INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

St. Jude Medical Warned for GMP Lapses at CardioMEMS Plant

St. Jude Medical revealed in an SEC filing that it received a Sept. 30 warning letter for GMP deficiencies at its Atlanta, Ga., facility following a June 8 to 26 inspection related to the firm's heart failure monitor, the CardioMEMS HF System.

The warning letter, which is not yet posted on the FDA's website, was included as an exhibit to the SEC filing.

According to the warning letter, the firm did not maintain an effective CAPA system and did not investigate known problems to determine root cause.

For example, the firm opened a CAPA for incorrect serial numbers on CardioMEMS hospital units on Nov. 26, 2014, but the CAPA wasn't closed, and the firm filed for an extension during the

(See **St. Jude***, Page 2)*

Special Counsel Clears FDA of Wrongs In Device-Related Whistleblower Case

The U.S. Office of Special Counsel has cleared the FDA after a whistleblower alleged the agency improperly approved colonography devices and a screening tool for breast cancer.

In a letter to President Barack Obama, Special Counsel Carol Lerner says the FDA's investigations into whether the colonography device and a Carestream digital mammography tool appeared to be reasonable. The FDA commissioner, along with the Office of Inspector General for the HHS, had detailed their findings in reports.

Specifically, the whistleblower alleged that during the review of a premarket notification for a computerized tomography image analysis software package made by GE Healthcare, FDA reviewers determined the product had a new intended use. As a result, they should have used the more stringent PMA review process for

(See **Lerner***, Page 6)*

St. Jude, *from Page 1*

inspection. The due date for completion of the investigation was originally Jan. 18.

Similarly, the firm opened a CAPA Nov. 5, 2014, for defects found in coated sensors, which included coating imperfections and fractured glass, but the investigation was never completed, even though the deadline was Dec. 5, 2014. The firm requested an extension during the inspection.

The company said the complete effectiveness verification and closure target date for the CAPA is January 2016. The FDA requests copies of activities related to these actions so they agency may evaluate them.

Investigators also observed that sterilization validation activities weren't documented for the heart failure device, and annual validation activities were not being performed.

The silicone coating process also was not adequately validated, and the firm only conducted one qualification study. "[H]owever, there is no documentation of the established parameters used at processing and no documentation showing repeatability of the HF coating process," according to the letter.

Finally, the FDA said St. Jude hadn't established procedures for quality audits.

St. Jude spokesman Justin Paquette tells *IDDM* that at the time of the June 2015 CardioMEMS postapproval inspection, the company was transitioning the Atlanta facility into its global quality system.

"In response to the observations, we submitted our corrective actions to FDA in July and provided updates in August and September.

"The FDA has acknowledged that the company appears to have adequately addressed the majority of the FDA observations," he adds.

Paquette says the FDA had not identified any specific concerns about the performance of CardioMEMS.

"We will continue manufacturing and shipping product from the Atlanta, Ga., facility, and customer orders are not expected to be impacted while we work to resolve the FDA's concerns," he says.

Read the warning letter here: www.fdanews.com/10-12-15-StJudeWL.pdf. The Form 483 is at www.fdanews.com/10-12-15-StJude483.pdf. — Tamra Sami

FTC Looks for Input on Wright-Tornier Merger

The FTC is seeking feedback on the proposed consent agreement that paves the way for the merger between Tornier and Wright Medical Group.

The consent agreement, published in the Oct. 8 *Federal Register,* is meant to resolve FTC accusations that the proposed $3.3 billion merger would lead to unfair methods of competition.

It details the planned divestiture of Tornier's U.S. rights and assets to its total ankle and total silastic toe joint replacements to Integra Lifesciences.

Last month, Tornier and Wright said that they would sell the rights to these orthopedic devices to Integra.

It's been about a year since the two said they planned to combine. The all-stock deal caught the attention of the FTC.

According to the consent agreement, the parties have 10 days after consummating the merger to relinquish their rights to Integra.

If, following a review, the FTC deems Integra an unacceptable buyer, the parties must scuttle the deal and find a commission-approved purchaser within six months.

Based on the comments it receives, the FTC will decide whether to withdraw from the consent agreement, modify it or make it final.

Comments are due Oct. 30. Read the analysis here: www.fdanews.com/101215-wright-tornier.pdf. – Elizabeth Hollis

FDA Orders Three Companies To Further Study Duodenoscopes

Olympus America, Fujifilm Medical Systems and Hoya's Pentax unit were given 30 days to submit postmarket surveillance studies to the FDA detailing how their duodenoscopes are reprocessed in healthcare facilities.

