DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

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Dear Ms. Westine and Ms. Busiek:

I am writing to express my profound disappointment in your proposed draft legislation on FDA oversight of cosmetic safety. As you know, FDA and your organizations worked diligently for over a year to reach agreement on a modernized regulatory framework that would provide American consumers with greater assurance of the safety of your industry's cosmetic products and the industry with greater regulatory certainty. In July 2013, FDA and your organizations reached agreement on a detailed framework for legislation that established an appropriate regulatory scheme, and generally outlined the user fees necessary to cover the costs of this new system. (A summary of the principles in the July framework agreement is attached.)

The ostensible goal of this legislation is to create a credible 21st century regulatory program for cosmetics, upgrading FDA's outdated and limited authority over cosmetic safety, and bringing U.S. oversight of cosmetics safety closer to that of other countries. Yet some of the provisions of the industry draft not only do not move us forward toward that goal, they would actually *reduce* FDA's current ability to take action against dangerous cosmetics. Taken together with the sweeping preemption provisions, which almost completely eliminate States' authority to protect their citizens from unsafe chemicals in cosmetics, the provisions of the draft industry bill could put Americans at greater risk from cosmetic-related illness and injury than they are today.

Contrary to the statements in your cover memo, the provisions in the draft industry bill are neither consistent with the framework agreement we reached last July nor "clarifications" of the principles contained in the agreement. Indeed, the memo mischaracterizes both the changes you have made and their significance. In fact, the provisions of the industry draft abandon the most important of the agreed-upon safety principles. In an attachment to this letter, I have detailed many of our concerns about the changes to our agreement in the industry draft and their real-

world consequences for consumers. To briefly summarize some of the ways that it would undercut the safety of American cosmetics, the industry draft would:

- Have Congress declare a wide range of potentially harmful chemicals "safe" for use in cosmetics without a credible scientific basis, shifting the burden to FDA to prove them unsafe through a lengthy rulemaking;
- Require FDA to affirmatively find other cosmetic ingredients "safe" even if we knew that they posed real and substantial risks to consumers;
- Require FDA to undergo a lengthy, unnecessarily burdensome process before declaring an ingredient unsafe, delaying actions to protect consumers by removing unsafe chemicals from cosmetics;
- Virtually eliminate FDA's ability to verify that cosmetic companies have substantiated the safety of their products;
- Undercut FDA's ability to enforce quality control rules for the safe manufacturing of cosmetics;
- Prevent FDA from receiving reports of most illnesses and injuries from improperly manufactured or otherwise dangerous cosmetics, as well adding a provision that would severely undermine FDA's ability to use the reporting system for its fundamental purpose: to detect signals of harm from cosmetics;
- Fail to give FDA the authority to require cosmetic companies to register annually with FDA, reducing the agency's ability to know who is making cosmetic products for sale to our citizens and what those products are;
- And finally, having severely restricted FDA's authority to keep unsafe cosmetics off the market, the industry draft would entirely eliminate States' ability to oversee any aspect of the safety of cosmetics.

The result of these changes is a bill that creates the appearance of a modernized cosmetics regime, but a reality that actually prevents federal and State governments from protecting Americans from unsafe cosmetics. Because your proposal meets none of the safety goals on which we had all agreed last year, I have difficulty seeing a path forward in this process. FDA has successfully negotiated many user fee agreements with other industries, and has learned to recognize when there is sufficient common ground to reach agreement. I no longer see that common ground here and thus cannot justify devoting further taxpayer resources to this negotiation. This was an historic opportunity to create a modern system for ensuring cosmetic safety that both American consumers and the rest of the world would have seen as strong and credible. I regret the loss of that opportunity.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine

Section-by-Section Analysis of Industry Draft Bill

The industry draft bill makes many significant changes to the framework agreement that undermine or eliminate the safety principles to which FDA and industry agreed. Some of the changes would actually weaken FDA's existing authority to protect consumers from unsafe cosmetics. This analysis describes the most detrimental of the changes made in the industry draft. This is not, however, a complete list of the changes in the industry draft to which FDA would object.

1. Cosmetic ingredient safety (Secs. 112 and 103)

A. Ingredients and non-functional constituents (chemical contaminants) "deemed" safe by the draft can cause serious risks to consumers (Sec. 112, pp. 34-36).

