INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 5, No. 21
Oct. 28, 2019

IN THIS ISSUE

HHS Inspector General to report on postmarket surveillance in 2020.....Page 3

FDA classifies internal massager, surgical instrument as Class II.....Page 3

Briefs: FDA Commissioner warns of shortages over sterilization facility closures … European Commission certifies first notified body under EU IVDR..... Page 3

EC releases guidance on qualifying software under MDR, IVDR .....Page 4

FDA calls for boxed warning for breast implants.....Page 4

Surgical lighting firm fails to validate design .....Page 5

Quality system failures observed at South Carolina facility.....Page 6

Validations, product control procedures lax at diagnostic lab .....Page 6

CDRH lists guidance priorities for 2020.....Page 7

Approvals: Shape Memory's embolic coil earns CE Mark … Solasia Pharma's Episil pain relief device approved in Korea.....Page 7

FDA Plans to Exempt Five Class II Devices From Premarket Notification

The FDA is proposing to exempt additional Class II medical devices from 510(k) premarket notification requirements.

The 21st Century Cures Act requires the agency to publish a notice in the Federal Register listing each type of Class II (special controls) device that no longer requires a 510(k) application. In the latest notice, the agency lists five device types: an optical position/movement recording system, an internal therapeutic massager, an accessory used in assisted reproduction, an instrument for press-fit osteochondral implants, and a phosphate buffered saline solution.

All but one of the device types will receiving partial exemptions. For example, the optical positioner's exemption is for prescription-only devices, while the assisted reproduction accessory exemption is limited to assisted reproduction laminar flow workstations.

Premarket notification of an optical position/movement recording system for OTC use "is necessary to ensure that the exercises and

(See **Exemptions**, *Page 2)*

South Korea Provides New Pathway for Innovative Devices

South Korea has updated its medical device regulations to provide a pathway for innovative technologies such as artificial intelligence, robotics and 3D printing technology applied to medical devices.

The new regulations, which take effect on May 1, 2020, include pre-market review criteria for devices with advanced and innovative technologies, Jin-young Yang, director general of the Medical Safety Bureau of Korea's Ministry of Food and Drug Safety (MFDS), said at the recent International Medical Device Regulators Forum in Russia.

One key aim of the legislation is to help South Korea be more competitive in the global market and to more quickly introduce innovative devices.

(See **South Korea**, *Page 2)*

Exemptions, *from Page 1*

activities led by the system are appropriate for a user's rehabilitation and to assess the measurement accuracy of the system," the agency said.

Similarly, a pelvic floor massager would require review if it is indicated for OTC use, has no mechanism for quantitative feedback or lacks a disposable covering.

In determining if 510(k)s are needed for a Class II device to show reasonable safety and effectiveness, the agency considers multiple factors, such as if the device has a history of false or misleading claims or of risks associated with its inherent characteristics. It also considers if changes that could impact safety and effectiveness can be easily seen by users before causing harm or if they don't raise the risk of injury, incorrect diagnosis or ineffective treatment.

The exempted device types will receive new product codes to differentiate them from devices that don't meet the exemption criteria, the agency said.

Read the *Federal Register* notice here: www.fdanews.com/10-25-19-Exemptions.pdf.
— James Miessler

South Korea, *from Page 1*

The new pathway includes several mechanisms for fast tracking approvals for innovative devices, including breakthrough devices that improve treatment for rare or intractable diseases, and priority reviews. The regulator provides additional support during the development and licensing phase, and the pathway includes a five-year post-market surveillance program.

The Act on Medical Devices provides a precertification application procedure, as well as a preferential R&D tax exemption for devicemakers that construct manufacturing facilities in the country.

In addition, a pre-certification program for innovative software allows devicemakers to exempt certain submission requirements by undergoing a pre-certification inspection. The program is modeled after the FDA's precertification program.

The updated regulations split in vitro diagnostics from medical devices for the first time in South Korea, because the regulator saw the need for specific support for IVD development and commercialization, Yang said.

