Cosmetic Safety Reform Discussion Draft

Title I: Cosmetic Safety

Section 101 – Registration of Cosmetic Facilities and Cosmetic Ingredient Statements

- Requires cosmetic companies to register with FDA and establishes a registration process.
- As part of the registration process, cosmetic companies must submit to FDA a cosmetic ingredient statement that includes, amongst other things, a list of all ingredients in a cosmetic product.
- FDA may suspend a company's registration or cosmetic ingredient statement if the agency has concerns that the product will cause serious adverse health consequences.

Section 102 - Review of Ingredients and Non-Functional Constituents; Safety of Finished Products

- Outlines process for FDA to collect data and information on cosmetic ingredients and requires FDA to review cosmetic ingredients to determine if such ingredients are safe for use in cosmetic products.
- Gives FDA authority to deem specific cosmetic ingredients unsafe.
- Requires cosmetic companies to maintain records about their products and attest to their safety before marketing the product.

Section 103 – Good Manufacturing Practices (GMPs) and Cosmetics

- FDA must review national and international standards to develop GMPs for cosmetic products. FDA must issue a final GMP regulation within three years of enactment.
- Large manufacturers would be required to comply with the final GMP regulation within 180 days of FDA finalizing, while small businesses would have to comply within two years.

Section 104 – Adverse Event Reports

- Requires companies to report any serious adverse events associated with its products to FDA within 15 days of learning of the event – this includes, among other things, reports of death, hospitalization, or disfigurement.
- Companies must report all adverse events to FDA (both minor and serious) semi-annually.
- Companies must include contact information on all cosmetic product labels for consumers to report any adverse events associated with use of the product.

Section 105 – Records Inspection; Mandatory Recall Authority

- Gives FDA authority to access company records during an inspection.
- FDA may order the recall of a cosmetic product if there is a reasonable probability that an adulterated or misbranded product is likely to cause a serious adverse health event or death, and the company refuses to conduct a voluntary recall.

Section 106 – Labeling

- FDA must require warnings on cosmetic product labels that are not appropriate for the entire population (e.g., unsafe for children or pregnant women) or that are for professional use only.
- Internet sites selling cosmetics must include full labeling information, including warnings.
- Cosmetic labels must include contact information where consumers can obtain additional information about the cosmetic product.

Section 107 – Coal Tar Chemicals

- FDA may review chemicals found in coal tar and used in cosmetics for safety.

Section 108 – Animal Testing Alternatives

- Companies are encouraged to use non-animal testing methods for the safety of cosmetic ingredients.
- Requires FDA to issue guidance on the acceptability of non-animal testing methods.

Section 109 – Preemption

- Language to be supplied at a later date.

Section 110 – Reporting

- FDA must submit annual performance reports to Congress on progress implementing this law, including the status of FDA's cosmetic ingredient safety reviews.

Section 111 – Small Businesses

- FDA, in coordination with the Small Business Administration, will provide assistance to small businesses to help such entities comply with requirements of this law. Further, FDA will be required to develop a plain language compliance guide to assist small businesses in complying with the registration and ingredient statement requirements.

Section 112 – Applicability with Respect to Certain Cosmetics

- States that companies complying with an over the counter (OTC) drug standard are deemed in compliance with all applicable requirements of this law.

Section 113 – Enforcement

- Makes conforming amendments to the FD&C Act to list penalties identified under this law.

Section 114 – Consumer Information

- Requires FDA to post on its website information for consumers about ingredient safety reviews, cosmetic recalls, and counterfeit cosmetic products.

Title II: Fees Related to Cosmetic Safety

Section 201 – Findings

- Authorizes user fees dedicated to cosmetic safety activities.

Section 202 – Authority to Assess and Use Fees

- Establishes a tiered fee structure to accommodate manufacturers of different sizes.
- Sets fee in the first year and adjusts fees in subsequent years to ensure FDA collects $20.6 million.
- Sunsets the law after fiscal year 2022 (i.e., program must be reauthorized to continue).

Section 203 – Direct Hiring Authority

- Gives FDA authority to directly hire cosmetic safety experts for three years after enactment.