INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Decree Clarifies Fines, Sanctions Under Brazil's Anticorruption Law

Devicemakers accused of bribing government employees to purchase their products face stiff fines and penalties in Brazil, now that President Dilma Rousseff has issued a decree implementing last year's anticorruption law.

The Clean Companies Act officially took effect on Jan. 29, 2014, but lacked supporting regulations on fine assessment, evaluation of business compliance programs and the structure of leniency agreements. The March 18 decree, known as Decree 8,420/2015, fills in many of those gaps.

Firms caught violating the law face minimum fines of either 1 percent of the previous year's profits or the sum of the value of the undue advantage gained through bribes plus the amount of the bribe. The maximum fine the government can impose is 20 percent of the previous year's profits or three times the undue advantage plus the amount of the bribe, the decree says.

Leniency for First-Time Offenders

In setting fines, the government will consider the seriousness of the offense, whether the company cooperated with investigators and whether high-level officers of the firm knew of the corrupt practices.

Violators face public shaming, too — both on government websites, which will air details of the offense, and at the company's place of business.

First-time offenders will sign leniency agreements with the federal comptroller general noting that repeat violations could lead to a loss of government contracts or enforcement of stricter compliance programs. To conclude a leniency agreement, the company must admit to wrongdoing, stop the offensive actions and cooperate with government investigators.

Violators must also establish a compliance program, supported by high-level staff, with standards of conduct that are applicable to all employees, suppliers and service providers. The program should include periodic training and risk analysis to make adjustments, when

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Brazil, *from Page 1*

needed. Other elements of a successful compliance program outlined in the decree include:

- Comprehensive and accurate accounting records;
- Specific procedures to prevent fraud in supplier bidding;
- An independent internal audit body;
- Well-established whistleblowing channels; and
- Established disciplinary measures in case of CCA violations.

The Clean Companies Act also gives the government authority to dissolve a company that regularly violates the law or was established as a front to hide the identities of individuals benefiting from corrupt activities.

Devicemakers need to be aware of the law because many doctors in Brazil are state employees, says Carlos Ayres, a senior associate for compliance at São Paolo law firm Trench, Rossi e Watanabe. Even ethics rules that previously passed muster in Brazil may warrant a second look due to the stricter revised standards, he tells *IDDM*.

Moreover, the new policy operates on strict liability, meaning lack of corrupt intent is no longer a defense if the government can show a company received an unfair advantage, Ayres says. For example, it's now considered illegal for a state-owned hospital to put out a request for proposals based on specifications from only one manufacturer. That means company sales reps need to be trained to ensure hospitals approach competitors for the same information.

Another challenge for devicemakers will be physician attendance at industry meetings. Companies will now have to demonstrate a clear rationale behind the trip. A decision to send a doctor to a conference held primarily in a language he or she doesn't speak may raise eyebrows, Ayres says.

View the decree, in Portuguese, at www.fdanews.com/03-30-15-brazil.pdf. — Elizabeth Orr

FDA Will Reward Indian Facilities That Shine on Quality Management

U.S. FDA officials visiting India laid out a new approach to facility inspections that would reward Indian devicemakers whose quality management systems exceed the minimum.

Under the proposal, high-performing facilities would be rewarded with less-frequent inspections and less scrutiny when proposing postapproval manufacturing changes, the agency says.

"To put it simply, the inspections can yield also carrots, and not just sticks," says Howard Sklamberg, deputy commissioner for global regulatory operations.

The FDA plans to pilot a program — using a questionnaire that will standardize the inspection process — to uniformly gather quality metrics and target Indian plants most likely to have compliance issues. But aggressive enforcement will remain an important part of the agency's efforts to ensure product quality, especially in cases where it finds devicemakers have tampered with or failed to protect the data they show investigators.

The India trip, which began in mid-March, included site visits in New Delhi, Goa, Chennai and Mumbai, FDA spokesman Jeff Ventura says. Cynthia Schnedar, director of the Office of Compliance, is also part of the delegation, which hopes to build on cooperative quality agreements launched last year when Commissioner Margaret Hamburg visited the country (*IDDM*, March 20).