Duodenoscopes have come under scrutiny after being linked to antibiotic-resistant infections in Chicago, Pittsburgh, Seattle and Los Angeles. Earlier this year, the FDA revealed that from January 2013 to December 2014, it received 75 adverse event reports involving about 135 patients linking use of the devices to the transmission of carbapenem-resistant Enterobacteriaceae.

Contributing to the problem is the devices' unique design, including small working parts and a moveable elevator mechanism with tiny crevices. The elevator is particularly difficult to clean and disinfect properly, the FDA has said.

William Maisel, deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health, says the agency is looking into factors that play a role in the transmission of antibiotic-resistant infections associated with duodenoscopes. The studies are intended to provide information about the effectiveness of current reprocessing instructions. To that end, the FDA has asked the manufacturers to design studies that answer the following:

- Are user materials, such as user manuals, brochures and quick reference guides sufficient to ensure adherence to the manufacturers' reprocessing instructions?
- What percentage of clinically used duodenoscopes remains contaminated with viable microorganisms after being reprocessed according to the manufacturer's instructions?
- What factors contribute to microbial contamination and what steps are necessary to adequately decontaminate the device?

— Elizabeth Hollis

Medtech Market to Approach $478B In 2020, Led by Medtronic

Where will the medical technology industry be in five years? That question takes center stage in a new report by Evaluate Medtech, which predicts a global market of about $478 billion in 2020.

After years of domination, Johnson & Johnson is expected to lose its lead in terms of sales. Last year, J&J raked in $27.5 billion in medtech sales, but its move toward divesting medical device and diagnostics units likely is going to cost it the top spot, particularly with the recent wave of megamergers.

Replacing J&J's in the top slot will be Medtronic, which continues to swallow up companies, the report, titled *EvaluateMedTech World Preview 2015,* Outlook to 2020 says. Since its nearly $50 billion megadeal with Covidien, Medtronic has bought 11 more companies with a combined price tag of $1.6 billion.

Elizabeth Cairns, who authored the report, says the device industry still may see megamergers, but smaller "tuck-in" deals also could be more prominent.

Device Giant

With all of its acquisitions, Medtronic is expected to be the leader in cardiology, raking in sales of about $11.6 billion by 2020. That represents a 21.4 percent market share, nearly double that of St. Jude Medical's 11.7 percent.

Other companies expected to gain ground are Becton, Dickinson (climbing to the number five spot) and Zimmer Biomet (climbing to number 13). Zimmer had been 20th in sales prior to its merger with Biomet.

(See **Market Forecast***, Page 4)*

Market Forecast, *from Page 3*

Despite losing its title as top medtech company, J&J is expected to remain the leader in orthopedics, with about $10.5 billion in sales in 2020, while Zimmer Biomet is anticipated to increase its market share. Overall, the orthopedics arena is expected to grow about 3.2 percent each year to $42 billion.

In diagnostics, Siemens is expected to remain number one, but GE will be nipping at its heels. The report predicts Siemens sales of $10.8 billion in 2020, followed by GE sales of $10.1 billion — 26.5 percent and 24.8 percent of the market, respectively.

The industry is also benefiting from a slew of FDA PMA and humanitarian device exemption approvals.

Compared with 2013, first-time PMAs and HDEs grew 43 percent to 33 in 2014 — and that total already has been reached this year.

Cairns says the FDA's performance, in combination with the merger trends, should help companies develop innovative technologies. — Elizabeth Hollis

Panel Examines Changing Medtech Business Climate

Start-up companies seeking funding for traditional "incremental" medtech ventures beware: Funding may not be as forthcoming as in the post.

According to Rick Anderson, managing director at PTV Healthcare Capital, simply designing a better trocar is not as attractive to investors as it once was.

Conventional medtech companies have recognized this fact and are looking to form nontraditional alliances, he said. Anderson spoke with other investment experts at AdvaMed 2015 in San Diego.

Leslie Bottorff, managing director for healthcare at GE Ventures, agreed with Anderson's assessment, noting that the business model is evolving and more devices are incorporating drugs or software.

Nick Manusos, vice president for global business development at Baxter International, cautioned, however, that when innovative outsiders such as Qualcomm partner with traditional medtech companies, they often are frustrated with the plodding pace of innovation and product development. Devicemakers need to learn to be more nimble, he said.

