
- **Average gross annual sales** 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**
  - 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

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1 Apply to domestic companies only
2 Average gross annual sales are averaged over 3 years
3 “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”