

## US Regulation of Advertising and Promotion for Drugs/Biologics

### Speakers

- Micheline Awad, MBA, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc.
- Carla Brooks, Senior Director, RA Advertising & Promotion, Blueprint Medicines
- Glenn Byrd, President, GByrd Ad-Promo Solutions, LLC
- Dale Cooke, JD, MA, President, PhillyCooke Consulting
- Richard Cleland, Assistant Director, Division of Advertising Practices, Federal Trade Commission
- Jean-Ah Kang, PharmD, Special Assistant to the Director, Office of Prescription Drug Promotion, CDER, FDA

### Agenda

All times are posted in Eastern Standard Time

**24 June 2021**

**Day 1**

12:00 pm – 1:00 pm	<p><b>Current FDA Environment for Advertising and Promotion</b></p> <ul style="list-style-type: none"> <li>• Update on OPDP oversight of advertising and promotion, including examples of recent compliance actions and process considerations.</li> <li>• Q&amp;A</li> </ul> <p>Jean-Ah Kang, PharmD, Special Assistant to the Director, Office of Prescription Drug Promotion, CDER, FDA</p>
1:00 pm – 1:15 pm	Break
1:15 pm – 2:30 pm	<p><b>Strategic Overview of Drug/Biologic Advertising and Promotion Regulation</b></p> <ul style="list-style-type: none"> <li>• Subtopics</li> <li>• Q&amp;A</li> </ul> <p>Glenn Byrd, President, GByrd Ad-Promo Solutions, LLC</p>
2:30 pm – 2:45 pm	Break
2:45 pm – 4:00 pm	<p><b>Consistency with Labeling - Analysis of Industry Implementation</b></p> <ul style="list-style-type: none"> <li>• Key topics TBA</li> </ul> <p>Micheline Awad, MBA, Director Regulatory Affairs, Advertising and Promotion, Neurocrine Biosciences, Inc.</p>

**25 June 2021**  
**Day 2**

12:00 pm – 1:00 pm	<p><b>FTC Hot Topics &amp; Law Enforcement: Trends in the Health Product Industry</b></p> <ul style="list-style-type: none"> <li>• FTC jurisdiction</li> <li>• Coordination with FDA</li> <li>• FTC advertising law basics</li> <li>• Law enforcement cases</li> <li>• COVID-19</li> <li>• Consumer reviews and influencers</li> <li>• Tips and resources</li> <li>• Q&amp;A</li> </ul> <p>Richard Cleland, Assistant Director, Division of Advertising Practices, Federal Trade Commission</p>
1:00 pm – 1:15 pm	Break
1:15 pm – 2:30 pm	<p><b>Direct-to-Consumer (DTC) Pharmaceutical Advertising – New Developments</b></p> <ul style="list-style-type: none"> <li>• Influencers</li> <li>• Native advertising</li> <li>• Social media</li> <li>• New platforms <ul style="list-style-type: none"> <li>○ Telemedicine</li> <li>○ Pandemic support</li> </ul> </li> <li>• Connected TV</li> <li>• Consumer brief summary</li> <li>• Q&amp;A</li> </ul> <p>Dale Cooke, JD, MA, President, PhillyCooke Consulting</p>
2:30 pm – 2:45 pm	Break
2:45 pm – 4:00 pm	<p><b>Payor Communications</b></p> <ul style="list-style-type: none"> <li>• Pre-approval Communications</li> <li>• Approved Products</li> <li>• Unapproved Products</li> <li>• Unapproved Uses of Approved Products</li> <li>• Q&amp;A</li> </ul> <p>Carla Brooks, Senior Director, RA Advertising &amp; Promotion, Blueprint Medicines</p>

\* Agenda is subject to change