Information exchange and knowledge sharing would be beneficial for devicemakers and exporters and help with capacity building, says Rajiv Nath, forum coordinator of the Association of Indian Medical Device Industry. He adds that the Central Drugs Standard Control Organization has been reluctant to regulate the vast field of medical devices.

At the same time, the U.S. regulatory model may not be the best model for India, Nath ventures, noting that regulation in India needs to be layered to separate the roles of legislator from those of regulator and of supervisory accreditation bodies from those of third-party conformity assessment bodies. — Jonathon Shacat

Diabetes Groups Urge Enhanced Trial, Registry Requirements

U.S. and European diabetes groups are recommending that an international registry be established to gather reports on insulin pump safety, citing lax EU device regulations that leave patients at risk.

The registry should include both technical and human errors and be searchable by keywords, components and pump, the groups say. It should also be publicly accessible.

The American Diabetes Association and the European Association for the Study of Diabetes also want pump makers to release information on how many people use their products and to be more transparent about clinical trial results. Manufacturers should publish data on their pumps' compatibility with specific insulin formulations and infusion sets, how well pumps perform over years of clinical use, the results of tests on recalled and returned pumps, and changes to device functions or features.

Greater Scrutiny Needed

The groups also call for research organizations to fund independent clinical trials on the safety, efficacy and outcomes of insulin pumps, and to support new and existing registries.

The concerns, laid out in an article in the April issue of *Diabetes Care*, center on the CE mark system that Europe relies on to approve new devices, which is less rigorous than the U.S. FDA premarket process. In particular, the EU system allows manufacturers to start selling pumps in Europe before ever launching the level of clinical trials required by the FDA, says Anne Peters, director of the clinical diabetes program at the University of Southern California and a coauthor of the article.

The authors sought feedback from devicemakers but received only three responses, none of which included the detailed information around recalls and adverse events that they say are necessary to improve insulin pump safety, Peters tells *IDDM*.

"It's naïve of me, not being in the industry, to tell industry what to do, but I know we don't have data that helps me as a doctor understand safety and efficacy," she says. Peters would like pump makers to release better data on pump durability to help her decide which devices to recommend to patients.

The FDA provided input on the report, Peters says.

Medtronic spokeswoman Pamela Reese says most of the actions called for by the ADA and EASD — such as premarket and postmarket quality procedures, rigorous clinical trials and continuous evaluation of customer feedback — are already policy at the company.

View the article at http://care.diabetesjournals.org/content/early/2015/03/13/dc15-0168.full.pdf+html. — Elizabeth Orr

LDT, BioCompatibility Final Guidance Make AdvaMed's Priority List

The U.S. FDA should finalize guidance documents on premarket and postmarket data collection, the proposed laboratory-developed tests framework and adverse event reporting, and biocompatibility standards before attacking other priorities, AdvaMed says.

The suggestions come in response to a recent device center document listing priorities in guidance development (*IDDM*, Jan 9). The agency divided planned guidances into "A" and "B" lists in the report.

In comments posted recently to regulations.gov, AdvaMed urged the FDA to finalize all existing draft guidance for which the comment periods have closed as quickly as possible, but singled out the four documents on the center's "A" list as particularly important to devicemakers. They are:

- Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval;
- Framework for Regulatory Oversight of Laboratory Developed Tests;

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- FDA Notification and Medical Device Reporting for Laboratory Developed Tests; and
- Use of ISO 10993-1, Biological Evaluation of Medical Devices Part I: Evaluation and Testing (Biocompatibility).

The letter also asks the FDA to prioritize final guidance on human factors testing, exempting certain devices from 510(k) clearance, expediting access for devices intended to treat unmet needs and reprocessing devices in healthcare settings.

AdvaMed deemed most of the draft guidance the FDA plans to issue this year of medium priority, with the exception of one calling for the use of symbols in device labeling, which the group considers more important.