"In this changing world, not partnering is not an option," Manusos emphasized. He stressed the need to be open-minded and consider partners that might not have been considered a decade ago.

"Partnerships can't be stressed enough," James Woods, principal of deals and valuations at PwC, tells *IDDM*. In the past, GE, Medtronic and other big players have not had to compete head to head with the likes of Google, Facebook and Samsung. Rather than trying to beat them, many are now trying to join them.

Woods says companies are recognizing that they must look outside the industry, as they aren't as agile internally. Devicemakers are looking for tuck-in acquisitions — deals that bring smaller companies into a division within the company.

Another change is the consumerization of healthcare. Anderson worries that medtech companies may be falling behind.

One trend that the panelists aren't keen on is crowdfunding. While Bottorff said GE Ventures had worked with Ourcrowd, a platform for accredited investors looking to invest in Israeli and global early stage companies, her group largely is shying away from unstructured funding.

Anderson struck a similar tone, noting that investing is for the long haul. Relying on people who invest a few thousand dollars at a time, then bail when times get tough, isn't a sound business strategy, he said. — Elizabeth Hollis

Shuren Looks to 2016 and Beyond In Device Center Update

While many stakeholders are excited about the 21st Century Cures Act recently passed by the House, industry should be mindful that the Senate version could be quite different.

"It will cost us money to implement," said Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health. While the House bill would cover much of the implementation costs, it remains to be seen what the Senate will do.

Shuren cautioned that the FDA may need to divert resources from existing programs if the eventual bill signed by the president is different. He expects action in the Senate to rev up in coming weeks, with passage of a bill possibly next year.

Shuren made these remarks during an update of CDRH's strategic priorities during the closing panel of AdvaMed 2015 in San Diego, Calif. He also made a few predictions on the center's 2016-2017 strategic priorities, which will build on current accomplishments.

The director touted CDRH's advances in strengthening the clinical trial enterprise, including increasing the number of early feasibility and first-in-human IDE studies submitted versus fiscal year 2013. The first nine months of 2015 year saw a 50 percent increase in the number of EFS submissions sent to CDRH, versus FY 2013.

Other areas are ripe for study:

- Quality by Design for medical device clinical studies;
- Improved IDE submission quality;
- Continued growth of the early feasibility study program;
- Leveraging evidence from clinical experience;
- Clinical trial simplification; and
- Use of modeling to reduce clinical trial size.

Shuren emphasized the need to simplify clinical trials. "What we're finding is that most things measured are never used," so instead of gaining data for the sake of obtaining it, "let's focus on quality," he said.

The CDRH director hopes to speed trials by incorporating modeling, which would allow sponsors to predict what the results will be, potentially saving time and money, he said.

Asked about President Barack Obama's nomination of Robert Califf to head the agency, Shuren said, "I think it's terrific. His vision for us is our vision." — Elizabeth Hollis

FDA Redoubles MDSAP Recruitment Effort as J&J Shares Its Experience

Speaking at AdvaMed 2015, FDA Associate Director for International Affairs Kim Trautman renewed her call for participants in the International Medical Device Regulator Forum's single audit pilot program, saying devicemakers have proven reluctant to join.

"Trust me, this is a much more optimal program," than the current system of multiple inspections devicemakers that do business in multiple countries face. While a Medical Device Single Audit Program inspection might last a couple of days longer than an FDA inspection, at least as much time — if not more — is lost preparing for visits from several regulatory bodies under the current system.

Her plea comes a month after the FDA released a mid-pilot report showing tepid interest among devicemakers in joining the MDSAP pilot. As of July 23, 45 sites had expressed interest in participating in the program; the target for the end of 2016 is 330 (*IDDM*, Sept. 18).

MDSAP is not going to go away, Trautman promised, adding the pilot will help iron out wrinkles in the single audit concept, and companies can benefit by going through the experience.

(See **MDSAP***, Page 6)*

Lerner, *from Page 1*

the software, which is used in colonography procedures.

Because the PMA process wasn't used, several devices were improperly approved as a screening tool for asymptomatic patients, exposing them to unnecessary, potentially cancer-causing CT scans, the whistleblower claimed.

The whistleblower also said the FDA has never cleared or approved a CT scanner for use in screening asymptomatic patients. In instructions for a similar device manufactured by Viatronix, the phrase "patient screening" is used, but refers only to screening and diagnosis of symptomatic patients. GE's reliance on PMA-approved Viatronix device for asymptomatic patients to support its 510(k) "was misplaced," the whistleblower alleged.

