Personal Care Products Safety Act (S.1113) Summary

Although the FDA has oversight of personal care/cosmetic products, they have little legal authority to actually regulate them beyond requiring that ingredients be included on the product label. They do not currently regulate the chemicals in these products, or even have the authority to issue a mandatory recall if a product is harmful. FDA has a voluntary program where companies can choose to do things like register and report health issues with their products, but this is not required. This has led to questions about the safety of certain ingredients, lack of clear guidance for companies, and a patchwork of state laws and regulations that are not uniform.

The Personal Care Products Safety Act was developed through consultation with the FDA, large and small companies in the personal care products industry and consumer/ health organizations. This legislation provides FDA with the authority to regulate personal care products and sets up a process for how this will be done, including the safety review of specific chemicals for use in cosmetic products. Below is a summary of what the bill does:

Requirements for Personal Care Product Companies

Register Facilities and cosmetic ingredients

- Companies register with the Food and Drug Administration (FDA)
- Companies disclose the ingredients they use
- Companies attest that they have safety records for their products

Adverse Event Reports

- Companies must report serious adverse events (such as infections that required medical treatment) to FDA within 15 days, and an annual summary of all reported adverse health events (including less serious reactions such as rashes).

Labeling and Public Ingredient Disclosure

- Specific labeling and warnings may be required for some products that contain ingredients not suitable for the entire population, such as for adult use only or for professional use only.

- Internet sites selling cosmetics must include full labeling information, including ingredients and any warnings.

User Fees

- Tiered structure is developed to accommodate manufacturers of different sizes, to equal $20.6 million per year. User fees like this are already used with pharmaceutical companies and medical device companies.

New Food and Drug Administration (FDA) Responsibilities

Safety of Personal Care Product Ingredients

- FDA will collect data and information on at least five ingredients (chemicals) per year and determine levels of safety for their use in these products. This includes determining how much of the ingredient may be used, and if it should be restricted to only certain types of products (not for use in children's products, etc).

Mandatory Recall

- FDA may order a recall if a product is likely to cause serious harm and the company refuses to do a voluntary recall. This is similar to what FDA can currently do for food products.

Develop Good Manufacturing Practices (GMPs)

- FDA will issue regulations that outline good manufacturing practices for how companies should safely manufacture personal care products. The FDA already does this for prescription and over-the-counter drugs. Now this will also be done for personal care products.

Animal Testing Alternatives

- FDA will encourage the use of alternatives to animal testing, and will provide guidance to companies on appropriate non-animal methods.

Small Businesses

- FDA shall provide technical assistance and additional flexibility for smaller companies to comply with the law. This includes giving them more time and a simpler process.
- Domestic small businesses under $500,000, or $1 million if producing in a private residence, do not need to register.

Preemption

- FDA's findings on the safety of personal care product ingredients will preempt state regulation of those ingredients (for use in personal care products) following the date of enactment of this legislation.

- State initiatives and laws in effect prior to the date of enactment are grandfathered and can remain in effect.

- States cannot implement new regulatory requirements for registration of companies, Good Manufacturing Practices, mandatory recalls, or adverse event reporting after the bill is passed into law.