



# Conversation with Industry: Steps to Take After Receiving a Violation Letter

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# Agenda

- Introduction of Panel and Case Study
- Drivers and Trends
- FDA's Decision-making Process
- Practical Tips for Managing Your Response

# Alden Pharmaceutical, Inc.

- ***Alden Pharmaceutical, Inc.*** is a global biopharmaceutical company with 30,000 employees worldwide
- Alden markets **GenXity**, one of two market-leading drugs for treatment of Generalized Anxiety Disorder (GAD) for adults (over 18)
- Alden has a multimedia marketing strategy that includes direct-to-consumer broadcast ads, internet ad buys, celebrity testimonials and digital/social media marketing



# Alden Launches GenXity Mobile....

- Alden collaborates with **NextTech, Inc.**, a digital health company, to develop a Rx-only, Class II mobile app as an adjunctive treatment for GAD
- Patients must complete a daily questionnaire describing their mood, diet, adherence to medication, etc.
- The app uses data from the HCP regarding dosing for GenXity, diagnosis, etc. with a wearable and patient-inputted data to provide “treatment sessions,” reminders and prompts to help the patient manage anxiety
- The frequency, focus and content of the treatments sessions are determined by a proprietary algorithm that continually analyzes patient data and adjusts treatment sessions based on trends in the data



**GenXity Mobile!**

*Revolutionizing Drug Delivery and Adherence for Anxiety*

- Integrated treatment and care solution for GAD
- Our mobile app is proven to provide better outcomes in patient monitoring and adherence
- Real-time updates for physicians and caregivers
- Easy to use and customizable

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# Alden Launches Multi-Media Marketing Campaign

- NextTech's CEO does a series of live interviews with major business news outlets discussing the collaboration with Alden
- In multiple interviews, she states that when the GenXity app is used as an adjunctive therapy with Alden's drug, it's a more effective treatment than stand-alone anxiety medications
- Alden launches a social media campaign with Twitter and Instagram testimonials featuring Lovato Bieber, an 18 year old global pop star with a large tween fan base
- The tweets and Instagram messages include video of Lovato performing to packed stadiums with his voice over describing how GenXity enhances his performance on stage

# Alden's Multimedia Campaign Continues....

- Alden launches a DTC Ad campaign that airs during the broadcast of a highly rated teen vampire drama
- The ad features youthful looking actors who discuss Alden's anxiety drug with claims that the GenXity app makes it easier to manage treatment
- The ad contains the standard "major statement" regarding the drug, but does not contain risk information related to the app

➤ **Alden receives an Warning Letter**

# Drivers and Trends

- **Driver:** The product is one of two market leaders in GAD—fostering a very competitive environment between Alden and its unnamed competitor
- **Some trends:**
  - Customers increasingly consume information through digital means
  - The human attention span has been measured at 8 seconds, according to research conducted by Microsoft (<https://www.scribd.com/document/265348695/Microsoft-Attention-Spans-Research-Report>)
  - Young adults are digital natives, making streaming TV a natural medium for a broadcast advertisement
  - Ad assets can be redeployed in banner ads and social media as-is, and in snippets on Instagram—to meet the 8-second attention span
  - Influencers such as the celebrity spokesperson are popular
    - Alden may also be thinking of other ways to reach the young adult market with demonstrations of the app: concert venues, ComicCon, craft beer festivals

# So Many Challenges

- Are the NexTech CEO's claims supported (GenXity + the mobile app are superior to existing drug treatments alone)?
  - Are her claims overly broad (GenXity specifically has a GAD indication; she is comparing it to a catchall of 'standalone anxiety meds')?
- Is there support for celebrity's claims that the app makes life 'easier'?
  - And how does that message get balanced?
  - Does the celebrity make clear the paid nature of the relationship?
  - Is the celebrity an actual user of the product, and is that made clear to the audience?
  - Has the drug+app combo been studied for stage performance enhancement?
- Is the chosen celebrity—with a huge tween fan base—appropriate when the product is indicated for ages 18+?
- Can 8-second video snippets from the branded TV ad be created as reminder (since there's no time for risk info)?
- Is Alden adequately educating HPCs on the product?
- TV ad on streaming media: Are the actors age-appropriate?
  - Is a drama series with a target audience of teens an appropriate place to advertise these products?
- What about presenting risk information and disclosures regarding the app?



