PERSONAL CARE PRODUCTS SAFETY ACT WORKS WITH SMALL BUSINESS

The Personal Care Products Safety Act (S.1014) would reform regulation of personal care products, requiring companies to ensure that their products are safe before marketing them and giving the Food and Drug Administration (FDA) the tools it needs to protect the public.

The Act would set up a basic regulatory structure that would give the FDA the same tools for ensuring the safety of personal care products as it uses to regulate food and drugs. Each year, the agency would do a safety review of five ingredients and contaminants. Companies would be required to register facilities and disclose ingredients they use to the FDA. Companies would also be required to report adverse health events and follow good manufacturing practices. The FDA would have the ability to recall dangerous products and require specific labeling and warnings for products that contain ingredients not suitable for all populations. The bill provides $20.6 million in annual revenue by registered companies through a tiered user fee structure.

Q: Do small businesses need to register their facilities and products with the FDA?

A: Domestic companies selling less than $100,000 annually in personal care products <u>would not</u> have to register their facilities or their products with the FDA.

The FDA may allow many small businesses selling between $100,000 and $500,000 annually in personal care products to submit simplified cosmetic ingredient statements, such as a basic listing of ingredients without ranges of concentrations. If the list of ingredients does not change from year to year, all companies, regardless of size, will have a simplified process.

Q: Do small businesses need to pay a user fee?

A: Small businesses selling less than $500,000 annually in the United States <u>would not</u> need to pay a user fee.

Only businesses with more than $500,000 in domestic sales, based on average sales over the previous three years, would have to pay a user fee. The tiered user fee structure is designed to accommodate companies of different sizes to equal $20.6 million per year in revenue. The bill provides a set user fee by tier for the first year, and then allows the FDA to adjust the fees based on inflation and the FDA workload, for the subsequent years. The user fees start at $250 per year for companies with sales between $500,000 and $2.5 million globally.

(OVER)

Q: Would artisan soap be covered under this bill?

A: Only soap products currently classified by FDA as a cosmetic would fall under this legislation.

This bill does not change the current definition of soap. Only soap products currently classified by FDA as cosmetics would fall under this bill. If a soap product does not make a cosmetic claim, is composed mainly of the "alkali salts of fatty acids," and it's only cleansing action is the result of the "alkali salts of fatty acids," it would not fall under this bill.

Q: Would small businesses have additional time to comply with new rules?

A: Yes, small businesses would be provided additional time and assistance.

Small businesses, defined as those with fewer than 500 employees and less than $500,000 annual domestic sales, would have extra time to register changes to their products and register new products, beyond the 60-day window required for larger companies.

Small businesses with fewer than 500 employees will have two additional years to comply with Good Manufacturing Practices that the FDA will provide regulations on.

The Small Business Administration and the FDA must provide technical assistance to small businesses regarding compliance with the law to ensure the process is simple and easy.