In addition, several documents not mentioned in the report should be considered high priority, the group said. These include updates to guidance on premarket approval modifications and manufacturing site changes, and device-specific guidance on codevelopment and nonmolecular types of multimarker panels. AdvaMed also wants to see an update of 2013 guidance on presenting risk-benefit information in space-limited internet platforms such as Twitter.

Eleven older guidances should also be reviewed and updated, AdvaMed said.

View AdvaMed's comment at www.fdanews.com/03-30-13-advamed.pdf. — Elizabeth Orr

Industry Moves Forward With Self-Certification Scheme

Indian devicemakers and governmental and nongovernmental partners have formed a steering committee to push forth a self-certification scheme for industry manufacturing best practices. The aim is to ensure the quality of Indian devices and eliminate sales of substandard products.

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India, *from Page 4*

The initiative kicked off in October with the signing of a memorandum of understanding by the Association of Indian Medical Device Industry, the Quality Council of India and the National Accreditation Board for Certification Bodies.

Under the scheme, QCI — with the help of AIMED — will identify globally accepted quality standards for categories of devices and determine their suitability for India. NABCB will provide accreditation services to conformity assessment and certifying firms that perform quality audits of manufacturers. QCI and AIMED will vouch only for those quality certificates that have been accredited by NABCB.

Rajiv Nath, forum coordinator for AIMED, says industry is "tired of the endless wait for an appropriate regulatory framework for quality certification of medical devices in the country" and ready to roll out a "world-class voluntary certification regime." — Jonathon Shacat

FDA's Shift on Wellness Products Surprising but Welcome, Expert Says

Manufacturers of general wellness products wondering how the U.S. FDA might regulate their goods should check how the agency deals with similar devices, an attorney says.

The FDA issued guidance in January clarifying that products that help manage weight loss, fitness, stress, sleep and other aspects of good health may enter the market unregulated. But Frederick Stearns, with the law firm Keller and Heckman, says the line between regulated and unregulated products may be blurry.

Stearns advises companies to see if similar products are actively regulated. If they are, "it is unlikely anything similar will be exempt" from regulation, he says.

The guidance defines general wellness products as products that maintain or encourage a general state of health without referencing a disease or condition or making claims about health benefits.

Generally, if products are of low enough risk, they are exempt from active oversight, Stearns says.

The FDA's broadening of its exemptions from jurisdiction to include products that claim to reduce the risk or impact of certain conditions as exempt from regulatory jurisdiction "is a surprise, but welcome to industry," he adds.

According to the guidance, weight management, physical fitness, and stress and sleep management are common subjects for wellness products, provided they don't reference a disease or condition. Examples include exercise equipment, video games and products such as pulse and food consumption monitors.

Products are not considered low risk if they are invasive or involve technology that risks user safety if controls are not applied, such as lasers that emit radiation.

Stearns notes that FDA's expansion of its regulatory exemptions, while a welcome development, contains "potential for abuse, since FDA will devote less attention to this category. Enforcement in this area may fall to the FTC to a large extent — such as claims made in advertising."

Stearns spoke during a recent FDAnews webinar on general wellness apps. — Charlotte Astor

Devicemaker Warned Over Sale of Unapproved Device

The U.S. FDA has warned the Zizion Group for marketing a medical device without premarket clearance.

In a March 12 letter to the Boca Raton, Fla., devicemaker, the agency says marketing of the company's Yes PRP Kit as "easy and accurate" for medical personnel violates the law because the kit hasn't received clearance for sale or for use in clinical trials.

The device is intended to extract blood and prepare platelet-rich plasma used in repairing damaged or injured body tissues, the warning letter says. But while the kit is similar to other previously cleared PRP devices, the law requires

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devicemakers to obtain FDA premarket clearance before offering them for sale, the agency adds.

Zizion has added the following statement to its Yes PRP Kit webpage: "Not FDA approved or cleared for the U.S. market. Pending FDA clearance."

