

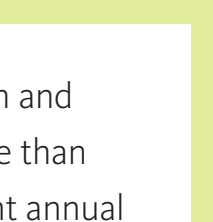


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Protecting your brand during a nutraceutical recall





Millions of Americans now rely on dietary supplements every day to boost their health and immune systems. The industry, marked by steady growth is expected to be worth more than \$400 billion by 2025. In the last year alone, the industry saw a record-high 12.1 percent annual increase in sale, which experts attribute to the COVID-19 pandemic that instilled fear into consumers and drove them to obsess over immune-boosting products.

But as dietary supplements increase in popularity, consumer advocates, regulators and lawmakers are increasingly concerned that the current regulatory system is inadequate to ensure the products on market are safe.

The regulatory environment surrounding the nutraceutical industry is complex, with multiple laws governing it in the U.S. alone. The most notable is the Dietary Supplement Health and Education Act of 1994 (DSHEA), which states:

- Manufacturers and distributors are prohibited from marketing products that are adulterated or misbranded, and are responsible for evaluating the safety and labeling of their products to ensure all DSHEA and FDA requirements are met.
- The FDA is responsible for taking action against adulterated or misbranded product after it reaches the market.

But many still argue the category is insufficiently regulated. Consumer advocates claim fraudulent and adulterated products containing hidden drugs or other undeclared ingredients remain on the market, purchased by consumers everywhere. Additionally, there are hundreds of companies making false claims about their products – something that became more apparent during the pandemic.

Additionally, as the market grows increasingly more global, companies face a complex patchwork of regulations. Some countries have an explicit set of regulations for the industry, others include nutraceutical products under food regulation and some require animal and/or human clinical studies. As the nutraceutical industry's regulatory environment grows increasingly complex, recall readiness is more important than ever.

We don't know exactly what the regulatory landscape will look like for dietary supplements, but stricter regulatory framework and enforcement activity is on the horizon. And one thing is certain: for products meant to benefit consumer health, a recall can be detrimental – especially if the event catches media attention.

Mismanaging a recall can have serious consequences for a company's brand and bottom line, including:

- Regulatory fines
- Civil lawsuits
- Criminal prosecutions
- Loss of customer trust and loyalty
- Charge backs and other fees incurred from retailers

With so much at stake, it is important that companies understand the most common causes of recalls within their industry, keep up to date with the changing regulatory environment and prepare for the likelihood of a recall by developing a comprehensive plan.



Recall risk landscape



Nutraceutical products accounted for 8.4 percent of all FDA food recalls from 2015-2020. These 285 recalls impacted 247 companies.

Over this five-year period, the top causes for nutraceutical recalls include undeclared allergens, followed by quality concerns, bacterial contamination and mislabeling issues. Undeclared allergens accounted for 31 percent of nutraceutical recall events and more than half of all recalled units.

While recalls dipped slightly during the pandemic, activity is expected to rebound once oversight activities resume and expand.

There has been an influx of companies targeted for falsely marketing supplements and other products claiming they can prevent, treat or cure the COVID-19 virus. The FDA issued warning letters to companies selling these products, but other regulatory agencies, such as the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DoJ), have also taken action to protect consumers. The desire among regulators and lawmakers to increase enforcement on everything from false marketing to unsafe products also cannot be understated.

But the real risk companies face is not whether they encounter a recall. It is how that event will impact the brand and reputation in an era marked by diminished consumer loyalty, increased competition and changing consumer behavior. That will be largely determined by how well the event is managed and how the corrective action is communicated.

Recall management

When a food recall is announced, even established brands can feel like they are facing a bet-the-company crisis. That's because the task of managing the details of a recall situation is dramatically different from a company's regular day-to-day operations.

The truth is an effective product recall quickly removes impacted products from shelves and restores consumer confidence. If not executed properly, however, the event can expose companies throughout the supply chain to potential litigation and brand damage. To compete in this ever-changing environment, nutraceutical companies need a combination of unparalleled experience, field-based services and data-driven technology.

As supply chains and industry regulations increase in complexity, nutraceutical recalls are becoming more prevalent. Companies facing recalls will need to effectively execute critical recall tasks such as:

- **Satisfying complex regulatory compliance obligations.** Companies must understand the regulatory environment, effectively communicate the recall to those affected, choose the right remedy and close out the recall as quickly as possible.
- **Identifying and notifying affected parties throughout the entire supply chain.** Companies must alert distributors, wholesalers, retailers, customers and other stakeholders in order to ensure affected product is no longer sold. Depending on the level of severity, a news release may also be required to notify the public. A combination of notification services, contact center support and an agile, global product removal team make the difference between a successful nutraceutical recall and a brand in crisis.
- **Coordinating seamless communication with all parties through a multi-channel communication center.** Once the recall is announced, it is critical to have an effective means of responding to consumer questions, including a well-staffed contact center and a dedicated website. A third party may be required to assist with this, depending on the scope of the issue. Customers should be advised of what action they should take and informed of what the remedy will be, such as a reimbursement or refund.
- **Evaluating claims and executing remedies.** When evaluating claims, companies should consider whether offering reimbursement and other remedies that go beyond standard compensation would help protect the brand.

