

5 KEYS TO BUILDING THE BRIDGE WITH FDA ON ADVERTISING AND PROMOTION CHALLENGES

1. What is the role of FDA in evaluating pharma advertising and promotion communications and what is FDA trying to achieve?

2. What do the reviewers at OPDP and APLB want from industry regulatory professionals?

3. What are the best approaches to building a collaborative relationship with FDA on pharma advertising and promotion matters?

4. How does the FDA/OPDP Research program contribute to guidance and policy development?

5. What are best practices in responding to and resolving an FDA enforcement (warning or untitled) letter?

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