The ministry saw the need to verify the accuracy of IVDs that diagnose diseases and it has developed a separate management system for IVDs that harmonizes with international standards.

The MFDS defines IVDs as reagents used ex vivo for the purpose of diagnosing disease, determining tissue or blood compatibility, and using human-derived samples as specimens. IVDs are classified according to their potential risks.

The new regulation also allows for simultaneous approval of corresponding companion diagnostics and drugs.

South Korea began requiring unique device identifiers for Class IV high-risk implantable devices in July. UDIs for Class III (serious risk) devices will be required by July 2020, UDIs for Class II (potential risk) devices will be required in July 2021, and lower-class Class I devices will need to carry UDIs by July 2022.

The ministry has developed draft guidelines on developing clinical trial protocols for medical devices that use artificial intelligence. It also drafted guidelines for 3D printed personalized medical devices.

HHS Inspector General to Analyze Postmarket Surveillance in 2020

HHS' Office of Inspector General (OIG) announced plans to release a report on medical device postmarket surveillance system next year.

The 2020 report will evaluate the methods the FDA uses in its passive postmarket surveillance system to identify safety concerns and will analyze how the agency responds to them.

"As the information that the FDA receives about medical device safety and effectiveness is increasingly gathered in the postmarket setting, it is more important than ever that FDA's postmarket safety surveillance system can effectively identify and act on safety signals," OIG said.

FDA Classifies Massager, Surgical Instrument as Class II

The FDA has categorized an internal therapeutic massager and an orthopedic surgical instrument used for osteochondral implants as Class II devices, assigning them special controls.

The special controls for the massager include labeling with adequate directions for use, nonclinical performance testing demonstrating electromagnetic compatibility, electrical safety and mechanical safety, and non-clinical performance testing showing the device performs as intended under anticipated usage conditions.

The orthopedic instrument must have geometric technical specifications proving it can safely position and place the implant, biocompatible patient-contacting parts, and labeling that identifies implants and instruments validated for use together, and validated methods and instructions for reprocessing any reusable parts.

Read the classification order for the internal massager here: www.fdanews.com/10-25-19-MDPhysicalMedicineTherapeutic.pdf.

Read the classification order for the surgical instrument here: www.fdanews.com/10-25-19-MDOrthopedic.pdf.

BRIEFS

FDA Commissioner Warns of Impacts From Sterilization Facility Closures

Acting FDA Commissioner Sharpless urged medical device manufacturers that use ethylene oxide facilities to assess their inventory for potential impacts of sterilization facility closures on their product distribution.

The call comes as Sterigenics facilities in Atlanta, Ga. and Willowbrook, Illinois are currently closed, and the company has announced that it will not reopen the Willowbrook facility.

Sharpless said the agency is coordinating with devicemakers and other stakeholders on impacts to medical device availability, as well as communicating with Sterigenics and medical device companies that may be affected.

He urged healthcare facilities to assess any medical supplies that undergo contract terminal sterilization via ethylene oxide prior to shipping and encouraged them to reach out to the agency for help in identifying substitute devices.

EC Certifies First Notified Body Under EU IVDR

The European Commission designated Germany-based Dekra Certification as the first notified body under the EU's In Vitro Diagnostic Regulation, which becomes effective in May 2022.

Dekra was also designated as a notified body under the EU Medical Devices Regulation, which becomes effective in May 2020.

The commission said it expects to have 20 notified bodies in place for both the MDR and the IVDR by the end of 2019, but the industry has been skeptical that it will reach that number.

MedTech Europe urged member states to "acknowledge that we are not on track," and to prepare for the lack of notified bodies.

The industry group flagged the need for more notified bodies for certification of new products, recertification, Eudamed, quality guidance, scientific bodies and harmonized standards.

EC Releases Guidance on Qualifying Software Under MDR, IVDR

The European Commission released guidance on qualifying software under the EU's Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

Software must have a medical purpose of its own to be qualified as medical device software (MDSW). Just as with any device, the intended purpose of the software is relevant for the qualification and classification of the software.

