Cosmetics Safety Reform Discussion Draft
September 2016

The Food and Drug Administration (FDA) is charged with oversight over cosmetics. However, unlike other products FDA regulates, such as drugs, foods, and tobacco, the agency's authority over cosmetics is outdated and more limited. Cosmetic products are not currently subject to any review before marketing, and cosmetic manufacturers are not required to report adverse events associated with their products or register with the FDA. The discussion draft would address these gaps in regulatory authority and would require companies to register and file cosmetic ingredient statements with FDA so FDA will, for the first time, have comprehensive information about what companies are manufacturing cosmetics, what products companies market to consumers, and what ingredients are in cosmetic products. The discussion draft also requires companies notify FDA about adverse events associated with cosmetics, gives FDA authority to hold cosmetic manufacturers accountable for the safety of their products, and allows FDA to conduct safety reviews of cosmetic ingredients and recall products associated with serious health events.

New Authorities Provided to FDA

- **Safety of Cosmetic Ingredients and Finished Products**
  - FDA will collect data and information on cosmetic ingredients and would be required to review such ingredients to levels of safety for their use in cosmetics. FDA would determine how much of the ingredient may be used in cosmetic products, as well as what the specified condition of use would be and if any warning labeling is required.
- **Mandatory Recall and Access to Records**
  - FDA will have access to cosmetic records during an inspection and would be able to order a mandatory recall if there is a reasonable probability that the product is adulterated and likely to cause a serious health event or death. This is similar to the authority FDA has currently for other products it regulates, such as food.
- **Labeling**
  - FDA must require warnings on cosmetic products that are not appropriate for the entire population, such as for children or pregnant women or that are for professional use only. Cosmetic labels must also include contact information where consumers can obtain additional information about the cosmetic product.
- **Additional Resources**
  - Provides FDA with $20.6 million in user fees to implement these additional authorities. Fees would be tiered based on the annual sales of the cosmetic manufacturer. FDA currently receives user fees from companies that manufacture other products it regulates, such as drugs, devices, and tobacco. In addition, FDA would be provided with authority to directly hire cosmetic safety experts to implement the new regulatory framework.

New Requirements for Cosmetic Industry

- **Register Facilities and Ingredients**
  - Cosmetic manufacturers, processors, packers, and holders would be required to register their facilities with FDA. Cosmetic manufacturers and processors would also have to register the cosmetic ingredients used in their products, and attest to the safety of the product and its ingredients.
- **Report on Serious Adverse Events**
  - Cosmetic manufacturers would be required to report any serious adverse events, such as hospitalization and serious rashes and infections, within 15 days, and report semi-annually to FDA all adverse health events, both minor and serious.
- **Comply with Good Manufacturing Practices**
  - Cosmetic manufacturers would be required to comply with good manufacturing practices established by FDA to ensure that cosmetic products are manufactured safely.