Federal Public Health Official Role in improving Cosmetic Safety

By

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Abstract

The National Institute of Environmental Health Sciences (NIEHS) reports that the Federal government has documented over 10,500 ingredients in cosmetic products (e.g., skin moisturizers, shampoos, perfumes, eye and facial makeup preparations, toothpastes, deodorants, etc.), yet only a small percentage of those chemicals have been tested for safety. Some of the tested chemicals have been identified as causes of cancer, birth defects, and damage to one’s ability to reproduce (EHP, 2006, p. 5). The Environmental Work Group, Campaign for Safe Cosmetics and similar non-profit coalitions have campaigned for consumer protection against the dangerous chemicals found in cosmetics. These organizations conduct research and/or advocate for safe products, and inform the general public of the possible harmful effects of chemicals. They seek local, state and national support from corporations, federal regulatory agencies and the legislative bodies of government to implement changes that would require manufacturers to disclose chemicals used in cosmetic products, use safe alternative ingredients, and to reduce the overall exposure of harmful chemicals to consumers. Research studies have found harmful chemicals in the blood, urine and breast tumor tissue of study participants, but the research has not produced conclusive evidence (1) of the source of the chemicals; (2) that the bioaccumulation of the chemicals has caused or will cause short-term or long-term harmful effects; or (3) that the chemicals directly cause cancer, birth defects, and other adverse health effects. The inconclusiveness of the research has led to ongoing controversy surrounding the safety of cosmetics. The Food and Drug Administration’s (FDA) has oversight authority for cosmetic safety, yet its current legal authority is narrow and does not provide the oversight
needed to mitigate the continual uncertainty related to cosmetic safety. FDA has no pre-market authority for cosmetic products, ingredients or labeling, with the exception of color additives. They assert that authorizing additional oversight would require legislative changes as well as additional fiscal and other resources. This paper argues the need for increased oversight and enforcement authority for the FDA, through statutory and regulatory changes, to ensure that cosmetics and personal care products are safe before they reach the shelves of wholesale and retail distributors. FDA must increase research efforts to determine the extent to which the ingredients in cosmetics contribute to adverse health effects.

A literature review revealed that the FDA has no authority to require manufacturers to report ingredients used in cosmetic products. This serious limitation of FDA’s oversight authority adds to the current debate and controversy surrounding three particular ingredients: phthalates, parabens and polycyclic musks. The concerns surrounding these three chemicals and others is so great, that two states, California and Washington have adopted legislation that provides their legislatures broader oversight authority as a means to improve safety of cosmetics and personal care products for their citizens.

Introduction

Millions of consumers throughout the world who use cosmetic products are reminded daily through various media that these products are associated with wealth, success and beauty. How these products are regulated differs from country to country. Consumers in the United States (U.S.) presume the ingredients in cosmetics and other personal care products are safe because the appropriate governing officials have approved the ingredients for use prior to the products being marketed to consumers. A review of the current U.S. statutes and regulations that govern
cosmetics safety reveals that federal officials have no authority over pre-market cosmetics, except for color additives and ingredients prohibited or restricted by regulation. While this paper is not intended to compare and contrast ingredient oversight of other countries with the U.S., it is important to note that the European Union (EU) prohibits or restricts 1100 toxic ingredients for use in cosmetics, while in the U.S.; the FDA prohibits or restricts only 11 ingredients. The primary difference in oversight between the two countries is the definitions of cosmetics and drugs. Many cosmetic products in the U.S. are considered drugs in the EU (CSC, para. 3; Pauwels & Rogiers, 2004, p. 16).

Consumer research organizations assert that the FDA does not understand the “scope and size of the potential health risks” from the ingredients found in many cosmetics (Houlihan, 2008a, p. 5). The cosmetic industry contends that consumers “can be confident” that cosmetic products are safe due to the rigorous regulatory standards and enhanced manufacturing testing (Engasser, Long & McNamee, 2007, p. 30).

**Background**

As a public health agency, what is FDA’s role in ensuring cosmetic safety? Let’s first examine public health leadership, how it has evolved, the responsibilities and the expectations. The role of a public health leader may be described as the front-runner for securing a healthy population. Achieving a healthy population through monitoring, intervention, and prevention is a daunting task that requires the partnering of stakeholders, such as, a diverse groups of public health professionals, governmental officials (elected and appointed) at all levels (local, state and Federal), community and industry leaders, academia, foundations, consumer and research organizations, the media and members of the general population.
Public health leadership (PHL), like leadership in other sectors, is constantly evolving. A significant evolution in PHL came with the Institute of Medicine’s (IOM) 1988 Report on the Future of Public Health that painted a dismal picture of the state of public health. The IOM expressed grave concerns and argued that unless there was a new vision for public health, that the U.S. would be unable to meet the future health challenges of the nation. The IOM report (1988) noted that the “disarray” in public health was caused not only by the functioning of the public health system itself but also by the population’s uncertainty of the mission of public health, the role of government to assure conditions in which people could be healthy, and inadequate resources necessary to achieve public health goals and objectives (pp. 6, 7). While PHL falls to governmental as well as non-governmental organizations, this discussion will focus of the role of government agencies.

The IOM recognized the need for governmental and non-governmental efforts, but noted that the role of the government is “unique” (IOM et al., 2008, p. 6). One unique aspect of the role of the government is its enforcement authority. In 1994, the Public Health Functions Steering Committee developed a framework for essential services:

1. Monitor health status to identify community health problems
2. Diagnose and investigate health problems and health hazards in the community
3. Inform, educate, and empower people about health issues
4. Mobilize community partnerships to identify and solve health problems
5. Develop policies and plans that support individual and community health efforts
6. Enforce laws and regulations that protect health and ensure safety
7. Link people with needed personal health services and assure the provision of health care when otherwise unavailable
8. Assure a competent public health and personal health care work force

9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services


The evidence of the acceptance of the IOM report (Scutchfield, Hiltabiddle, Rawding and Violante, 1997) in the public health community can be found in agencies at all levels of government, universities, associations and others working to build a network of trained public health professionals and leaders capable of ensuring the delivery of the core functions. The Centers for Disease Control and Prevention’s funding of the National Public Health Leadership Institute, beginning in 1990 (and continuing today) is but one example of the impact of the IOM report (NPHLI, 2009, para. 1).

