



Specializing in FDA Regulatory Matters

REACTIVE STRATEGIES: FDA WARNING LETTERS RE: ADVERTISING & PROMOTION

Norma Skolnik

Sept. 26, 2017

KEY STEPS IN RESPONDING TO A WARNING LETTER

- Assure that all parties recognize the seriousness of an FDA Warning Letter
- Identify all points and promotional materials covered in FDA Warning Letter
- Contact all impacted parties (Legal, Regulatory, Marketing, Product management, Ad agencies) and meet to plan needed response steps and follow up.

KEY STEPS IN RESPONDING TO A WARNING LETTER

- Identify all similar advertising & promotional materials that might contain violations covered, including social media websites.
- Plan for discontinuing use of impacted advertising and promotion, taking corrective action steps, and a timeline for corrective action implementation.

KEY STEPS IN RESPONDING TO A WARNING LETTER

- **Rx Drugs:** Communicate with FDA OPDP about proposed corrective action and submit plan to disseminate corrective message. If FDA doesn't agree with the proposed plan, negotiate with the Agency.
- **OTC Drugs:** Respond directly to letter, usually from FDA District office or CDER. Call identified FDA contact if needed prior to formal response.

STEPS IN RESPONDING TO A WARNING LETTER

- Draft and internally circulate FDA Warning letter response prior to responding, making sure to allow adequate time for revisions prior to response deadline (usually 15 working days).
- If company disagrees with charges in the Warning Letter, reach out to OPDP (or CDER contact for OTC drugs). There's also the option of escalating the issue within CDER. Advise to work with OPDP first if at all possible.



Specializing in FDA Regulatory Matters

Norma Skolnik

EAS Consulting Group, LLC

571-447-5500

Nskolnik@easconsultinggroup.com

www.easconsultinggroup.com

Thank You