The company did not respond to requests for comment by press time. Read the letter, issued by the FDA's Office of Compliance and Biologics Quality, at www.fdanews.com/03-25-15-Zizion.pdf. — Charlotte Astor

Experts Divulge Best, Worst In Inspection Practices

Devicemakers can help to facilitate facility inspections — and improve their inspection experience — by engaging in constructive conversations with agency investigators, a U.S. FDA official says.

Firms should confirm the scope of the inspection and ask for specifics on what the investigator will be reviewing, says William MacFarland, director of the Center for Devices and Radiological Health's Division of Manufacturing and Quality. They should also ask how they can help investigators by having documents ready and moving the inspection along in a timely fashion.

On the flip side, it is never a good idea to become resistant right away, MacFarland warns. Not doing what you can to help and answering questions defensively, or not at all, can start an inspection off on the wrong foot, he says.

MacFarland was on a panel of experts who spoke about best and worst inspection practices at FDAnews' recent Medical Device Quality Congress in Bethesda, Md.

Julie Larsen, director of inspection readiness services at BioTeknica, says the best step

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Inspections, *from Page 6*

devicemakers can take to prepare for inspections is to define employees' roles in a front or back room and then train them accordingly. One of the worst things a firm can do is not document and keep track of investigator requests, she adds. Failing to stay on top of things can slow an inspection and reflect negatively on the company.

Larry Kopyta, vice president of quality assurance and regulatory affairs at Omnyx, says firms should have standard operating procedures in place and ensure staff are trained properly and behave appropriately during the inspection. He also suggests that firms take down any funny posters or other displays to convey a serious tone.

The worst practice Kopyta has witnessed is a failure to organize documents requested by an inspector. He notes how an inspector once asked for a large number of documents and an employee wheeled them in on a cart, stacked up and unorganized in a box. — Kellen Owings

AHWP Releases Handbook On Medical Device Regulation

Countries looking to develop a medical device regulatory regime should take a total lifecycle approach starting with listing products and implementing premarket controls, the Asian Harmonization Working Party says.

Regulations should address clinical trials during the product development stage, registration and licensing as a device is placed on the market, maintenance and corrective actions taken while the device is in use and changes made to the device as it nears the end of its lifecycle, the group says. A new guidebook offers recommendations and tools for bridging the gap between emerging markets and those with established device regulations.

Basic regulatory controls should include registration and licensing of device dealers and products, premarket controls, quality management systems, risk-management processes and postmarket surveillance. Once devicemakers are registered or listed, countries should build a database of devices on the market that includes the manufacturer's contact information, AHWP says.

The group recommends using the definition of "medical device" developed by the Global Harmonization Task Force, which takes into account the many different forms devices may take. Once a general definition is put into place, regulators should look at issuing policies to clarify what will and will not be regulated as a device.

AHWP also recommends using harmonized standards for postmarket vigilance and QMS—such as ISO 13485 on device quality management systems. QMS auditing can be outsourced to a third party, the group says.

Premarket assessment of devices is a huge regulatory burden that not all economies will be prepared to take on, AHWP notes. Countries without the resources to perform the reviews should start by maintaining a list of devices on the market and then add requirements for detailed review of safety and performance as resources permit. A transparent and predictable risk-classification system should be an important consideration in device reviews, the group says.

As for overall responsibility, AHWP recommends national legislation to provide oversight and funding, supported by regulations and guidelines issued and implemented by a national authority.

AHWP's 23 member countries include China, India, South Africa, Saudi Arabia, Thailand and Chile.

View the guidebook at www.fdanews.com/03-30-AHWP.pdf. — Elizabeth Orr

Health Canada Moves Ahead With Safety Rules, Limits Trade Secret Disclosures

Canada's health minister is being given a powerful new slate of tools to deal with medical device safety problems.

Under draft guidance issued Thursday, the minister would receive powers to publicize new

(See **Vanessa's Law**, *Page 8)*

Vanessa's Law, *from Page 7*

information about a device's safety risks and to demand labeling changes, recalls and postmarket studies.

The guidance, which would implement last year's Protecting Canadians from Unsafe Drugs Act, or Vanessa's Law, spells out that the health ministry must provide manufacturers with supporting documentation when it wants to take action on a safety issue, and manufacturers will have time to respond and refute the government's position.

