

BUILDING A WORLD-CLASS ADVERTISING AND PROMOTION REVIEW PROGRAM

DEC. 10-11, 2019

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MIAMI BEACH, FL

AN INTERACTIVE WORKSHOP PRESENTED BY PHILLYCOOKE CONSULTING AND FDANEWS

Agenda

Day 1

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| 8:00 a.m. – 8:30 a.m. | Registration and Continental Breakfast |
| 8:30 a.m. – 9:30 a.m. | Pre-approval Communications <ul style="list-style-type: none">• How to meet your SEC requirements for disclosing information while not running afoul of FDA pre-approval promotion prohibitions |
| 9:30 a.m. – 9:45 a.m. | Break |
| 9:45 a.m. – 11:00 a.m. | From Day of Approval through Commercial Launch <ul style="list-style-type: none">• Understanding the timeline and key dates for communications• Minimizing the pain, while maximizing the impact of initial promotional communications |
| 11:00 a.m. – 11:15 a.m. | Break |
| 11:15 a.m. – 12:00 p.m. | Essential Advertising & Promotion Regulations <ul style="list-style-type: none">• A review of all the requirements for product promotion of drugs and medical devices, including product name usage, fair balance, and directions for use |
| 12:00 p.m. – 1:00 p.m. | Lunch |
| 1:00 p.m. – 1:45 p.m. | Essential Advertising & Promotion Regulations Part 2 |
| 1:45 p.m. – 2:00 p.m. | Break |
| 2:00 p.m. – 2:45 p.m. | Disease Awareness Communications <ul style="list-style-type: none">• A review of FDA's withdrawn guidance on help-seeking communications• Keys for using disease awareness communications prior to approval• Essential information for compliantly continuing efforts after approval |

2:45 p.m. – 3:00 p.m.

Break

3:00 p.m. – 4:00 p.m.

DTC Print & TV

- Brief Summary Requirements for Print Promotion
- DTC Television Promotion vs. YouTube Promotional Videos
- Developing a major statement

4:00 p.m. – 4:15 p.m.

Break

4:15 p.m. – 5:00 p.m.

Off-Label Information

- Avoiding Off-Label Promotion
- Scientific Exchange Exemption
- Responding to Unsolicited Requests
- Distributing Off-label Reprints
- Latest court cases and other developments in off-label information

5:00 p.m.

Session Wrap-up, End of Day One

Day 2

8:00 a.m. – 8:30 a.m.

Continental Breakfast

8:30 a.m. – 9:15 a.m.

Standards of Evidence for Promotional Claims

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

9:15 a.m. – 9:30 a.m.

Break

9:30 a.m. – 10:15 a.m.

Standards of Evidence for Promotional Claims Part 2

- Key considerations for developing compliant search engine marketing ads, including Google's latest changes

10:15 a.m. – 10:30 a.m.

Break

10:30 a.m. – 12:00 p.m.

Using Social Media Compliantly

- A review of the three social media guidances released in 2014
- Postmarketing Submissions (2253 Filing)
- Presenting Risk Information in Space-Limited Contexts
- Correcting Misinformation on Third-party Sites

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. – 3:00 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.

3:00 p.m. – 3:15 p.m.

Break

3:15 p.m. – 3:45 p.m.

The Promotional Review Process

- An overview of 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

3:45 p.m. – 4:15 p.m.

Continuing Regulatory Intelligence

- Ad/promo is an area of ongoing developments. This session looks at some of the key resources to stay on top of the latest updates.

4:15 p.m.

Wrap-up and Adjourn Workshop