The role of PHL comes with tremendous responsibility and obligation. Rowitz (2009) argues that an effective public health leader must have the following prerequisites: “a commitment to social justice, an understanding of democracy, an understanding of the political process, communication skills, mentoring skills, decision-making skills, and the ability to balance work and like outside work” (p. 112). Turnock (2004) describes public health leadership as “an agent of social change by identifying health problems and risks and stimulating actions toward their elimination” (p. 234). These few simple words are the charge to take action for hundreds of thousands who make up the public health system. Identifying actual or potential health problems and then taking action to mitigate or eliminate the problems requires the engagement of most, if not all, stakeholders identified at the beginning of the leadership discussion. Stakeholders may come to the table with their individual agendas, and some, such
as elected officials, have more influence than others. Public health leaders must understand the positions of all stakeholders, whether in support of or against their efforts. This understanding provides the foundation for an effective strategy. "The leader needs two intellectual abilities that are usually not formally assessed in an academic way: he needs to have a sense for the unknowable and be able to foresee the unforeseeable" (Greenleaf, 1991, pp. 21-22). Despite the inevitable opposition of some stakeholders, public health leaders are servants of the population. They must be committed to the values and mission of the agencies they lead. There are two words that resonate in the mission statements of most if not all public health agencies, “protect and provide”.

FDA is a Federal agency under the purview of the Department of Health and Human Services. Its mission includes “protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation” (FDA, 2009, What We Do). FDA’s role as a public health agency involves assuring conditions in which people can be health, ensuring that its decisionmaking is based on a public health perspective and not the perspective of the industry it regulates; and providing the public essential public health services.

**Literature Review**

The FDA administers the Federal Food, Drug and Cosmetics Act (FD&C Act) [regulatory authority granted to FDA]; and the Fair Packaging and Labeling Act (FPLA) [regulatory authority granted to Federal Trade Commission and FDA], two primary statutes that govern cosmetic safety. The FD&C Act, which was enacted in 1938, prohibits the marketing of adulterated and misbranded cosmetics. A product is considered adulterated if (1) it contains any
substances that cause harm to health when used as prescribed, or under customary use (except for hair dyes), (2) it consists “in whole or in part of any filthy putrid, or decomposed substance”, (3) it has been contaminated, (4) its container contains substances that can cause harm to health, or (5) it contains a color additive (except for hair dyes) (FDA, 2005, para. 2).

The Act defines cosmetics as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap” (FD&C Act of 1938). The definition is broad and includes products such as skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants.

Under, the FD&C Act, cosmetic products are considered mislabeled if the information contained on the labeling is false or misleading; the labeling does not include required information; required information does not display in a noticeable manner; its container is made in such a manner as to mislead the consumer; it is “a color additive, other than a hair dye, that does not conform to the applicable regulation issued under section 721 of the FD&C Act”; or the packaging and labeling is in violation of the Poison Prevention Packaging Act of 1970 (FD&C Act of 1938).

FDA’s statutory authority for color additives is much broader, under the FD&C, “color additives, except for coal tar hair dyes”, are required to be pre-approved by the agency before being used in “food, drugs, or cosmetics, or in medical devices that come in contact with the bodies of people or animals for a significant period of time” (FDA, 2010, para.1).
FDA’s regulations permit the inspection of cosmetic manufacturing facilities, the collection of samples for examination and analysis, and regulatory actions against manufacturers that distribute adulterated and/or misbranded products. Cosmetic manufacturers are permitted to use any ingredient except for those ingredients in color additives or the 11 cosmetic ingredients which are prohibited or restricted by the FDA (Exhibit 1).

The purpose of the FPLA is to inform the consumer by providing value comparison and to prohibit unfair and deceptive packaging and labeling of consumer goods. FDA administration of FPLA relates to packaging and labeling of foods, drugs, cosmetics and medical devices. The basic requirements of the FPLA include the (1) identification of the product, (2) the manufacturer’s place of business and (3) the content in terms of net weight or number of items (FTC, Fair Packing). In more than three decades, the FDA has made no significant efforts to improve cosmetic safety through increased regulatory oversight.

In 1974 the FDA established the Voluntary Cosmetic Registration Program (VCRP) as a voluntary registry program that applies to cosmetics sold in the United States. The VCRP collects data post-market, does not apply to cosmetic products for professional use only (salons, health care professionals, research and analysis), and does not apply to free gifts and samples or cosmetics made in an individual home to sell to friends. To register, a manufacturer provides the type and location of the business [the business trade names, type of business, address including post office zip code]; and/or product ingredient information. The registered information can be accessed electronically at the FDA website (FD&C Act of 1938).

FDA’s dictionary and product database report 4,066 registered ingredients, while the Environmental Working Group (EWG) compiled a listing of ingredients for 29,037 products found in its database with 8,821 unique ingredients. (EWG is a national non-profit organization
in Washington D.C. formed to protect public health and the environment. The group is one of the
more vocal advocates of cosmetic safety issues.) The difference between the data shown in the
two databases is 4,755 ingredients (Houlihan, 2008b, para. 25). Clearly, this difference raises
questions of effectiveness of the VCRP. The program has no teeth. It is voluntary, without
enforceable requirements, and no enforcement authority.

The FD&C Act of 1938 was passed during a pro-industry period, when the United States was
recovering from the Great Depression. The cosmetics industry was allowed to operate under a
system of self-regulation, which illustrates the industry’s level of influence on and the
relationships with public health leaders and lawmakers at that time. Seventy-two years later,
very little has changed with FDA’s oversight and regulatory authority of the cosmetics industry.
Some argue that FDA’s longstanding incestuous relationship with the industry is the reason no
change has occurred. Dickerson from Medical Device and Diagnostic Industry magazine (2010)
writes, “Proindustry FDA culture is firmly entrenched. Not only is collaboration in product
reviews officially encouraged, but good relationships across the regulatory fence hold the
prospect of a possible future career in a well-paid industry job” (para.11). A limited review of
industry placement of senior FDA officials immediately following their departure from the
agency revealed the following:

- John Bailey, former head of FDA’s Office of Cosmetics and Color - Personal Care Products
  Council (Industry Association), Chief Scientist (PCPC, 2006)
- Jane E. Henney, M.D., former FDA Commissioner (1/17/1999 – 1/19/2001) – AstraZeneca
  (Pharmaceutical company), Board of Directors (FDA, 2009; AstraZeneca, 2009)
- Daniel Schultz, former FDA Director of the Center for Device and Radiological Health –
  Greenleaf, LLC, Senior Vice President (Dickerson, 2010)
This limited review is not an accusation or evidence of inappropriate relationships between the regulator and the industry, but it does raise questions concerning the influence former FDA senior officials could have on oversight and governance once they go to work in private industry; as well as current officials’ ability to regulate a potential future employer. Similar relationships existed in the late 1980’s with the Federal Home Loan Bank Board. Federal regulators’ inappropriate relationships with the leadership of saving and loans banks led to the fall the Federal home loan bank system. However, FDA’s relationship with the industry has deeper consequences because it can lead or has led to harmful health conditions in unsuspecting consumers. It can be argued that public health is founded in social justice (Turnock, 2004, p. 14.), where the good of the society outweighs the need of an individual. In this instance social justice would argue that the FDA’s relationship with the industry impedes its ability to advocate for the necessary oversight authority.

Industry Voluntary Oversight

Without federal authority to screen ingredients in cosmetics before they enter the market, the safety of cosmetics and personal care products falls to the industry that manufactures the products. In 1976, the cosmetic trade association, Cosmetic, Toiletry and Fragrance Association, now known as the Personal Care Products Council (PCPC) established a voluntary industry program, the Cosmetic Ingredient Review (CIR) to determine whether ingredients are safe under the conditions of use. CIR is comprised of expert panelists from private and public sectors.
(CIR, 2009, Procedures). The CIR review process and findings are purported to be independent of the PCPC and the cosmetic industry (CIR, 2008 Annual Report), however the CIR is funded by PCPC. During the CIR’s thirty plus years of operation, they have only reviewed 16 percent of the ingredients in products. CIR reviews found 1067 ingredients safe, 446 safe with qualifications, 10 unsafe and insufficient data on 124 ingredients (CIR, 2010, Cosmetic Ingredients). Dr. Bailey noted while serving as the head of the FDA’s Office of Cosmetic and Color that, "In the absence of the CIR program, there would be no systematic examination of the safety of individual cosmetic ingredients" (Houlihan, 2008a, para. 9). The CIR has recommended restrictions on chemicals beyond those identified by FDA and has identified an additional 10 ingredients as unsafe for use in cosmetics (Exhibit 2).

*Growing Debate and Continued Controversy*

FDA and CIR together have restricted or prohibited only 21 (Exhibit 1 and 2) of the thousands of chemicals found in cosmetic products. The industry maintains that the exposure level of these potentially harmful chemicals is minimal while consumer groups and some government officials continue to raise concerns surrounding the bioaccumulation of these chemicals, and their potential long-term impact on human health. On average, adults use 9 personal care products daily, with 126 unique chemical ingredients (EWG, 2004, para. 1).

The fact that only 16 percent of ingredients in cosmetics have been reviewed by a voluntary body and of that percentage only 21 ingredients have been prohibited for use raises significant questions about FDA’s commitment to the core functions of public health. Several of the Essential Services for Public Health as presented in the role of public health leadership section of the paper, suggest that public health agencies and private sector providers should empower the
public on health issues; use scientific knowledge as the basis for decision-making; and assure the public of the commitment to their needs, through various policy making and enforcement tools. FDA contends that they are limited by the requirements of the FD&C Act; however, there is no evidence that FDA has aggressively partnered with Congress to seek broadening of its oversight authority.

CDC’s National Health and Nutrition Examination Survey (NHANES) is a good reference point for data and statistics on the health of the public. NHANES was established in 1960 and is used as a tool to gather data on the health and nutrition of adults and children in the U.S. The survey is administered through interviews and physical examinations. The interviews include questions on health matters, and “demographic, socioeconomic and dietary” status; and the physical examination includes “medical, dental, and physiological measurements” and “laboratory tests”. (CDC, 2009, NHANES, para. 1, 3.) This survey provides the essential services of monitoring and detecting health hazards through surveillance.

The CDC’s 2009 Fourth National Report on Human Exposure to Environmental Chemicals reports on the findings of the NHANES during 2003 and 2004, and provides a period in time assessment of the public’s exposure to environmental chemicals. The report also includes some results from prior surveys (years 1999-2000 and 2001-2002). The 2003-2004 survey included more than 2600 participants (aged 6 years and older) and measured 13 phthalate metabolites [metabolite is a chemical alteration of the original compound produced by body tissues.] in the urine and/or blood samples of the participants (CDC, Fourth National Report, p. 3). CDC contends that biomonitoring data alone does not indicate that the chemicals found cause disease or harm to human health; and that research separate from the report is required to determine if the chemical exposure levels can be associated with disease and adverse
health effects. Biomonitoring is "the direct measurement of people's exposure to toxic substances in the environment by measuring the substances or their metabolites in human specimens, such as blood or urine" (CDC, National Biomonitoring Program, para. 1). CDC selects chemicals for the report based on the following criteria:

- Existing research and scientific data on environmental chemical exposure
- The severity of known or suspected health effects due to the exposure
- The "need to assess the efficacy of public health actions to reduce exposure to a chemical"
- The availability of a biomonitoring analytical method with adequate accuracy, precision, sensitivity, specificity, and speed
- The availability of sufficient quantity of blood or urine samples
- The incremental analytical cost to perform the analyses" (CDC, Fourth National Report, p. 4)

A review of CDC's Fourth National Report revealed at least six chemicals commonly found in cosmetics and personal care products. While the NHANES report provides extensive details regarding each chemical, this paper only includes a listing of the six chemicals identified in the report as used in cosmetics (Exhibit 3). While it is true that there are several ingredients in cosmetics that are of considerable concern, there are three particular ingredients that are the subject of significant and heated debate and controversy: phthalates, parabens and polycyclic musks. Of these three chemicals, only phthalates is mentioned in the NHANES report.