However, if the response is deemed inadequate the minister could order the company to comply. The guidance also would put limits on who can have access to proprietary information devicemakers supply to the ministry to investigate new risks. Only foreign regulatory bodies, expert advisors, and public health and safety personnel could view trade secrets.

Firms Lack Legal Recourse

When Vanessa's Law was passed in November, some manufacturers feared it would allow the health minister to disclose any trade secrets to virtually everyone, including investors with no role in health and safety.

The new protections may still be inadequate, says attorney Simon Elliott with Foley & Lardner in Washington, D.C., adding they appear to be general statements of principle, rather than legally binding limitations.

The guidance also lacks any legal recourse for companies that feel the health minister disclosed too much confidential business information, Elliott says.

Health Canada has posted an online survey for stakeholders to provide feedback on the guidance. Comments close May 25.

Read the guidance at www.fdanews.com/03-26-15-VanessasLawGuidance.pdf. The survey is at www.fdanews.com/03-26-15-VanessasLawSurvey.pdf. — Lena Freund

Deadline for Registering Devices In Malaysia Is June 30

Devicemakers have until June 30 to register their products in Malaysia and regulators there are already anticipating a backlog of applications.

Nearly 5,000 applications for product registration have been received, but the authority had envisioned receiving more by now, says Zamane bin Abdul Rahman, chief executive of the Medical Device Authority. Many companies are waiting for fast-track registration mechanisms and guidelines that will come out by mid-April, he tells *IDDM*.

The registration deadline was triggered by the 2012 Medical Device Act and its implementing regulations, which included a three-year transition period.

Under the expedited mechanism, companies whose products have been certified in the U.S., EU, Canada, Australia or Japan can register without undergoing a conformity assessment in Malaysia. However, they must verify their credentials with an MDA-recognized conformity assessment body within five years, Rahman says.

Compliance Will Be Closely Monitored

Novel products are not covered by the fast-track mechanism, as they may have risks, Rahman notes. Class A products with no measuring function that are nonsterile and nonactive are exempt from registration, though firms must request exemption via forms on the authority's website.

Devices will be monitored closely to ensure compliance with the regulations, Rahman says, adding that deviations and adverse incidents could trigger a recall.

Applications submitted by the June 30 deadline will go onto a transition list, meaning they can be sold in Malaysia pending registration, says Ames Gross, president of Pacific Bridge Medical.

Products that aren't on the transition list will likely take a long time to register and can't be imported into the country until they are, Gross tells *IDDM*. — Jonathon Shacat

Pakistan Adopts Medical Device Regulatory Framework

The Pakistani government has enacted legislation establishing a formal regulatory framework for medical devices and in vitro diagnostics.

The law, known as the Medical Device Rules, 2015, creates a risk-based classification system with principles of safety and performance, conformity assessment and registration requirements, and rules for product labeling. It also sets standards for conformity assessment bodies that certify devices before they enter the market.

A Medical Device Board, housed within the Drugs Regulatory Authority of Pakistan, will be responsible for registering CABs and devices, licensing establishments and issuing import and export permits.

The law also calls for devicemakers to have quality management systems that comply with ISO 13485. Manufacturers of Class B products must maintain a QMS, but may exclude design and development control and process control. Class C and D devices require a full QMS and on-site audits to verify compliance.

Companies seeking to register devices in Pakistan must provide clinical evidence of the product's safety and effectiveness. Data from trials in the U.S., EU, Canada, Japan and Australia will be accepted for registration, the law says.

Registration fees are set at US $200 for locally manufactured devices and $1,000 for imported devices. Other fees range from $10 for an export permit to $1,000 for an establishment license.

The law also covers good distribution practices, customs clearance certificates, vigilance systems that include distribution records, complaint handling, problem reporting, corrective actions and recall procedures. Manufacturers of Class B, C and D devices are subject to audit of the postmarket surveillance system by a CAB.

