Virtual Program:

US Regulation of Advertising, Promotion and Labeling for Medical Devices (2-Part Series)

18 & 20 June 2019

Agenda

Part 1: Tuesday, 18 June 2019

Welcome & Housekeeping — **12:00 - 12:05 pm**
RAPS Host

Intended Use & Off-Label Promotion — **12:05 - 1:05 pm**
Bradley Thompson, JD, RAC
Member, Epstein, Becker, & Green, P.C.

- Understanding the law and past FDA enforcement of off-label use promotion
- Mechanisms of discussing off-label uses
- Off-label use and clinical trial strategy
- The context of off-label use discussions
- Social media promotion and other evidence of intended use
- Legal challenges to FDA enforcement
- Q&A

Break — **1:05 - 1:25 pm**

Device Claims Substantiation & Comparative Claims — **1:25 - 2:25 pm**
Stuart Kim, JD, MS
VP & Associate General Counsel, Regulatory
Cardinal Health

- An in-house perspective on reviewing marketing collateral for devices (with examples)
- Thoughts on using real-world evidence and real-world data to support device claims
- Q&A

Wrap Up — **2:25 - 2:30 pm**

Agenda is subject to change.

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Part 2: Thursday, 20 June 2019

Welcome & Housekeeping — 12:00 - 12:05 pm
RAPS Host

Navigating Federal Trade Commission (FTC) Requirements for Medical Devices — 12:05 - 1:05 pm
Joanne Hawana, MS, JD
Member, Mintz Levin

- FTC jurisdiction
- FTC advertising substantiation principles
- Endorsements and social media
- Enforcement trends and guidance
- Q&A

Break — 1:05 - 1:25 pm

Companion and Combination Products — 1:25 - 1:55 pm
Carol Cooper, MS, RAC, IM(ASCP), RM(AAM)
Principal Consultant, CM Cooper and Associates

- In Vitro Diagnostics (IVD)s for use with drugs and biologics
- Medical devices for use with drugs and biologics
- Analyte Specific Reagents (ASRs) and Research Use Only (RUO) assays
- Q&A

Wrap Up — 1:55 - 2:00 pm

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