



Know your environment.  
Protect your health.

### **2017 Personal Care Products Safety Act: Small Business Provisions<sup>1</sup>**

- **Average gross annual sales<sup>2</sup> 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)**
  - Simplified registration form and a simplified safety substantiation (can substantiate just by using recommended concentrations, available medical/scientific guidance, etc.) 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
  - No requirement to report the discontinuation of the manufacture of a cosmetic product or category until the next annual registration period
  - Requirement to maintain safety records for 2 years after the product is no longer marketed, rather than 5 years
  - No requirement to annually report adverse events
- **Generic small business provisions<sup>3</sup>**
  - 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.
  - Period longer than 60 days to notify FDA of changes to the information required to be in cosmetic ingredient statement
  - FDA will provide guidance on section 609 safety substantiation
  - Simplified good manufacturing practices
  - 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 \$2 million in 2017: \$0
  - Gross annual sales between \$2 million and \$5 million in 2017: \$250
  - Gross annual sales between \$5 million and \$10 million in 2017: \$350
  - Gross annual sales between \$10 million and \$20 million in 2017: \$500

<sup>1</sup> Apply to domestic companies only

<sup>2</sup> Average gross annual sales are averaged over 3 years

<sup>3</sup> “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”