US Regulation of Advertising, Promotion and Labeling for Drugs

Agenda
Part 1: Tuesday, 25 June 2019

Welcome & Housekeeping
RAPS Host
12:00 pm

Indications for Use & Off-Label Promotion
Glenn Byrd, MBA, RAC
President, GByrd Ad-Promo Solutions LLC
12:05 pm
- Labeling consistency
  - What is it?
  - What is FDA's view?
- Practical implementation of FDA guidance
- What does the FDA-approved labeling say?
- What data are in your BLA/NDA?
- Practice of Medicine vs. Industry Promotion
- Q&A

Break
1:05 - 1:25 pm

Claims Substantiation & Comparative Claims
Eileen Valenta
Principal, Valenta Consulting, LLC
1:25 pm
- Data substantiation
  - Indications, safety and efficacy
- Comparative and superiority claims
- Use of graphics and images
- Real-world evidence
- Q&A

Wrap Up
2:25 - 2:30 pm

Agenda is subject to change.
# US Regulation of Advertising, Promotion and Labeling for Drugs

## Agenda
### Part 2: Thursday, 27 June 2019

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<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>12:00 pm</td>
<td>Welcome &amp; Housekeeping</td>
<td>RAPS Host</td>
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<tr>
<td>12:05 pm</td>
<td>FTC Hot Topics &amp; Law Enforcement</td>
<td>Carolyn Hann, JD, Chief of Staff for Advertising Practices, FTC</td>
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<td></td>
<td>Trends in the Health Product Industry</td>
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<td>1:05 - 1:25 pm</td>
<td>Break</td>
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<td>1:25 pm</td>
<td>Direct-to-Consumer (DTC) Pharmaceutical Advertising</td>
<td>Alan Minsk, JD, Partner, Arnall Golden Gregory LLP</td>
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<td>1:55 - 2:00 pm</td>
<td>Wrap Up</td>
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- FTC jurisdiction
- Coordination with FDA
- FTC advertising law basics
- Law enforcement cases
- Endorsements and social media
- Tips and resources
- Q&A

- FDA guidance of DTC
- Endorsement and testimonials
- Social media
- Q&A

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