An FDA report acknowledged that during the review of the GE device, two of the reviewers raised concerns about the safety of using the devices for screening of asymptomatic patients, arguing that the Viatronix device was not cleared for such a purpose, according to Lerner's letter. However, after examining the reviewer's actions, the agency concluded the original Viatronix device was an appropriate predicate for asymptomatic screening, letting the approval stand.

The whistleblower also accused the FDA of not heeding reviewers' concerns that Carestream didn't include proper data to support its PMA for a digital mammography device. FDA managers allegedly failed to follow the review and approval procedures and approved the application, despite concerns about the device's effectiveness in detecting cancers that appear as microcalcifications in the breast.

Several documents related to the PMA also were missing or unsigned. The FDA commissioner's report concluded the errors were minor and didn't compromise the legal or scientific basis for PMA approval.

The whistleblower concerns have made the FDA realize that more transparency in the premarket review process is needed, Lerner says.

Lerner's letter is available here: www.fdanews.com/101215-letter.pdf. — Elizabeth Hollis

MDSAP, *from Page 5*

Case in point: device giant Johnson & Johnson nominated three of its facilities to participate in the program.

Among the company's goals in joining the pilot were "what do we want to learn through this process and what is the value that we're going to bring to the business," said Karen Parker, senior director of regulatory compliance at J&J.

Parker had tips for those interested in having a single audit, including educating internal teams about MDSAP's requirements.

Prior to the audit, the J&J sites developed open lines of communication with the auditing agency, which allowed them to determine the logistics and gather proper documentation, Parker noted.

It's also imperative to have experts on hand — even if they must be accessed remotely — to help complete the audit, she said.

Parker added that the inspection was prescriptive and driven by an IMDRF companion document that helps explain the program. She said the company had to pull different records during inspections at different sites to show each met regulations. It was an "aha moment," she said.

Trautman said devicemakers should expect the single audit process to get easier as people gain familiarity with it.

Earlier this year, James Hamer, global director of quality assurance and regulatory affairs at Arthrex, a North Naples, Fla., orthopedic surgical supply company, detailed some of his organization's experiences as the first company to go through a MDSAP audit (*IDDM*, April 17). He told *IDDM* that manufacturers planning to participate in the program should enhance their knowledge of Australian and Brazilian regulations, which include fine details. He added that his company will stick with MDSAP audits in the future.— Elizabeth Hollis

Experts Examine Challenges To Developing Pediatric Devices

Even as the FDA and industry collaborate to champion development of pediatric devices, it is clear that more work must be done.

That was the conclusion of experts speaking at a panel on pediatric and rare disease device development at AdvaMed 2015 in San Diego, Calif. They cited a lack of incentives, smaller market size, the specialization of pediatric device development and the cost of conducting clinical trials as barriers industry faces.

"Children are not just small adults," said Charles Berul, division chief of cardiology and co-director of the Children's National Heart Institute at the Children's National Health System in Washington, D.C.

Berul demonstrated just how acute the need showing photos of children with implanted pacemakers and defibrillators visible from outside their bodies.

Mark Carlson, vice president of global clinical affairs and chief medical officer at St. Jude Medical, cited Centers for Disease Control and Prevention statistics indicating that about 120,000 babies are born each year in the U.S. with any one of 45 types of birth defects, including about 40,000 with congenital heart defects.

Despite this need, the demand for pediatric medical devices doesn't cover R&D investments. Carlson said his company's size allowed it to dive into the pediatric arena. "If we were smaller, we wouldn't necessarily have the same ability," he said.

Berul noted that it is often individual laboratories and universities trying to innovate in this area, rather than industry.

Eric Chen, director of the FDA's humanitarian use device program, said the agency has taken steps to address this complicated area, particularly when it comes to testing devices in children.

Chen added there are incentives for studies of pediatric and orphan drugs on the pharmaceutical side, including user fees. Opportunities do exist on the device side, including the Pediatric Device Consortia Grants Program, which has provided advice on the development of more than 500 devices since 2009.

In a report accompanying its fiscal 2016 funding bill, the Senate Appropriations Committee praises the grants program and calls on the agency to fund it "at the highest possible level," and at least at the same level as last year (*IDDM*, July 31).

Chen also cited a device needs assessment that the FDA launched two weeks ago via a web-based clinician survey, which is getting good response.