In order to be qualified as medical device software, the product must first fulfill the definition of software according to Article 2(1) of the MDR. To be qualified as in vitro diagnostic medical device software, the product must also fulfill the definition of an IVD according to Article 2(2) of the IVDR.

The guidance clarifies that software can directly control a medical device (as in radiotherapy treatment software), it can provide immediate decision-triggering information (as in blood glucose meter software), or it can provide support for healthcare professionals (as in ECG interpretation software).

"It is important to clarify that not all software used within healthcare is qualified as a medical device. For example, 'simple search,' which refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information does not qualify as medical device software," the Commission says.

Software that alters the representation of data for a medical purpose would qualify as medical device software — such as searching images to support a diagnosis or evolution of therapy, or software that locally amplifies the contrast of the finding on an image display.

Software that alters the representation of data for cosmetic or compatibility purposes does not qualify as medical device software. The guidance includes a decision tree for determining if software qualifies as MDSW or IVD software.

Read the guidance here: www.fdanews.com/10-25-19-Guidance.pdf.

FDA Calls for Boxed Warning On Breast Implants

The FDA released new labeling recommendations and called for a boxed warning for breast implants in a new draft guidance.

The boxed warning should be included on physician and patient labeling materials, the guidance advises. It should make clear that breast implants are not lifetime devices, that the chance of developing complications increases over time, and that additional surgery may be required.

The warning should note that breast implants have been associated with the risk of developing breast implant-associated anaplastic large cell lymphoma, and that implants may be associated with symptoms like fatigue or joint pain, the agency says.

The guidance recommends that a patient decision checklist should be included at the end of a patient informational booklet or brochure, to facilitate consultations between surgeons and patients.

Patients with silicone gel-filled implants who are not experiencing symptoms should have either an ultrasound or MRI five to six years after getting the implant to check for rupture and then every two years after, the agency advises. If patients are experiencing symptoms or have uncertain ultrasound results for rupture, then they should be screened with an MRI.

Information about the product's ingredients should be included on labeling materials in a way that is easy for patients to understand, the agency says. The guidance suggests manufacturers include the product's unique device identifier, boxed warning, and web links to the patient decision checklist, boxed warning and labeling for the specific implant on patient device cards.

Read the draft guidance here: www.fdanews.com/10-23-19-BreastImplantLabelingCertainGuidance.pdf. — Jordan Williams

Surgical Lighting Firm Fails to Validate Design, Evaluate Complaints

Failure to validate design under defining conditions, poor documentation and failure to evaluate complaints were a few of the deficiencies observed during an FDA inspection of surgical lighting manufacturer Sunnex's Charlotte, North Carolina facility.

Sunnex failed to establish written design validation procedures for its surgical and exam lights, and it wasn't able to provide device history records, according to the 12-item Form 483. The firm lacked a record of its design verification activities for one of its transformers and lacked a process validation plan for its medical lights soldering process.

Service reports for repaired medical lights were missing critical information such as service performed and tests and inspection data. In addition, complaints involving the possible failure of a device to meet any of its specifications were not reviewed or evaluated, the 483 said.

The firm received customer complaints for malfunctioning and nonconforming medical light devices that were not investigated, but it "did not perform root cause investigations to determine the failure mode to prevent reoccurrence of the nonconformities or to identify potentially defective devices that were distributed," the FDA official wrote.

Sunnex didn't document re-work and re-evaluation activities in the device history record, and the DHR didn't record the final disposition of the device components.

The firm's president told the FDA investigators that Sunnex had not established procedures to ensure the device design was translated into production specifications, and it did not maintain a device master record.

Finally, procedures for finished device acceptance were not established, and documents were not approved by designated individuals. For example, UDI labeling procedures weren't approved before being issued, the 483 said.

Read the Form 483 here: www.fdanews.com/10-25-19-sunnexllc483.pdf.