Advertising is also covered under the law. Devicemakers must get MDB approval before running an ad and cannot spend more than 5 percent of their annual revenues on product promotions.

The law comes a little more than two years after Pakistan's drugs authority was established and accomplishes what neighboring India has repeatedly failed to do — create a distinct framework to oversee medical devices.

Pakistan will face challenges, such as resources at the government level to regulate devices and sufficient reimbursement opportunities for companies in the market, not to mention hospitals and trained healthcare workers that can properly use devices, says Vince Suneja, CEO of TwoFour Insight Group.

Pakistan's device market is small and growth is affected by ongoing sociopolitical problems and recurring security threats, says BMI Research. Total volume in 2013 was about US $260 million, with the market projected to reach $352 million by 2018. Imports account for more than 90 percent of the market, with surgical instruments comprising the bulk of the limited domestic manufacturing sector, the firm says.

Many of the sections in the law include templates. Read device rules at www.fdanews.com/03-15-DRAP-Regulation.pdf. — Jonathon Shacat

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Mr. Cooke's practice specializes in helping FDA-regulated companies develop compliant promotional tactics and improve the promotional review. He is the author of Effective Review and Approval of Digital Promotional Tactics and is currently at work on a book about compliant social media usage for prescription product manufacturers.

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

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- **Assuring Your Promotions Meet FDA Off-Label Standards** Successfully navigating 4 major traps that can earn you a warning letter fast.
- **Itching To Do More With Social Media?** Discover how to get your message out there … without crossing the line.

DAY ONE | MAY 13

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. - 9:45 a.m.

Pre-approval Communications

- How to meet your SEC requirements for disclosing information while not running afoul of FDA pre-approval promotion prohibitions

9:45 a.m. - 10:30 a.m.

Disease Awareness Communications

- A review of FDA's help-seeking guidance
- Keys for using disease awareness communications prior to approval. Essential information for continuing communications efforts post-approval compliantly.

10:30 a.m. - 10:45 a.m.

Break

10:45 a.m. - 11:15 a.m.

From Day of Approval through Commercial Launch

- Understanding the timeline and key dates for communications
- Minimizing the pain, while maximizing the impact of initial promotional communications

11:15 a.m. 12:00 p.m.

Essential Advertising & Promotion Regulations

- A review of all of the requirements for product promotion, including product name usage, fair balance, directions for use

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. - 1:45 p.m.

Format-Specific Promotional Requirements

- DTC television promotion
- Brief summary requirements for print promotion

1:45 p.m. - 2:30 p.m.

Substantial Evidence & Other Standards

- A review of the substantial evidence standard, what fails to meet that standard, and when other standards apply

2:30 p.m. - 2:45 p.m.

Break

2:45 p.m. – 4:00 p.m.

Off-Label Information

- Avoiding off-label promotion
- Scientific exchange exemption
- Responding to unsolicited requests
- Distributing off-label reprints

4:00 p.m. - 4:30 p.m.

The Promotional Review Process

- An overview of a the standard promotional review process
- Essential traits for any effective process
- Key decisions in establishing or improving performance
- Effective use of metrics for evaluating performance

4:30 p.m.

Session Wrap-Up, End of Day One

DAY TWO | MAY 14

8:30 a.m. – 9:00 a.m.

Continental Breakfast

9:00 a.m. - 9:45 a.m.

Integrating Digital Promotion

- Key considerations for evaluating the compliance of digital promotional tactics and their integration into the overall promotional mix

9:45 a.m. - 10:15 a.m.

Social Media Part 1

- Overview of the platforms, issues, and a review of the status of FDA guidance

10:15 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:30 p.m.

Social Media Guidances

- A review of the three social media guidances released in 2014: 2253 Filing, Presenting Risk Information in Space-Limited Contexts, & Correcting Misinformation on Third-party Sites

12:30 p.m. - 1:30 p.m.

Lunch

1:30 p.m. - 3:15 p.m.

Promotional Review Board Practicum

- Workshop participants will apply the lessons from the earlier part of the workshop to specific product promotions. They will work in teams to evaluate specific promotional tactics, determine what (if any) parts of the promotion are problematic, and how to provide direction to a brand marketer to make the promotions compliant.