- **Managing recall logistics and product reconciliation.** It is important to quickly coordinate shipment returns from distribution centers and remove affected products from store shelves. In doing so, the instructions for handling recalled products must be crystal-clear. Otherwise, companies can end up throwing other profits down the drain by removing non-recalled products with similar packaging or different batch, lot or code numbers. A field force can also help keep this type of shelf sweeping from occurring. Companies must also consider how they will handle, document and sustainably dispose of any returned product so it is never combined with unaffected product, inadvertently reentering the marketplace.
- **Conducting on-site effectiveness checks and monitoring compliance with product handling requirements through quality audits.** As affected product is removed from the market, effectiveness checks should be performed to validate the process and ensure data is accurately collected for regulatory reporting.

As an added twist, grocers that sell under a private label are held to the same standards as nutraceutical producers themselves. Ensuring compliance with the complex requirements of a global marketplace requires extra attention. In this competitive market, any food preparation slip-ups need to be dealt with promptly in order to maintain a strong company image.

Scrambling to keep the public up to date while overseeing these details can be a logistical whirlwind. That's why it's important to have a recall strategy plan already in place. When company departments, distribution partners and consumers are educated in the proper order, it's easier for brands to ride the wave of a recall and avoid any extra public scrutiny.

Manufacturers and retailers can ensure the quick removal of all affected products from stores by proactively defining a recall management process before events occur. Organizations that take swift action in putting their recall plan into effect are best positioned to mitigate risk and prevent irreparable brand damage.

Recall planning

Creating and maintaining a recall plan– and then testing that plan with mock recalls – should be a top priority.

The plan should include:

- **A designated recall management team with specific responsibilities.** This will help hold individuals accountable for their role in effective recall execution.
- **Consumer complaint evaluation and investigation process.** Companies should determine the process for identifying the root cause of the issue. Companies must also have a detailed plan for determining the nature of the health hazard, with guidelines for actions and remedies necessary depending on the severity of the risk.
- **Process for accurate recall scoping.** Companies need to be prepared to quickly and accurately identify where the product is being sold and how to get it off shelves, out of homes and back to the company for storage and ultimate destruction.
- **Notification procedures for informing regulatory agencies involved and partners upstream and downstream.** It is important to consider the pressures and challenges facing retailers, who may feel compelled to respond to product shortages, recalls and other supply related issues by reallocating shelf space or discontinuing a product line entirely. Failure to take this into account when working with your customers may keep your products off store shelves. If the product is sold direct to consumer, companies should be prepared to handle the complexities of an e-commerce recall.
- **Consumer engagement plan.** Communicating with consumers under normal business conditions is more challenging than ever before. But when food safety concerns make headlines, these challenges increase exponentially. Intense media coverage often leads to a deluge of calls, even from customers who have not purchased or consumed the product in question. Plan now for how to provide immediate, concise and helpful information to consumers and customers across all communications channels. The ability to do so will build rapport and trust with customers while significantly reducing potential miscommunication and opportunities for error.
- **Reverse logistics and product handling process.** Determine how to effectively remove products throughout the supply chain in a way that minimizes risk to manufacturers and grocers around the globe. Consider reconciliation, storage and disposal requirements once the product is retrieved.
- **Process for identifying and providing recall remedies.** When it comes to recall remedies, companies have several options available. A full refund or coupon for replacement is a common option. Be prepared for when a health issue arises, as many consumers will appeal for reimbursement of medical-related costs.
- **Detailed method for closing out the recall.** This depends on detailed data for regulatory reporting. Too often companies need to expand a recall after an initial announcement. These organizations have a much harder time recovering from the regulatory, retailer and consumer fallout. But effective recall planning – from initial investigation through to event close-out – can mitigate these risks.

By starting with a robust recall insurance policy and a comprehensive recall preparedness strategy, companies big and small are better suited to handle these complex scenarios. Delivering high-quality products is easier when the proper regulatory reporting data is organized and ready at a moment's notice.

Conclusion

When it comes to recalls, it's often not a matter of if, but when.

While the costs associated with a recall can have a major impact on bottom lines, the costs of poor recall management are far greater. Brands that are willing to tackle recall management plans before problems arise are better equipped to navigate the challenges with confidence.

In addition to developing a plan, companies should consider investing in recall insurance to protect the organization in the event of a recall. While many standard liability policies already have a "recall" endorsement, they often fall short of covering the wide range of expenses incurred, including logistics and crisis communications.

The steps involved in recall planning may sound overwhelming, but dealing with a recall on the fly is even more daunting. Recall ready companies can respond quickly and efficiently - and having expert advice throughout the entire process can help mitigate risks to companies and consumers alike.