The Breast Cancer Fund, 2008 Edition of the State of Evidence, The Connection Between Breast Cancer and the Environment, presents illuminating research findings on the link between radiation and chemicals in the environment to the rate of breast cancer. The report summarizes findings of over 400 epidemiological and experimental studies, and echoes the same policy concern
as so many other consumer and research organizations. That is, there is no Federal authority to
pre-screen ingredients before most cosmetic products are marketed, and the lack of Federal
oversight authority places the general public at health risk. While the *State of Evidence*
addresses a broad range of chemicals contributing to the current breast cancer rate, this paper
will only focus on the chemicals found in cosmetics and personal care products, specifically
those chemicals classified as endocrine-disrupting compounds (EDCs) (BCF, 2009).

The *State of Evidence* discusses the 2007 Silent Spring Institute’s review and analysis of
epidemiological data to find evidence of a link between certain chemicals and breast cancer
rates. It is generally accepted that exposure to natural estrogen may increase the risk of breast
cancer. Xenoestrogens, synthetic agents that mimic the actions of estrogen, are one type of EDC
but others may “disrupt normal biological processes by disturbing not only the actions of the
estrogens, but also those of other hormones including the androgens and thyroid hormone. All of
these disruptions may increase the risk for breast cancer” (BCF, 2009, p. 8). EDCs can be found
in a host of pesticides, fuels, plastics, detergents, industrial solvents, tobacco smoke, prescription
drugs, food additives and personal care products (Hormonally Active Agents, 1999;
Environmental Pollutants, 2003). Phthalates and parabens were specifically named in the report
as EDCs found in cosmetics and personal care products. Phthalates are plasticizers and are found
in such products as skin moisturizers, nail polish, and hair sprays, and are classified as EDCs
because of their effects on the hormonal system. Research has shown that some phthalates can
alter cell culture systems, “increase cell proliferation in MCF-7 breast cancer cells and ...inhibit
the anti-tumor action of tamoxifen in MCF-7 breast cancer cells” (BCF, 2009, pp. 49, 50).
Parabens are preservatives and are classified as EDCs because they have been found to be a
“weak estrogen mimicker and cause human breast tumor cells (MCF-7 cells) to grow and
proliferate in vitro” (BCF, et al, 2009, p. 50). Parabens are used in cosmetics including such products as underarm deodorants, hair products, and shaving creams. Several types of parabens have been found in samples from breast tumors.

Neither the National Toxicology Program nor the National Cancer institute (National Institute of Health); or the International Agency for Research on Cancer (The World Health Organization) have deemed EDCs as human carcinogens. There is a body of research on wildlife species that shows a causal relationship, but research on humans is less conclusive (BCF, 2009, p.37). The FDA acknowledges their awareness of consumer concerns with these chemicals but note at current they [FDA] find no safety risk (FDA, 2000, Ingredients Prohibited).

On December 2, 2009, the Senate’s “Full Committee and Subcommittee on Superfund, Toxics and Environmental Health joint hearing entitled, “Oversight Hearing on the Federal Toxic Substances Control Act” heard testimony on the amount and level of industrial chemicals that can be found in the human body. During the hearing, Senator Frank R. Lautenberg, mentioned the findings of the Environmental Working Group’s (EWG) December 2, 2009 Report on “Pollution in People“. The EWG reported that a 2-year study (2007 and 2008) found over 200 chemicals in the umbilical cord blood of 10 babies from racial and ethnic minority groups (Lautenberg, 2009). The findings from the research revealed that infants are exposed to hazard chemicals through the placenta prior to birth. The chemicals Tonalide and/or Galaxolide (polycyclic musk) which are ingredients of cosmetics and personal care products were found in 7 of 10 cord blood samples tested. These chemicals are synthetic fragrances used to mimic natural musk (EWG, 2009, p. 22). The report notes that the health risks to humans are unknown but that a few studies suggest that these chemicals “disrupt hormones” and “damages organisms’ defense” (EWG, et al, 2009, p. 22).
The NIEHS reports that polycyclic musk presents a concern for bioaccumulate but the toxicity and environmental risk of the chemical is low. However, NIEHS also notes that there is evidence to support the effects this chemical has on marine mussels but not on human health (Nitromusk and Polycyclic, 2004). It [polycyclic musk] interferes with the activity of their multidrug efflux transporters. Cells naturally resist toxicants through the transporters, “proteins that keep foreign chemicals from entering cells” (Whiff of Danger, 2005. p. A50). There is concern that these findings could translate to human health, that medications (pharmaceuticals) and other chemicals (not naturally produced) could cause similar long-term effects in humans.

John Bailey, Chief Scientist for the Personal Care Products Council (PCPC) and former head of FDA’s Office of Cosmetics and Color, provided testimony at the hearing and contends the fragrances used in cosmetics and personal care products are safe and are regulated by the FDA. PCPC, originally founded in 1894 as the Manufacturers Perfumes’ Association of the United States, is a leading national trade association for the cosmetics and personal care products industry (PCPC, Centennial History). Dr. Bailey argued that the detection of chemicals in a human body through the process of biomonitoring is not proof that a person has been exposed to a toxic level of the chemicals (Bailey, 2009). He supported the industry’s position with a quote from the Centers for Disease Control and Prevention’s, “Interpretation of Report Data, Important Factors” which states “The measurement of an environmental chemical in a person's blood or urine does not by itself mean that the chemical causes disease” (CDC, Fourth Annual Report, p. viii).
Efforts to Improve Product Safety and to Inform the Public

In the absence of Federal authority to pre-market cosmetic products, some States, consumer groups, and the industry itself have taken steps to improve product safety. The efforts on part of the states should not come as a surprise because state public health leaders and professionals play an essential role in implementing public health policies and programs. The U.S. Constitution vested in the States primary responsibility for the health care of its population. The IOM stated that “...states are and must be the central force in public health” (IOM, 1988, p. 8). Federal agencies and the legislative branch of government pass statutes, promulgate regulations and develop Federal programs. State public health agencies monitor the effectiveness of local public health delivery systems. Local public health agencies (LPHA) are responsible for ensuring that health problems are monitored and that mitigating services are available. LPHAs are on the frontline. State and Local government actions have been significant in mitigating health concerns such as tobacco use reduction, reduction in teenage pregnancies, adolescent vaccinations, etc.

