The US retailer Claire's announced a voluntary recall of three cosmetic products in March, but not until days after the US Food and Drug Administration (FDA) issued a safety alert and independent test results confirmed the presence of asbestos.

Claire's disputed the results, saying the FDA tests showed “significant errors” and mischaracterised fibres in the products as asbestos. Nevertheless, the retailer withdrew the products out of an “abundance of caution”.

The asbestos claim and subsequent standoff between the FDA and Claire’s drew renewed attention to the lack of regulatory oversight that the FDA has over the US cosmetics industry, coming against the backdrop of more than 11,000 ongoing civil cases over Johnson & Johnson’s talcum powder.

Currently, with some limited exceptions such as color additives, the FDA does not require a pre-market review of cosmetic products prior to commercialisation, and US law generally permits manufacturers to determine their own safety testing or, indeed, whether to test cosmetic products at all.

Essentially, the FDA monitors cosmetics safety by reacting to product complaints, reviewing scientific literature or evaluating after-the-fact safety testing. As demonstrated by the Claire’s incident, even for a suspect product, the FDA has no power to force a recall of a cosmetic.

The FDA said in its 5 March announcement that it plans to work with Congress to update the regulatory framework for cosmetics that has been in operation for more than 80 years and, as discussed further below, the agency recently announced plans to gather information from manufacturers to inform its next steps.

**FDA cosmetics regulation**

The Federal Food Drug and Cosmetic Act (FFDCA) defines cosmetics as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance ...”

The category includes not only make-up (lipstick, eye shadow, etc) but also “personal care products” used by men, women and children (including those for hair care, skin care, nail care, perfumes and shampoo), so long as their intended uses are limited as noted above. Any additional therapeutic use could subject a product to another set of regulations, typically the drug requirements.

For instance, the FDA regulates cleansing shampoo as a cosmetic, but anti-dandruff shampoo is both a cosmetic and a drug because it also is intended to cure, mitigate, treat or prevent a disease of the body. Similarly, deodorants are cosmetics, but antiperspirants are drugs.

Claims on product labeling and even consumer perception can establish a product’s intended use and, therefore, how the FDA regulates that product, which can make a tremendous difference. For example, drugs need to...
obtain FDA approval prior to commercialisation or need to conform, for certain over-the-counter (OTC) products, to OTC drug monographs which, loosely speaking, are like recipe books that set forth dosage form, strength and other conditions under which certain active ingredients are generally recognised as safe and effective (Grase).

Although unsafe cosmetics would be considered adulterated under the FFDCA, the FDA regulatory framework for products that are categorised only as cosmetics is minimal, especially compared to the regulation of products in the EU and other countries. The table below contrasts the regulation of cosmetics in the EU vs. the US, including and especially the 2013 EU Cosmetics Regulation vs. the FFDCA:

<table>
<thead>
<tr>
<th>EU Requirements</th>
<th>US Rubric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit certain information prior to placing products on the market</td>
<td>Manufacturers choose whether to share their safety information with FDA</td>
</tr>
<tr>
<td>Report product non-conformities that may pose risks to human health</td>
<td>Cosmetics cannot be adulterated or misbranded but are not subject to affirmative reporting requirements for non-conformities</td>
</tr>
<tr>
<td>Comply with good manufacturing practices (GMP)</td>
<td>No GMP regulations (only nonbinding recommendations) for cosmetics</td>
</tr>
<tr>
<td>Conduct safety assessments that contain specified data</td>
<td>Manufacturers generally define how they test their products and ingredients for safety</td>
</tr>
<tr>
<td>Comply with list of more than 1,300 prohibited substances and hundreds of restricted substances</td>
<td>Except for colour additives and a few restricted ingredients, cosmetic manufacturers can use almost any substance in a cosmetic without FDA approval (though products that are harmful to health would be considered adulterated)</td>
</tr>
<tr>
<td>Follow safety and adverse event reporting requirements</td>
<td>No mandatory adverse event reporting</td>
</tr>
<tr>
<td>Register all cosmetic products in a centralised database</td>
<td>Registration with FDA is voluntary (though some US states require registration of cosmetic manufacturers and distributors)</td>
</tr>
</tbody>
</table>

All three of these bills would require cosmetic manufacturers to register with the FDA, manufacture products in accordance with good manufacturing practices (GMPs), report adverse events, and would require FDA to review for safety certain ingredients used in cosmetic products.

Two of the bills also would give the FDA recall authority over cosmetic manufacturers and require them to submit cosmetic ingredient statements to the FDA for each of their cosmetic products. In addition to these comprehensive reform bills, 2018 also saw the introduction of the Children’s Product Warning Label Act.
which would require manufacturers of cosmetics marketed to children to demonstrate that they are free of asbestos or carry a warning label that the product has not been evaluated for asbestos contamination.

Reinvigorated Interest
The Claire’s incident seems to have reinvigorated interest in cosmetics legislation. In the subsequent days after the recall, US Senator Dianne Feinstein reintroduced the Personal Care Products Safety Act, and US Representatives Debbie Dingell and Jan Schakowsky reintroduced the Children’s Product Warning Label Act.

Also in March, California lawmakers introduced the Toxic-Free Cosmetics Act, which would ban the sale in California of makeup that uses 20 highly toxic chemicals known to cause cancer or reproductive harm, including asbestos, lead and formaldehyde. This renewed focus on the cosmetics industry, together with calls for change from industry players including Johnson & Johnson and the Personal Care Products Council, could be the catalyst to change the US regulatory framework for cosmetics.

Indeed, on 24 April, despite the departure of FDA Commissioner Scott Gottlieb, the FDA announced that it has randomly selected 900 manufacturing establishments to participate in a voluntary survey, approved last July, regarding current quality management and safety practices used in the cosmetics industry.

The survey will explore topics such as written procedures and records, buildings and equipment, materials and manufacturing, and quality control/product testing. It is unclear, however, to what extent the new commissioner will push for cosmetics regulatory reform.

That said, manufacturers and retailers may want to consider staking out their positions now on proposed actions that may affect their products, before their products become the center of unplanned attention as a result of an emergent event.

This means that manufacturers should keep current on the latest FDA developments and may want to consider providing input or comments when the opportunity arises, for instance, at the FDA’s 5 June public meeting to receive input on cosmetics regulation in preparation for its meeting with the International Cooperation on Cosmetics Regulation, an international group of cosmetics regulatory authorities.

In addition, cosmetics manufacturers who sell products in the US and who are operating without a formal quality system should at least familiarise themselves with the fundamentals of quality controls, if not implement the basic elements of a quality system with documented procedures designed to ensure a consistent process and control over changes.

Those that already have a system should make sure their systems are sufficiently robust to maintain quality control and produce products fit for their intended use. A helpful place to start regarding FDA expectations is the FDA draft guidance, Cosmetic Good Manufacturing Practices (2013), although information from the voluntary survey may lead to further revisions.

As noted earlier, an unsafe cosmetic product would be considered adulterated under the FFDCA. As such, robust safety testing of formulae prior to commercialisation, as well as testing of incoming raw materials and finished products prior to release, are essential to confirm that components and finished products meet internal standards and customer expectations.

Even if the FDA does not heighten US cosmetic regulation in the immediate future, a robust quality system makes good business sense by:

• instilling trust in customers and maintaining a company’s reputation;
• mitigating unexpected, negative and costly outcomes; and
• minimising business impact when problems do occur through traceability of affected products and identification of the root cause.

Good business practices take a proactive approach to quality, and any future legislative or regulatory changes, which may be more likely due to events like the Claire’s incident, may make such practices mandatory.