Five Steps to QSR-Compliant Purchasing Controls

The FDA is placing an ever-keener eye on device manufacturers' purchasing controls, including supplier qualification processes and vendor-related record keeping, as an important part of its Quality System Inspection Technique (QSIT). Although the FDA considers purchasing controls to be a routine part of even the most basic QSIT inspection under the Production and Process Controls section of the Quality System Regulation (QSR), devicemakers are failing to meet basic requirements of 21 CFR 820.50 time and again.

Only six paragraphs in length, 820.50 seems easy enough to digest, but FDA warning letter statistics paint a different picture. Forty percent of 2016 warning letters that cited Quality System Regulation violations included purchasing control problems.

"That tells us that there's some significant issues that device manufacturers are having in purchasing controls that FDA investigators are uncovering," says Dan O'Leary of Ombu Enterprises. The ability to find and fix these problems yourself is your best defense against 483s and warning letters, O'Leary says.

But to do that, you first need to go deeper into those six short paragraphs to get at the heart of the FDA's intentions and build a purchasing controls system that meets them. There are five simple steps, tied closely to the precise regulatory language governing purchasing controls, that can bring devicemakers smoothly from noncompliance to a robust purchasing controls program that meets or surpasses QSR requirements. The five steps are:

- Evaluate and qualify suppliers;
- Determine the necessary controls over each supplier;
- Establish active record-keeping procedures;
- Establish and maintain purchasing data for all suppliers; and
- Establish and adhere to appropriate acceptance criteria and activities for all products received from suppliers.

Excerpted from the FDAnews management report: *QSR Compliant Purchasing Controls: A Five-Stage Plan*.

Quality System Failures Found At Highland Industries

An FDA inspection of Highland Industries' Cheraw, South Carolina facility uncovered numerous quality system deficiencies including missing validation and manufacturing records and test reports, along with a slew of other documentation failures.

Highland Industries manufactures composites for medical devices such as imaging equipment, implants, orthopedics and prosthetics.

Process validation activities and results weren't documented and approved, according to the 483, which said that lack of adequate validation resulted in the manufacturing process not having defined operating parameters and specifications for ozone levels.

The FDA found no manufacturing records or test reports for various process validation equipment installations and performance qualifications.

The firm also lacked procedures for finished device acceptance to ensure finished devices meet acceptance criteria. Acceptance activities required to meet the device master record specifications were not defined, the associated data is not reviewed, and there was no documented signature and date authorizing the release of manufactured devices, the agency said.

Read the 483 here: www.fdanews.com/10-25-19-highlandindustriesinc483.pdf.

Validation, Procedures To Control Product Lax at IVD Lab

Procedures for accepting in-process product and procedures to control products that don't conform to specifications were found to be lacking at Eurofins Viracor's Lees Summit, Missouri, facility during a July 23-26 FDA inspection.

The diagnostic laboratory didn't include guidance for testing and retesting of nonconforming product during manufacturing of its Class II ImmuKnow immune cell function assays. Numerous acceptance records failed to pass quality control, but no retesting was conducted, the 483 said.

The FDA concluded that the firm's procedures didn't control nonconforming product. For example, definitions for severity and probability were not included in the standard operating procedure, and certain high-risk variables didn't require corrective and preventive actions.

Two nonconformances were classified as low priority/high risk, and both records indicated that an investigation for remedial actions was conducted, but there was no documentation of investigations. The firm was also cited because it had no formally designated unit to review and evaluate complaints.

Read the 483 here: www.fdanews.com/10-25-19-eurofinsviracorinc483.pdf.

CDRH Releases Guidance Priorities for Fiscal 2020

CDRH released a list of priority guidances it plans to publish during fiscal 2020, including a "A-list" of final and draft guidances.

