



# FDA ALERT

## Approved Listings & Explanations of Regulated Technology

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# FDA's Strategic Plan for Regulatory Science

- Mission Statement
  - Responsible for protecting the public health [1]
- Regulatory Science
  - Priority Area 8: Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products [2]
- Designing the Solution
  - Know the audience
  - Reach the audience
  - Ensure audience understanding
  - Evaluate the effectiveness of communication about FDA regulated products



[1] (FDA, 2017)

[2] (FDA, 2016)

[3] (Enviroics Research, 2018)

# Current Access to Information through the FDA

MedWatch

VAERS

Safety Reporting Portal

MAUDE

openFDA API

*" We recognize it can be challenging to figure out where to report concerns or problems to the FDA "*

*-Anna Fine, Pharm.D., M.S., director of the FDA's Health Professional Liaison Program [1]*

Consumers need a centralized, customizable portal to report, and learn about, problems, complications, or recalls regarding FDA regulated products in real time

FDA ALERT is a  
smartphone-based mobile app



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- Scan a QR code on product label
  - Access all FDA verified/approved information
- Feature that gauges user understanding
- Alert feature for "subscribed" products and medications when changes, recalls, etc. occur
- Feature for reporting adverse events/side effects



# Impact/Benefits of ALERT

- Provides users with up to date information/warnings on FDA regulated products
- Easily accessible to consumers when making medical decisions & purchases
- Ensures the consumer has been presented with pertinent information
- Allows for comparison of similar products/medications to help consumer make a more informed decision
- Consolidate adverse event/side effect reporting