The survey will close by the end of the month and will be followed by a report demonstrating the need for devices to address pediatric and rare diseases.

A symposium organized by the Children's National Health System's Sheikh Zayed Institute for Pediatric Surgical Innovation is set for Oct. 23, in Washington, D.C. Participants will examine incentives to stimulate pediatric device development; more information is available at www.pediatric-surgery-symposium.org. — Elizabeth Hollis

India, UK Agencies Sign MoU on Devices

With an eye toward information exchange and protecting public health, the UK's Medicines and Healthcare products Regulatory Agency signed an agreement with India's Central Drugs Standard Control Organization to increase collaboration on medical devices.

The MHRA has a similar agreement with health regulators in the U.S. and China. Last year, the agency conducted 49 inspections in India.

"It's essential that the commitment to good quality manufacturing comes right down from the top levels of management to those on the factory floor, and throughout the entire industry," said MHRA Chairman Michael Rawlins.

The two regulators are discussing next steps for the collaboration. – Elizabeth Hollis

BRIEFS

Cardinal Completes Cordis Buy

Dublin, Ohio-based Cardinal Health has completed its $1.9 billion acquisition of Johnson & Johnson's Cordis cardiology and endovascular devices business. The deal will give Cardinal access to products in the cardiovascular, wound management and orthopedics fields. Integration efforts are expected to be completed over the next few years. The Cordis business will report to Don Casey, Cardinal Health's medical segment CEO, who is a former J&J executive.

Medtronic to Halt Sales of Glucose Sensor

Medtronic is discontinuing sales of its Sof-sensor glucose sensor, effective Dec. 1. The devicemaker says the decision is not related to safety or performance issues, and technical support for the sensor will continue. The sensor is used with the Paradigm Real-Time insulin pump, Paradigm Real-Time Revel insulin pump and the Guardian Real-Time continuous glucose monitoring system.

TVA Medical Lassoes $15M in Funding

Austin, Texas-based TVA Medical has completed a $15 million Series C round of financing with the backing of new investors Baxter Ventures and Boston Scientific. Existing investors also joined the round. The investment will fund the continuation of clinical activities and accelerate market development of the EverlinQ EndoAVF System, a catheter-based technology designed to create hemodialysis access for chronic kidney disease patients.

ICU Medical Scoops Up Excelsior

San Clemente, Calif.-based ICU Medical has signed an agreement to acquire Excelsior Medical, a maker of devices used to disinfect and protect access into a patient's bloodstream, for $59.5 million. ICU intends to sell the operating assets of Excelsior's SwabFlush product and the prefilled saline and heparin flush syringes to Medline Industries for $27 million.

Hoya Buys Knecht & Müller

Tokyo, Japan-based Hoya has acquired prescription lens maker Knecht & Müller AG, expanding its footprint in Germany, Austria and Switzerland. Hoya produces eyeglasses, medical endoscopes, intraocular lenses and optical lenses, along with key components for semiconductor devices, LCD panels and hard disk drives. Terms of the deal were not disclosed. Following the acquisition, current Knecht & Müller Chairman Peter Müller will step down. Oliver Fischbach, general manager of Hoya Lens Germany GmbH, will take over his duties. Meanwhile, Igor Merhar, Knecht & Müller AG's head of business development, will take over as country manager.

Novadaq Inks Deal With Arthrex

Novadaq Technologies has signed a co-marketing agreement with Arthrex, an orthopedic company. The agreement involves Novadaq's Pinpoint upgrade kit, which allows the integration of its SPY imaging technology into Arthrex's Synergy system, combining the fluorescence imaging and 4K white light endoscopic system.

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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.

"Dale is easy to listen to. The material covered is comprehensive. The sessions covered what I believe is beneficial to those responsible for ad/promo review"

— Tim Williams, VP of Regulatory Affairs, CR Bard

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DAY ONE | NOV. 17

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 | NOV. 18

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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☐ **Check Enclosed:** payable in U.S. funds to FDAnews

☐ **Charge my**: ☐ Visa ☐ MasterCard ☐ AmEx

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HOTEL INFORMATION INFORMATION:

Nov. 17-18, 2015

Hilton Washington DC/Rockville Hotel and Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852

Toll Free: (800) HILTONS
+1 (301) 468-1100

www.RockvilleHotel.com

Room rate: $215 plus 13% tax
Reservation cut-off date: Oct. 26, 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.