December 2023

COSMETIC SAFETY

Better Planning Would Enhance FDA Efforts to Implement New Law

GAO Highlights

Highlights of GAO-24-105542, a report to congressional requesters

Why GAO Did This Study

Cosmetics accounted for approximately $43 billion in revenue in the United States in 2021, according to U.S. Census data, with tens of thousands of cosmetic products and formulations on the market. Consumer groups and some scientists have raised concerns that cosmetics may contain substances that harm human health. In December 2022, a new law—MoCRA—took effect, expanding FDA's authorities to oversee cosmetic safety.

GAO was asked to review FDA oversight of cosmetic safety. This report examines (1) research on the safety of selected substances in cosmetics and (2) FDA actions to implement its new authorities and the extent to which these actions addressed selected leading practices for agency reforms. This report also includes information on state laws and regulations that prohibit or restrict substances in cosmetics.

GAO reviewed scientific literature and FDA documents and interviewed FDA officials. GAO compared FDA actions to implement MoCRA with selected leading practices for agency reforms. GAO uses the term "reforms" to include organizational changes, such as those needed to implement new statutory authorities.

What GAO Recommends

GAO is making seven recommendations to strengthen FDA's efforts to implement its new cosmetic safety oversight responsibilities, including developing implementation and strategic workforce plans. FDA concurred with the recommendations.

View GAO-24-105542. For more information, contact: Steve Morris at (202) 512-3841 or morriss@gao.gov, or Karen Howard at (202) 512-6888 or howardk@gao.gov.

What GAO Found

Research has established that certain substances found in cosmetics are potentially harmful to human health. However, the effects can be difficult to confirm, in part because they may take years to develop. Most of these potentially harmful substances are added by manufacturers to serve a specific function. For example, parabens are chemicals added as preservatives to prevent the growth of microorganisms such as bacteria, but parabens have been linked in some studies to endocrine problems (i.e., hormone imbalances). Other substances may be present unintentionally as impurities, such as asbestos in talc, or as byproducts of manufacturing. Inhalation of asbestos is associated with mesothelioma, a type of cancer that develops on the lining of internal organs.

Examples of Potentially Harmful Substances in Cosmetics

Intentional Ingredient	Impurity
Parabens, preservatives used to prevent the growth of bacteria, are found in cosmetics such as foundation, and have been linked to endocrine problems.	**Asbestos contamination in talc** may be associated with cancer and has been found in makeup products that contain talc, such as blush.

Sources: GAO; Subbotina Anna/stock.adobe.com; Jacob Kearns/stock.adobe.com. | GAO-24-105542

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) significantly expands the regulatory authority of the Food and Drug Administration (FDA). MoCRA requires FDA to take several actions (e.g., issue standards for detecting asbestos in talc) by specific dates through December 2025. FDA has taken important steps to implement MoCRA, such as designating its Chief Scientist to lead FDA's implementation efforts. However, FDA has not fully addressed leading practices that help ensure the success of agency reforms—in this case, the organizational changes necessary to implement the law. For example:

- FDA has not developed an implementation plan for MoCRA. According to FDA's Chief Scientist, the agency is using MoCRA itself as its roadmap for implementation efforts. However, MoCRA generally does not detail interim steps or deadlines, as called for by project management guidance.
- FDA has not developed a strategic workforce plan, as called for by leading practices, to help ensure that the agency has the necessary personnel with the requisite skills and competencies to exercise its new authorities.

According to FDA's Chief Scientist, the agency had not developed such plans because FDA had been focused on meeting near-term MoCRA deadlines. By more fully addressing the leading practices, including planning, FDA can better ensure successful implementation of MoCRA and promote cosmetic safety.