The A-list priorities for final guidances include:

- Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices;
- Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies;
- 510(k) Third Party Review Program;
- Safer Technologies Program for Medical Devices;
- Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices;
- Labeling Recommendations for Surgical Staplers;
- Nonbinding Feedback After Certain FDA Inspections of Device Establishments;
- The Accreditation Scheme for Conformity Assessment Pilot Program;
- Recognition and Withdrawal of Voluntary Consensus Standards;
- Clinical Decision Support Software;
- Multiple Function Device Products: Policy and Considerations; and
- Device-Specific Criteria Guidance(s) for Safety and Performance Based Pathway Implementation.

The A-list draft guidance for the year ahead include:

- Labeling and Informed Decision Checklist for Breast Implants;
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices;
- Distinguishing between Medical Device Servicing and Remanufacturing;
- Computer Software Assurance for Manufacturing, Operations, and Quality System Software;
- Procedures for Handling Post-Approval Studies Imposed by PMA Order;
- Postmarket Surveillance Under Section 522 of the FDCA;
- Unique Device Identification: Policy on Enforcement of GUDID Submission Requirements for Certain Class I Devices;
- Pragmatic Generation of Validity Evidence for Patient-Reported Outcome Measures Used in Medical Device Submissions; and
- Device-Specific Criteria Guidance(s) for Safety and Performance Based Pathway Implementation.

Read the full notice here: www.fdanews.com/10-25-19-CDRH.pdf.

APPROVALS

Shape Memory's Embolic Coil Grabs CE Mark

Shape Memory Medical has received the CE Mark for its TrelliX embolic coil system, a device that obstructs or occlude blood flow in vascular abnormalities.

The device's indications include intracranial aneurysms and other neurovascular abnormalities, including arteriovenous malformations and embolizations in the peripheral vasculature.

The company claims the coil is "a game-changing product, particularly for medium to giant aneurysms, that may offer significant advantages in neurovascular and peripheral vasculature applications."

Solasia Pharma's Episil Pain Relief Device Approved in Korea

South Korea's National Institute of Medical Device Safety Information has approved Solasia Pharma's pain relief device, a product that

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

Approvals, *from Page 7*

delivers episil oral liquid for creating a protective film over oral wounds.

The pocket-sized medical device is indicated for managing and relieving oral cavity pain resulting from chemotherapy or radiotherapy. The device has already been cleared in the U.S., the EU, Japan and China.

According to clinical results, episil quickly provides oral pain relief and physical protection that lasts up to eight hours.

FDA Clears AI Reconstruction Tech For Canon Medical's CT Scanner

The FDA granted Canon Medical's ultra-high resolution CT system 510(k) clearance for its Advanced Intelligent Clear-IQ Engine (AiCE).

The company's Aquilion Precision and Aquilion ONE / Genesis edition computed tomography systems use a deep learning algorithm to separate the signal from noise, suppress noise and enhance signal.

The Aquilion Precision uses deep learning neural networks "specifically trained to perform one task — reconstruct images that are sharp, clear, and distinct," the company said.

Cortechs' Brain Disorder Monitor Snags Brazilian Clearance

Cortechs Labs received regulatory clearance in Brazil for its NeuroQuant neurodegenerative brain disorder monitor.

The device software helps to diagnose and monitor neurodegenerative brain disorders using magnetic resonance imaging. In five to seven minutes, the results are available for review in picture archiving and communication systems.

NeuroQuant produces volumetric measurements of a patient's brain structure and compares the measurements to a normative database that adjusts for gender, age and intracranial volume.

The software was previously cleared in the U.S., EU, Canada, Australia and South Korea.

Fidmi Earns FDA Clearance For Enteral Feeding Device

Fidmi Medical received 510(k) clearance for its low-profile enteral feeding device, a gastronomy tube designed to deliver nutrients to patients.

The device can be used for initial placement as well as replacement and features an inner tube that is easily replaceable by patients at home, eliminating the need to visit healthcare facilities for replacement procedures.

The company noted that complications from gastronomy tubes are common and tube replacements are often necessary due to clogging and dislodgements.