3:15 p.m. - 3:30 p.m.

Break

3:30 p.m. - 4:15 p.m.

Continuing Regulatory Intelligence: Staying Abreast of Ad/Promo News

- Ad/Promo is an area of ongoing developments. This session will cover the most prominent sources for keeping up with these developments.

4:15 p.m. - 4:30 p.m.

Wrap-up and Adjourn Workshop

"Dale was very engaging and informative. I like the interactive portion where we reviewed actual ads."

— 2014 Workshop Attendee

WHO WILL BENEFIT?

- Advertising and marketing managers
- Social media teams
- Promotion review committee members
- Medical affairs
- Continuing education and tradeshow organizers
- Regulatory compliance officers
- PRC coordinators
- Legal counsel
- Compliance
- Executive management
- Outside ad agencies and marketing consultants

"[Dale is] an animated speaker who seems to know something about everything and has no shortage of opinions. This is potentially very dry and dull material. Dale brings out the exciting and humorous aspects especially well. It's an engaging two days."

— Michael Benedetto, Editorial Group Leader, FCB Health

"This is normally a dry topic, but with Dale it was anything but dry. Dale gave one of the best, most engaging presentations. Dale is highly knowledgeable and also very entertaining."

— Ellen Derrico, Global Head, Market Development - Life Sciences & Healthcare, QlikTech

"As a fellow regulatory professional, Dale is one of the most deeply knowledgeable experts I've heard on this complicated subject. As the pharmaceutical industry is experiencing, digital promotional tactics can trip up even experienced regulatory professionals, but Dale showed how basic principles can be applied to develop compliant promotional materials."

— Kathleen Koons, Sr Regulatory Affairs Manager, DJA Global Pharmaceuticals Inc.

Course Binder Materials:

Full slides from the PowerPoint presentations

Reference documents:

FDA Advertising & Procedural Guidances

- Help-Seeking Guidance
- DTC Broadcast Guidance & Q&A
- FDAAA Pre-Dissemination Review Requirements
- Product Name Guidance (All three versions from 1999, 2012, and 2013)
- Presenting Risk Information Guidance
- Social Media Guidances
  - Postmarketing Submissions Requirements
  - Responding to Unsolicited Requests for Off-label Information
  - Presenting Risk Information in Space-limited Contexts Correcting Third-party Misinformation
- Distributing Off-Label Reprints

Relevant Sections of Code of Federal Regulations

Form 2253

PhRMA Principles on DTC Advertising

PhRMA Principles on Interactions with Healthcare Professionals

Pre-approval Promotion Checklist

Effective Review & Approval Process Checklist

Keys to Evaluating Promotional Review Systems List of Key Resources for Continuing Education

Articles by Dale Cooke

- Developing Compliant Search Engine Marketing Campaigns (Publication Date of September 2014)!
- Industry Standards for Linking Disease Awareness Websites to Product Promotion!
- Patient Testimonial Videos: FDA Actions on Risk Information Presentation!
- Presenting Risk Information on Websites!
- Where Things Stand on FDA Guidance on Social Media (Publication Date of September 2014)

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HOTEL INFORMATION INFORMATION:

May 13-14, 2015

Embassy Suites Raleigh-Durham
Airport/Brier Creek
8001 Arco Corporate Drive
Raleigh, NC 27617

Toll Free: (800) EMBASSY
+1 (919) 572-2200

www.RaleighDurhamAirportBrierCreek.EmbassySuites.com

Room rate: $169.00 plus 12.75% tax
Reservation cut-off date: April 28, 2015

TEAM DISCOUNTS:

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Multi-attendee discounts are available and will be calculated at check out.

2-4 attendees – 10%
5-6 attendees – 15%
7-9 attendees – 20%
10+ attendees – 25%

TUITION:

Tuition includes all conference presentations, conference materials, two breakfasts, two lunches and refreshments.

CANCELLATION AND SUBSTITUTION:

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.