This unique system is often confusing to the public due to the involvement of all levels of government. An example is the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) administered at the Federal level by the Food and Nutrition Service (FNS), United States Department of Agriculture. The program’s funding is authorized annually by Congress via Federal grants. FNS provides the funding to all 50 states for the purchase of “WIC foods, nutrition education, breastfeeding promotion and support and administrative costs” (USDA, 2009, para. 2). At the state level the program is administered using 90 WIC state agencies, 2,200 local agencies and 9,000 clinic sites (USDA, 2009, para. 3).
State Efforts

The states of California and Washington have recently passed legislation designed to improve the safety of cosmetics and personal care products. The California Safe Cosmetic Act of 2005, effective January 2007, requires manufacturers to report to the California Department of Health Services (DHS) use of potentially hazardous ingredients and to submit health effects data. This is in contrast to the FDA’s voluntary registration program. The bill also grants the DHS’ Division of Environmental and Occupational Disease Control investigatory authority. The division may conduct an investigation of products that contain chemicals identified as causing “cancer or reproductive toxicity or other ingredients of concern” (CSC Act of 2005, p.92). The California bill highlights several significant facts and points:

- Independent testing in the United States and abroad revealed some cosmetic products contain chemicals known to or suspected of causing cancer and reproductive toxicity
- Like FDA’s authority, pre-market safety screening is not authorized in the Bill
- Like FDA’s authority, prior approval of ingredients is not authorized in the Bill
- The Bill does not authorize DHS the authority to regulate ingredients in cosmetic products
- Women of childbearing years have the greatest percentage of product usage
- Beauty care workers are the most exposed population
- Ingredients used in fragrances are exempt from inclusion of product labeling
- The Division of Environmental and Occupational Disease Control in DHS may conduct workplace investigations and analysis
- Safe ingredients are available for use as substitutes for harmful chemicals
While this Bill does not grant the state authority to regulate ingredients in cosmetic, it does require the manufacturer to report harmful ingredients and their health effects. This reporting is the first step in assisting the state in informing and educating its citizen of the potentially harmful ingredients in certain cosmetic products. The legislation was sponsored by the National Environmental Trust, Breast Cancer Action, and Breast Cancer Fund. Kevin Reilly, DHS, Deputy Director of Prevention Services, indicated that the “Legislation sponsors believe that the basis of the law is the public’s right to know” (California Enacts, 2006, para. 2). California’s partnering with consumers and advocates to address the shortcomings of the FD&C Act; and the health concerns of its citizens led to the passing of the CSC Act of 2005. The state of California exercised its authority to provide assurance (core function of public health) to the people of the state by taking positive steps to ensure safety of cosmetic products sold and used; and to mitigate the health risk of its citizens, particularly, women of childbearing age, children and employees of nail and beauty salons (CSC Act of 2005). The California Cosmetic Safety Program (CCSP) administered by the California Department of Public Health has established online reporting of chemicals known to or suspected of causing cancer and/or reproductive toxicity from companies making $1,000,000 or more from California consumers and/or other states (effective January 2007 (CDPH, 2009, para. 1.). CCSP plans to make the reported information available to the public so they may make informed decisions prior to the purchase of cosmetics (CCPH, 2009, What’s New).

The Bill met opposition by the industry, particularly, Procter & Gamble (P&G) and PCPC. Salgado (2006) reports that P&G paid lobbyists over $90,000 in the first half of 2005, and PCPC spent more than $600,000 in the last two legislative sessions to kill the Bill (Salgado, 2006, para 1-2). California’s strategic partnering can serve as a model for states as well as FDA.
The only other state to pass legislation to increase cosmetic safety is Washington. In 2008, the state of Washington passed the Children’s Safe Products Act (CSPA), effective July 1, 2009. This Bill, known as the Toxic Toy, is aimed at the safety of products for kids and it imposes stricter standards on manufacturing reporting than the Consumer Product Safety Improvement Act (CPSIA) signed by President George W. Bush in August 2008. Washington’s CSPA included products such as children’s cosmetics, jewelry, toys, products for sucking, teething, or to facilitate sleep, and children electronic products. The Act:

- Prohibits the manufacture and sale of children products containing lead, or cadmium
- Requires the Washington State Department of Ecology to identify and report high priority chemicals
- Requires manufacturers of children’s products report annually on products containing high priority chemicals
- Requires manufacturers of products that become restricted by law to notify sellers of the requirements of the law; recall the products and reimburse the sellers and any purchasers of the product
- Violators of the Bill are subject to civil penalties up to $5000 for each violation on the first offense. Thereafter, violators are subject penalties up to $10,000 for each offense (CSC Act of 2005) Children’s cosmetics and car seats are not covered in the Federal CPSIA, but are included in Washington State’s law.

Washington’s partnering effort is another excellent example of the state fulfilling its assurance function and strategic partnering. Washington understands the significance of influence and relationships in policymaking. The lead sponsor of its Bill was Representative Mary Lou Dickerson (D-Seattle), supported by Washington’s the health care practitioners. Dr.
Richard Grady, MD, pediatric urologist and board member of Washington Physicians for Social Responsibility, stated “We have a responsibility to ensure that our children’s minds and bodies do not bear the burden of damage from toxic chemicals in any product, and especially toys...legislative action is a victory for children’s health and futures” (Valeriano, 2008, p. 1,7).

**Industry and Consumer Groups Efforts**

Skin Deep, a cosmetic safety database developed by EWG provides consumers and the industry with vital information on cosmetic products, their ingredients, toxicology and health concerns related to the ingredients. Regulatory classification of ingredients if known is included in the database. Regulatory information is not limited to the U.S.; Skin Deep contains publicly available information from regulatory bodies throughout the world. The database contains over 25,000 products (EWG, Skin Deep).

In January 2007, the Personal Care Products Council (PCPC) established a Consumer Commitment Code (CCC) to provide assurance to consumers and state and federal regulators of the industry commitment to the safety of cosmetic and personal care products. Regrettably, the CCC does not impose any requirements; all actions so noted in the CCC are voluntary (Exhibit 4).