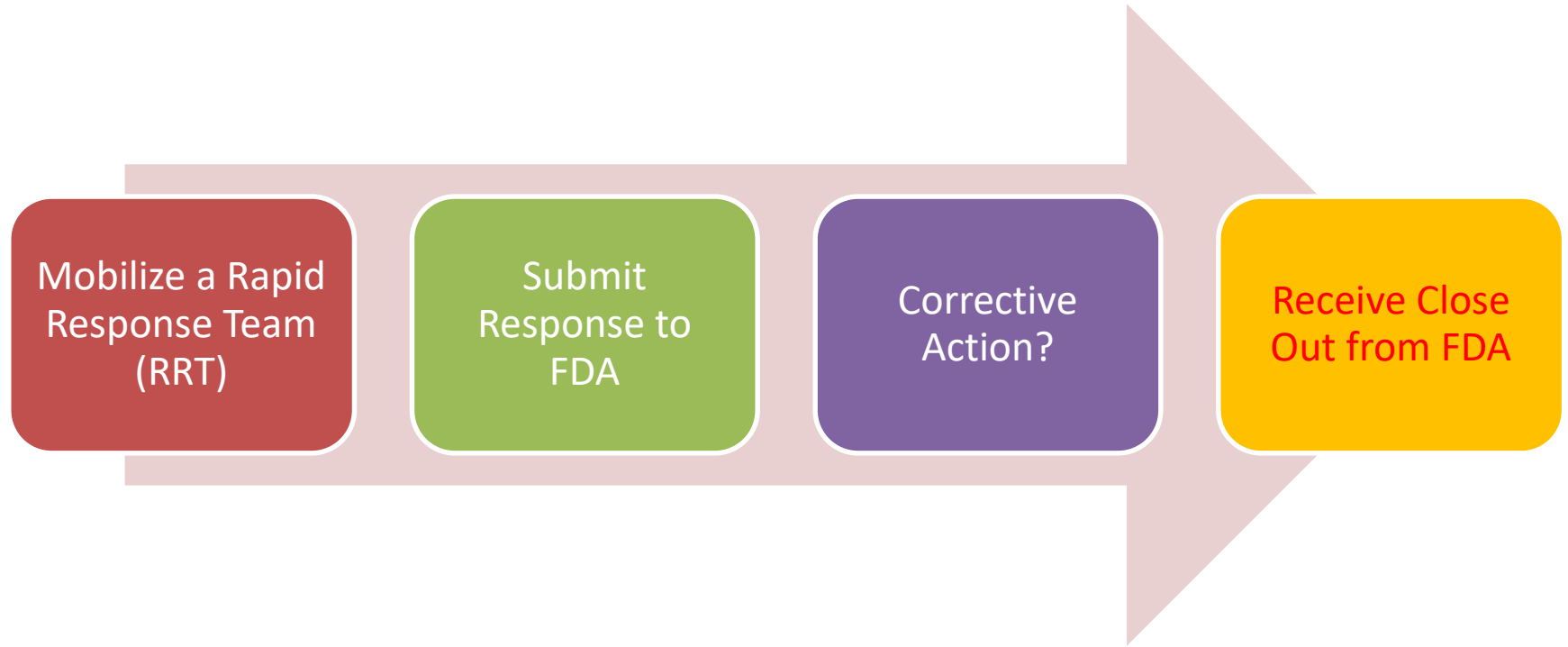
# Some Enforcement Categories

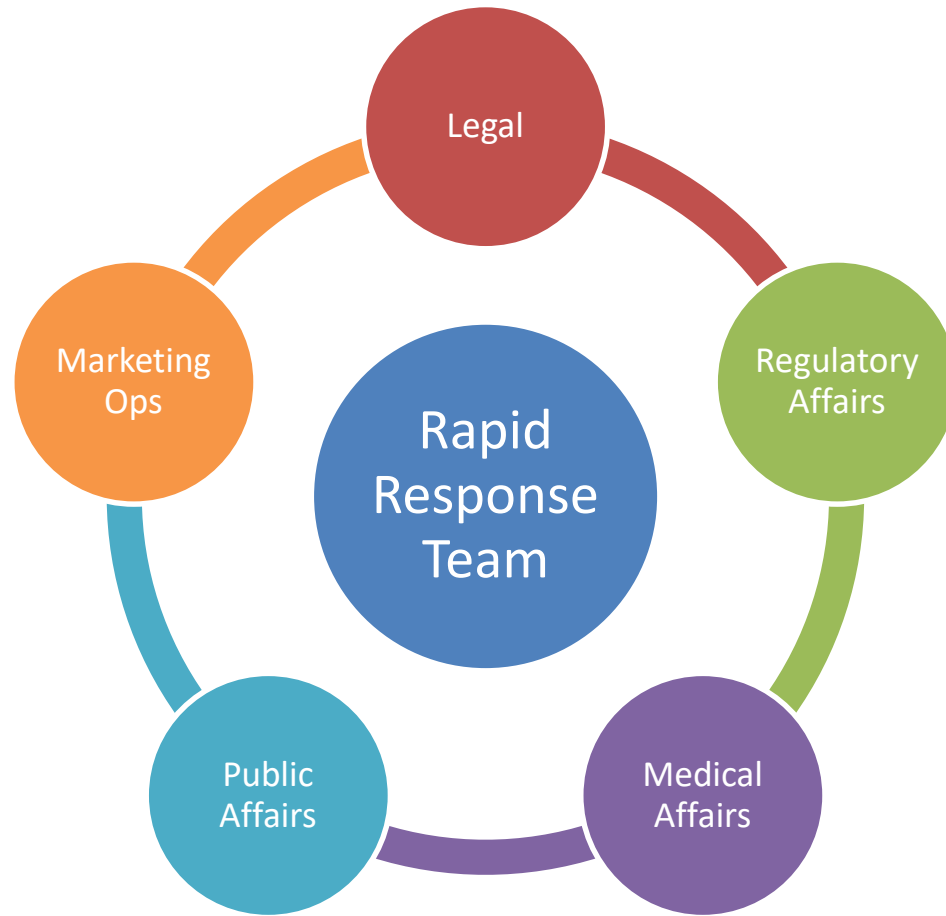
- Social media
  - 3 Untitled Letters (Eskata, Tirosint, Tasigna)
  - 1 Warning Letter (Diclegis)
- Live or videotaped interviews
  - 8 Untitled Letters (Eskata, Gliadel, Cofelemer, Antineoplastics, Ampyra, Injectafer, Estring, Flublok)
  - 3 Warning Letters (Kaletra, Photofrin, Juxtapid)
  - Some other letters did not refer to interactions on TV program as “interviews”
- Testimonials
  - 12 Untitled letters (Livalo, Herceptin, Premarin, Vivitrol, multiple, Ethyol, Zaditor, Tamiflu, Quadramet, Ampligen, Migranal, Flovent)
  - 7 Warning Letters (Xeloda, Quadramet, Adderall XR, Kaletra, Ultram ER, Testopel, Copaxone)
- TV Broadcast Ads
  - 52 Untitled Letters (too many to list here)
  - 6 Warning Letters (Yaz, Enbrel, Muse, Flonase, Lescol, Epipen)

# Potential Agency Considerations

- Type of violations/claims
- Potential threat to public health
- Prior communications
- Depth and breath of dissemination
- Speaker

# Developing an Effective Response Plan





Develop an Action Plan

Review & assess impact

Communicate with Sr.  
Leadership

Lead the response to FDA

Thank You!