

2019 Personal Care Products Safety Act: Small Business Provisions¹

- **Average gross annual sales² below \$500,000 (or below \$1 million if produced in a private residence)**
 - Exempt from requirements of PCPSA

- **Average gross annual sales between \$500,000 and \$2 million (or between \$1 million and \$2 million if produced in a private residence)**
 - Have a simplified registration form UNLESS making:
 - products intended for the eye area
 - lip products with color
 - products that are injected
 - products intended for internal use, or
 - products meant to alter appearance for more than 24 hours
 - Only required to maintain safety records for 2 years after the product is no longer marketed, rather than 5 years
 - Annual adverse events reports are not required

- **Generic small business provisions³**
 - Have a period longer than 60 days to submit an initial new cosmetic ingredient statement for products first marketed or reformulated after the date of enactment. Must submit annually thereafter.
 - Have simplified good manufacturing practices
 - Have 2 years from date of enactment to comply with good manufacturing practices, rather than 180 days
 - FDA will provide technical assistance to small businesses to comply with PCPSA

- **Modest registration fees for all companies with gross annual sales below \$20 million**
 - Gross annual sales less than \$10 million in 2018: \$0
 - Gross annual sales between \$10 million and \$20 million in 2018: \$500

¹ Apply to domestic companies only

² Average gross annual sales are averaged over 3 years

³ These provisions just say “small business” or “businesses that meets the applicable industry-based small business size standard established by the SBA under Section 3 of the Small Business Act” or “meet Small Business Administration standard for a small business”