The Compact for Safe Cosmetics (CSC) is also partnering with the cosmetic industry. The CSC has agreed to assist and support their industry partners to educate and inform consumers. To meet CSC’s commitment agreement, signers must (1) comply with the U.S. regulatory requirements for cosmetics and the EU Cosmetic Directive; (2) disclose all ingredients of all cosmetic products; (3) utilize EWG’S Skin Deep database for publishing product information; (4) comply with ingredients prohibitions and restrictions and use safer
available ingredients; (5) demonstrate the safety of the products using data that is available to the public; and (6) actively participate in CSC’s efforts. Over 1400 companies have taken the pledge (CSC, Compact for Safe Cosmetics).

Retailers have also joined the effort to increase product safety. In 2008, Whole Foods Market and CVS (largest U.S. Drug Store Chain) committed to safer ingredients by banning cosmetic products that contain certain ingredients. Whole Foods has identified over 300 ingredients that are considered unacceptable, including parabens, polypropylene and polyethylene glycols, sodium lauryl and laureth sulfates. These ingredients serve as preservatives, cleaners and conditioners and fragrances. Whole Foods conducted three years of scientific research and found some adverse effects from use of products containing these ingredients. Whole Foods list goes beyond the requirements of FDA and CIR (WFM, 2008). CVS has banned hexachlorophene, mercury compounds, chlorofluorocarbons, bithionol, chloroform, halogenated salicylates, vinyl chloride, zirconium and methylene chloride. All but one of CVS’s banned ingredients are prohibited or restricted by the FDA (CVS, Cosmetics and Personal Care).

Method

The literature search on cosmetic safety concerns began with the NIEHS website and their Community Outreach & Education Program online lesson: Beauty or the Beast? This lesson referenced related articles and provided website links to several public and private sector resources including but limited to the FDA, the Campaign for Safe cosmetics, the Environmental Working Group, EHP articles, California’s Department of Public Health and more. Key search words from selected from this lesson included: safety of personal care products, chemicals used
in cosmetics, harmful health conditions from cosmetic ingredients, FDA, FDA's relationship with the cosmetic industry and Congress and cosmetic safety.

Research data on chemicals found in humans was found from the Centers for Disease Control and Prevention, National Institute of Health, the Environmental Working Group, and the Breast Cancer Fund. General searches were conducted in the University of North Carolina's and CDC's e-libraries for findings published during the past 5 years.

Research data on chemicals used in cosmetics and product information was obtained from the FDA, CIR, Skin Deep database and NIH. General internet searches were conducted through Google, Google Scholar, and Yahoo and CDC intranet/internet.

Research pertaining to the cosmetic safety oversight was found from FDA, the National Archives and Records Administration and a general internet search using Google, Google Scholar and Yahoo.

Conclusion

FDA's oversight authority is narrow and lacks efficacy in vital areas of cosmetic safety, pre-marketing of products, ingredients and labeling. Their VCRP has yielded disappointing results and is overshadowed by Skin Deep. The well documented longstanding relationship between the FDA and the cosmetics industry as well as the pilfering of FDA executives to industry leadership positions sharply conflicts with the core principles of public health leadership. Public health leaders, unlike the leaders in industry, pledge a commitment to safeguard the health and well being of the public. FDA appears to have lost sight of that pledge and their mission. They argue that their authority is limited and resources are insufficient to address the needed oversight. The FD&C Act was enacted 72 years ago and to date there have
been very few amendments. Meanwhile, there is no evidence that FDA has made appreciable efforts to partner with consumers, advocacy groups or the industry to introduce effective legislation that would strengthen their oversight authority. It could be argued that FDA desires not to disrupt their current relationship with the industries they regulate in spite of the fact those relationships impede their ability to be effective public health leaders.

The battle for improved cosmetic safety has fallen to the non-regulators. Over the past five years, consumer groups and the cosmetic industry have sought improved product safety through voluntary commitment to safe product programs, and have called for greater regulatory authority and increased research by public health officials. Scientific research continues to raise more and more questions about the bioaccumulation and the long-term effects environmental chemicals will have on human health. To date there is no conclusive scientific evidence that directly links chemicals found in cosmetics to harmful health effects. Federal public health officials at the CDC, NIH and FDA have acknowledged that additional research is necessary.

The IOM 1988 report marked a new, different and well needed strategic direction for public health but there is little or no evidence that FDA is supportive of the new approach. In fact, some may argue that their limited regulatory and policies changes in cosmetic safety over the past decades is a reflection of their indifference with the IOM 1988 recommendations. HHS, FDA and Congress must be held accountable for assuring the public that FDA bases its decisionmaking on a public health perspective, and that the agency embraces the core principles of public health by providing the public needed essential services. During the past two years Congress has convened hearings to explore concerns raised by consumer and research groups about chemical used in cosmetics and personal care products. FDA’s leadership has an obligation to ensure the agency provides conditions for a healthy public; through ongoing
evaluations of its cosmetic safety authority compared to its mission, seek external input from stakeholders, proactively achieving corrective remedies (increased oversight and scientific research) and conduct continual program evaluations to ensure programs are meeting the public health needs of the nation.

Recommendations

Ensuring cosmetic safety is complicated and there is no quick fix. FDA leadership must take necessary steps to assure the public that the agency is grounded in the principles of public health. They can begin the process of assurance by considering the following recommendations:

- Consumer Education: The vast majority of the U.S. consumer presumes cosmetic products are safe and proved by Federal officials. Public notice of product information must be provided to the consumer prior to the purchase on a cosmetic product. The industry must be required to educate consumers using all media forums currently used to advertise their products (TV commercials, magazines, in-store posters, newspaper, leaflet and brochures past along with free samples, etc.). A well performing public health system would be informing, educating, and empowering people about health issues. An example of an evidence-based intervention for educating and empowering is reducing the use of tobacco. The CDC reported in 2000 that “educational strategies, concluded in conjunction with community- and media-based activities, can postpone or prevent smoking onset in 20 to 40 percent of adolescents” (para. 17).

- Establishment of a Federal advisory committee or board to provide advice and recommendations to FDA and HHS on policy and scientific matters relating to cosmetic safety including recommendations for industry requirements and additional research. The
committee would be comprised of Federal officials from various public health and environmental agencies, industry and academic experts as well as public members. This body would report to the FDA Administrator, hold meetings open to the public and publish periodic consumer reports. FDA has similar committees for food and drug safety: Drug Safety and Risk Management Advisory Committee and the Food Advisory Committee. This strategy provides the agency’s leadership an opportunity to partner with the community in identifying and solving health problems.

