



Summary We were engaged by a Mid-Atlantic pharmaceutical company to review new FDA guidelines and take actions to combat pharmaceutical counterfeiting. Our client invested in several strategies to follow the FDA guidelines and asked us to review other industry manufacturing processes in consumer packaging and make suggestions on how to improve manufacturing and augment current strategies.

Analysis We reviewed the FDA Guideline and investigated other FDA-regulated manufacturers of consumer goods.

Our review of the FDA guidelines raised following concerns:

- Guidelines would lead to increased regulatory pressure on distribution channels
- Guidelines would require systematic overhaul of means and methods of production, distribution, and consumption
- Guidelines would be difficult to measure to justify investment

In Summary the FDA Public Response to Combating Counterfeit Drugs was to encourage manufacturers to:

- Engage private sector stake holders and government agencies
- Focus on secure packaging/distribution technology
- Engage a broader study to accurately map the risk of counterfeit imports
- Create an alert system to monitor supply chain
- Strengthen Distribution system to monitor at each level



Challenge

- Helping our client engage in a thoughtful exchange with policy makers to address regulatory and safety concerns
- Pointing to effective methods used in consumer manufacturing processes that have proven effective without additional regulatory oversight
- Being practical about our clients ability to integrate new initiatives in in addition to current strategies in question by regulatory

Solution Our suggestions:

- Develop PMO to coordinate with internal public relations and action initiative teams
- Initiate a public affairs campaign on the socio-economic impact that counterfeiting has on the cost of healthcare
- Adopt laser product encoding on shipments and utilize license activation codes to enable shipments
- Hold buyers, broker, distributors, insurers, and that party manufacturers to higher business practice standards and demand that security of the brand be equally as important.

Conclusion

Our client presented our findings to their leadership team which adopted several of our suggestions.

Follow-Up

Our suggestions helped our client launch a successful PMO and PR campaign to raise business to business awareness of their position on the issue and more effectively coordinate with external agencies.