies can offer. The report looks at the growing trend toward observational research and how provisions in the 21st Century Cures Act create even more incentives to rely on real-world evidence in the development of medical products. The report covers:

- Provisions of the 21st Century Cures Act related to observational studies and gathering of real-world evidence
- The evolution of patient-focused research
- How observational studies can be used in the preapproval and postmarket stages
- The potential for saving time and money
- 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

Order your copy of **The 21st Century Take on Observational Studies: *Using Real-World Evidence in the New Millennium*** and learn effective uses of observational studies in both the preapproval and postmarket phases; how to identify stakeholders and determine what kind of data they needed, and how the FDA's view on observational research is evolving.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/55020
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 **The 21st Century Take on Observational Studies** 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)

Virginia customers add 6% sales tax.

17FLYR-N