- Policy Development and Enforcement Authority: FDA’s cosmetic safety mission is limited by existing laws. The FD&A must be broaden to include mandatory manufacturers registration, pre-marketing (products, ingredients and labeling screening) authority and fiscal resources to support and the publication of manufacturers ratings based on the safety of their ingredients. California and Washington have provided excellent examples of how partnering with multiple stakeholders resulted in progressive legislation and policies focused on meeting the health needs of the community. The state changes would not have been possible without its leadership involvement, from the public health agencies to state Congressional representatives. FDA must use similar leadership strategies in developing its public health policies so to assure the public that the agency is addressing and supporting their health efforts and concerns.

- Increased Research: The current debate on cosmetic product safety is stemmed from the inconclusive scientific evidence surrounding chemicals found in cosmetics and bioaccumulation, the long-term effect of environmental chemicals to human health. Federal officials and consumer group repeatedly stressed the need for additional research. The research is essential in determining the long-term effect of chemicals already found in human
blood and urine samples. The tenth essential public health service involves research that leads to innovative remedies to health concerns and problems. As an HHS agency, FDA has the support of its sister agencies, CDC and NIH. Research collaborations between these agencies may yield the conclusive scientific evidence for linking or not linking ingredients in cosmetics to harmful health conditions. The partnering of these agencies can ease FDA’s Federal funding burden and increase the private sector stakeholder base capable of producing creditable research findings.
## Exhibit 1. Ingredients Prohibited & Restricted by FDA Regulations (FDA, 2000)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Prohibition or Restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bithional</td>
<td>The use of bithionol is prohibited because it may cause photo-contact sensitization (21 CFR 700.11)</td>
</tr>
<tr>
<td>Chlorofluorocarbon propellants</td>
<td>The use of chlorofluorocarbon propellants (fully halogenated chlorofluoroalkanes) in cosmetic aerosol products intended for domestic consumption is prohibited. Ozone depletion. (21 CFR 700.23)</td>
</tr>
<tr>
<td>Chloroform</td>
<td>The use of chloroform in cosmetic products is prohibited because of its animal carcinogenicity and likely hazard to human health. The regulation makes an exception for residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient (21 CFR 700.18)</td>
</tr>
<tr>
<td>Halogenated salicylanilides</td>
<td>These are prohibited in cosmetic products because they may cause photocontact sensitization (21 CFR 700.15)</td>
</tr>
<tr>
<td>Hexachlorophene</td>
<td>Because of its toxic effect and ability to penetrate human skin, hexachlorophene (HCP) may be used only when an alternative preservative has not been shown to be as effective. The HCP concentration of the cosmetic may not exceed 0.1 percent. HCP may not be used in cosmetics that in normal use may be applied to mucous membranes, such as the lips [21 CFR 250.250]</td>
</tr>
<tr>
<td>Mercury</td>
<td>Mercury compounds are readily absorbed through the skin on topical application and tend to accumulate in the body. They may cause allergic reactions, skin irritation, or neurotoxic manifestations. The use of mercury compounds as cosmetic ingredients is limited to eye area cosmetics at concentrations not exceeding 65 parts per million (0.0065 percent) of mercury calculated as the metal (about 100 ppm or 0.01 percent phenylmercuric acetate or nitrate) and is permitted only if no other effective and safe preservative is available for use. All other cosmetics containing mercury are adulterated and subject to regulatory action unless it occurs in a trace amount of less than 1 part per million (0.0001 percent) calculated as the metal and its presence is unavoidable under conditions of good manufacturing practice [21 CFR 700.13]</td>
</tr>
<tr>
<td>Methylene Chloride</td>
<td>The use of this substance in cosmetic products is prohibited because of its animal carcinogenicity and likely hazard to human health (21 CFR 700.19)</td>
</tr>
<tr>
<td>Prohibited cattle material</td>
<td>To protect against bovine spongiform encephalopathy, also known as &quot;mad cow disease,&quot; cosmetics may not be manufactured from, processed with, or otherwise contain, prohibited cattle materials. These materials include specified risk materials; material from nonambulatory cattle, material from cattle not inspected and passed, or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, and hides and hide-derived products, and milk and milk products. [21 CFR 700.27, as amended]</td>
</tr>
<tr>
<td>Sunscreen in cosmetics</td>
<td>Use of the term &quot;sunscreen&quot; or similar sun protection terminology in a product's labeling generally causes the product to be subject to regulation as a drug. However, sunscreen ingredients may also be used in some products for nontherapeutic, nonphysiologic uses (for example, as a color additive or to protect the color of the product). To avoid consumer misunderstanding, if a cosmetic product contains a sunscreen ingredient and uses the term &quot;sunscreen&quot; or similar sun protection terminology anywhere in its labeling, the term must be qualified, in accordance with 21 CFR 700.35(b), by describing the benefit to the cosmetic product provided by the sunscreen ingredient. Otherwise, the product may be subject to regulation as a drug [21 CFR 700.35]</td>
</tr>
<tr>
<td>Vinyl Chloride</td>
<td>The use of vinyl chloride is prohibited as an ingredient of aerosol products, because of its carcinogenicity [21 CFR 700.14]</td>
</tr>
<tr>
<td>Zirconium-containing complexes</td>
<td>The use of zirconium-containing complexes in aerosol cosmetic products is prohibited because of their toxic effect on lungs, including the formation of granulomas [21 CFR 700.16]</td>
</tr>
<tr>
<td>Ingredients</td>
<td>Safety Concern</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chloroacetamide</td>
<td>Skin sensitization</td>
</tr>
<tr>
<td>Ethoxyethanol and Ethoxyethanol Acetate</td>
<td>Reproductive and Developmental Toxicity</td>
</tr>
<tr>
<td>HC Blue No. 1</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Hydroquinone</td>
<td>Should not be used in leave-on cosmetic products; renal toxicity</td>
</tr>
<tr>
<td>p-Hydroxyanisole</td>
<td>Skin depigmentation</td>
</tr>
<tr>
<td>4-Methoxy-m-Phenylenediamine</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>4-Methoxy-m-Phenylenediamine Hydrochloride</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>4-Methoxy-m-Phenylenediamine Sulfate</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Pyrocatechol</td>
<td>Carcinogenicity (unsafe for leave-on products, insufficient data for hair dyes)</td>
</tr>
<tr>
<td>Name of Chemical</td>
<td>General Information</td>
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<tr>
<td>Acrylamide</td>
<td>Small organic molecule existing as a white crystalline powder in its pure state. Commercially, acrylamide is synthesized and used in the production of polyacrylamide polymer, gels, and binding agents. Polyacrylamides are useful water-compatible polymers used in water treatment, mineral processing, pulp and paper production, and in the synthesis or compounding of dye materials, soil conditioners, and cosmetics.</td>
</tr>
<tr>
<td>Benzophenone - 3 (2-hydroxy-4-methoxybenzophenone)</td>
<td>It is commercially synthesized as a sunscreen for use in lotions, conditioners, and cosmetics. It is also used as a UV stabilizer in plastic surface coatings and polymers.</td>
</tr>
<tr>
<td>Lead</td>
<td>Less common sources of incidental or unique lead exposure are numerous: lead-glazed ceramic pottery; stained glass framing; pewter utensils and drinking vessels; older plumbing systems with leaded pipes or lead soldered connections; lead-based painted surfaces undergoing renovation or demolition; imported children’s trinkets and toys; lead-containing folk remedies and cosmetics.</td>
</tr>
<tr>
<td>Phthalate</td>
<td>Phthalates are industrial chemicals that are added to plastics to impart flexibility and resilience and are often referred to as plasticizers. There are numerous products that contain phthalates: adhesives; automotive plastics; detergents; lubricating oils; some medical devices and pharmaceuticals; plastic raincoats; solvents; vinyl tiles and flooring; and personal-care products, such as soap, shampoo, deodorants, lotions, fragrances, hair spray, and nail polish.</td>
</tr>
<tr>
<td>Benzyllbutyl Phthalate</td>
<td>Benzyllbutyl phthalate (BzBP) is a solvent and additive used in products such as adhesives, vinyl tile, sealants, car care products, and to a lesser extent, some personal care products.</td>
</tr>
<tr>
<td>Di-n-butyl Phthalate, Di-isobutyl Phthalate</td>
<td>Industrial solvents or additives used in many personal care products such as nail polish and cosmetics, and also in some printing inks, pharmaceutical coatings, and insecticides.</td>
</tr>
<tr>
<td>4-tert-Octylphenol</td>
<td>4-tert-Octylphenol, an alkylphenol, is used to manufacture alkylphenol ethoxylates, which are anionic surfactants used in detergents, industrial cleaners, and emulsifiers. Commercial formulations of alkylphenol ethoxylates usually contain a mixture of oligomers and isomers, and the polyethoxy chain may consist of up to 50 ethoxy units. Less frequently, the various alkylphenols have also been used as emulsifiers and modifiers in paints, pesticides, and some personal care products.</td>
</tr>
</tbody>
</table>
Cosmetic products are the safest products regulated by the U.S. Food and Drug Administration (FDA), a fact that has been recognized by a number of FDA Commissioners over the last several decades.