Philips Earns FDA Approval For Low-Dose Drug-Coated Balloons

The FDA approved Royal Philips' two new Stellarex 0.035" low-dose drug-coated balloons for peripheral artery disease patients.

The 150mm and 200mm balloons have the agency's go-ahead for treating de novo and restenotic narrowing in two upper leg arteries, the native superficial femoral or popliteal arteries.

The approval broadens the available options for physicians treating peripheral artery disease patients with a high risk of recurrent narrowing of an artery previously cleared with a stent or angioplasty.

WCG FDANEWS

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

Editorial: Declan Conroy
+1 (703) 538-7644
dconroy@fdanews.com

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

Multi-User Sales: Bailey Sterrett
+1 (703) 538-7637
bsterrett@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • www.fdanews.com

Reporters: James Miessler, Jordan Williams, Colin Stoecker

President: Cynthia Carter

WCG FDANEWS

Complaint Management for Devicemakers: *From Receiving and Investigating to Analyzing Trends*

Complaint management is essential to a functioning quality management system.

Understanding the FDA's Quality System Regulation isn't enough — you must also master ISO 13485:2016 and the new EU MDR. They all require devicemakers to conduct trending in some form or another. But none of them tell you HOW.

This new edition of the best-selling **Medical Device Complaint Management** fills in that gap for you.

In addition to teaching the principles of successful complaint management …

- Receiving, documenting and investigating complaints
- Determining when complaints are reportable
- Using complaints to update risk management data …

… the new report teaches you how to analyze trends in your complaint files to spot opportunities for product and program improvement.

You'll learn:

- The difference between a record and a report
- Acceptable trend analysis methods (NEW)
- How not to write yourself into a corner on complaint SOPs
- And more…

It's certain that your complaint management system will come under intense scrutiny in your next GMP inspection. Make sure you can show investigators not only how you have reacted to problems but also how you learn from them and use that information to drive continual improvement.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578
   or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/54565
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 ***Complaint Management for Devicemakers: From Receiving and Investigating to Analyzing Trends*** 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. _____

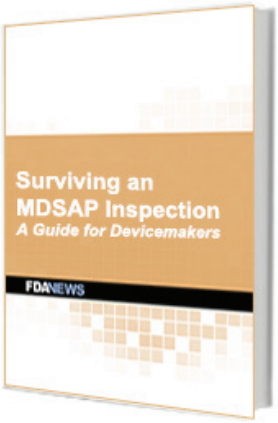
Expiration date _____

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

Virginia customers add 6% sales tax.

19FLYR-N

WCG FDANEWS



Surviving an MDSAP Inspection: *A Guide for Devicemakers*

Currently, Australia, Brazil, Canada, Japan and the United States are participating in the MDSAP program. If you pass one MDSAP inspection you'll be ready to pursue marketing authorization in five separate countries.

But, if you're going through MDSAP for the first time your experience will be very different from regulatory inspections you've gone through in the past.

- You'll know exactly when and how often to expect an audit
- You'll know exactly how long the audit will be
- You'll know exactly what questions the auditor will ask

The prescriptive nature of the MDSAP model makes it relatively easy to prepare for an audit — if you know what to expect. **Surviving an MDSAP Inspection** provides all the information you'll need to understand the MDSAP model. You'll learn:

- The standard schedule for and duration of audits
- Specific areas auditors will examine and questions they will ask
- Different types of audits involved, such as initial certification, surveillance, desk and site audits
- How to create a checklist to make sure all your bases are covered
- The MDSAP grading system and how nonconformance issues can be escalated — and consequences of getting a bad grade

The management report also includes a copy of the MDSAP Companion document — the official guide — auditors will follow.

Order your copy of **Surviving an MDSAP Inspection: *A Guide for Devicemakers*** and know what to expect from an MDSAP audit and how to prepare for it.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/56226
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 ***Surviving an MDSAP Inspection: A Guide for Devicemakers*** 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.

19FLYR-N