To further strengthen industry safeguards for consumers, the Personal Care Products Council has instituted a Consumer Commitment Code for the cosmetic industry. This incorporates and strengthens some practices already in place for most companies, such as the current reporting of manufacturing establishments; and it includes new practices such as a Safety Information Summary Program that makes information relevant to cosmetic product and ingredient safety readily available to the FDA upon request.

The Council's Board of Directors unanimously supports the principles and practices embodied in this Code. It will formally take effect for all Council members on January 1, 2007. Throughout 2006, the Council will commit substantial resources to educating its members on the practices embodied in the Code and gaining their commitments to the Code. The Council will also reach out to many related trade associations and other organizations to encourage broad recognition of the Code by 2007.

During this time, we will continue to work closely with the Food and Drug Administration to provide as much information regarding cosmetic safety as the agency needs to evaluate the safety of the products. In providing FDA with access to this information we seek to provide consumers with the continued confidence that the proper-steps are being taken by government and industry to assure the continued safety of all cosmetic products, and to allow consumers to make fully informed choices when purchasing cosmetic products.

The following principles constitute the Personal Care Products Council Consumer Commitment Code:

1. A company should market cosmetic products only after ensuring that every ingredient and finished product has been substantiated for safety. The decision that an ingredient has been substantiated for safety may be based on a finding by the Cosmetic Ingredient Review Expert Panel that such ingredient is safe for the use intended by the company or on other appropriate data and information.

2. When marketing a cosmetic product containing an ingredient that exceeds limits on concentration or product type established by the Cosmetic Ingredient Review Expert Panel, a company should possess information sufficient to substantiate the safety of the ingredient for its intended use in such product and be willing to make that information available for inspection by the Food and Drug Administration.

3. When marketing a cosmetic product containing an ingredient for which the Cosmetic Ingredient Review Expert Panel has found insufficient data to determine safety, a company should possess information sufficient to substantiate the safety of the ingredient for its intended use in such product and be willing to make that information available for inspection by the Food and Drug Administration.

4. A company should participate in the applicable parts of the FDA Voluntary Cosmetic Reporting Program set forth in 21 CFR Parts 710 and 720 for products marketed in the United States, and file timely reports regarding its manufacturing establishments and ingredient usage.

5. Although adverse events that are both serious and unexpected are extremely rare for cosmetic products, a company should notify the Food and Drug Administration of any known serious and unexpected adverse event as a result of the use of any of its cosmetic products marketed and used in the United States. “Serious” and “Unexpected” are defined in accordance with FDA’s definition for such experiences related to drugs in 21 CFR 314.80(a). Information related to other product experiences as described in the Council’s Safety Information Summary Program should be maintained in the safety information summary described in Paragraph 6 below. Such information should be made available for inspection by FDA under the conditions specified in that program.

6. A company should maintain a safety information summary of ingredient and product safety information and data regarding its cosmetic products marketed in the United States as specified in the Council’s Safety Information Summary Program Guideline, and make any information in that safety information summary available for inspection by FDA under the conditions specified in that program. (PCPC, Commitment Code)
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