The draft adds a new section that we did not discuss with you. It "deems" a wide variety of chemicals to be safe for use in cosmetics, based on a questionable array of findings that these chemicals are safe when used in food, drinking water, and drugs. Even if there were evidence of harm from a deemed-safe chemical, FDA could do nothing to remove or restrict its use in cosmetics until the agency went through rulemaking, a process that generally takes several years. And States are specifically preempted from taking actions against use of these chemicals in cosmetics.

We believe that this provision will put consumers at risk. There is no credible scientific basis for claiming that evidence on the safety of ingesting a chemical guarantees the chemical will be safe when used on the skin, inhaled (as can occur with spray-on cosmetics), or absorbed through mucus membranes (e.g., the eyes, nose, and female genitals). These different routes of absorption (through the GI tract, the skin and hair, mucus membranes, or the lungs) can create very different risks to humans, and may require different restrictions for safe use. In the list of "safe" chemicals in the draft bill, there are many that could harm consumers if used in cosmetics by manufacturers. Yet, the fact that these chemicals would be listed as safe and largely exempt from regulation is likely to encourage manufacturers to use them.

Moreover, some of the findings that would form the basis for deeming a chemical to be safe for use in cosmetics provide little confidence in the safety of the chemical. For example, the process for determining that a food ingredient is GRAS does not have to involve any FDA safety review; in many cases, a "self-determination" of general recognition of safety is made by the company that wants to market a food ingredient or a food product containing the ingredient, and the company is not even required to notify FDA of its determination or of its the use of the chemical. The draft would also deem a contaminant in a cosmetic to be safe if it was present at a level established in "informal statements." Whatever the industry intended to include with this potentially sweeping phrase, by definition these are not official safety findings. The inclusion of GRAS self-determinations and informal statements as bases for deeming chemicals safe highlights the lack of scientific credibility underpinning this provision.

Box 1. Examples of potential harm from "deemed safe" ingredients:

Ascorbic acid and sodium hydroxide are listed as "generally recognized as safe" (GRAS) for use in food as buffers or neutralizing agents, without restrictions. They are also used in cosmetic products, like hair straightening, relaxing, or waving products, for similar purposes. Under the draft bill they would be deemed safe without restriction. However, when improperly formulated, such hair products have been shown to cause severe damage to the hair and scalp, including discoloration, breakage, and permanent hair loss. High levels of ascorbic acid, leading to a very acidic formulation, were implicated in the large group of adverse events associated with Rio Hair Naturalizer in the mid-1990s. Yet, under the draft bill, FDA could not act against dangerous cosmetics containing these ingredients until it had completed a lengthy rulemaking, and States could take no action whatsoever.

Many oils and essential oils are used in food; some are approved as food additives, some are listed by FDA as GRAS, and some have been "self-determined" to be GRAS by individual manufacturers, in most cases without restrictions. There is growing interest in using these oils in "natural" cosmetics. Although they are not toxic when consumed in food, some oils are toxic when applied to the skin. Cumin oil, while safe in food, can cause the skin to blister. Certain citrus oils used in food can also be harmful in cosmetics, particularly when applied to skin exposed to sun.

Retinol and retinyl palmitate are forms of Vitamin A, and are listed as GRAS for use in human food without restrictions. These substances are also widely used in "anti-aging" cosmetics, but there are significant scientific questions about whether they increase the risk of skin cancer in amounts above 1%. These safety questions are currently under review by the National Toxicology Program. Yet under the draft bill, retinol and retinyl palmitate would be deemed safe in cosmetics at any level. Even if NTP found that they caused harm at levels in some current products, FDA would be unable to take action against those products without first completing a lengthy rulemaking process, and the States would also be barred from any action to protect their citizens.

B. The draft weakens and delays FDA's safety review of ingredients and non-functional constituents in cosmetics and sweeps away all State regulation (Sec. 103, p. 11-21)

A separate safety provision governs FDA's ability to review certain ingredients and non-functional constituents (NFCs). Under our July agreement, FDA would conduct a safety review of ingredients and NFCs on a prioritized list, at a rate of about 5 per year, and determine whether the chemicals were safe, unsafe, or safe with restrictions. The chemicals could be found safe only if there was evidence to support a "reasonable certainty" that the ingredient or NFC would cause "no harm" when used in cosmetics, the same standard that has been used successfully by FDA for over 50 years before approving food and color additives. The agreement recognized that "minor, transient reactions in some users" should not prevent such a finding of safety. Once FDA reached a final determination on the safety of an ingredient or NFC, the States would be preempted from reaching a different determination on the human health effects of that cosmetic ingredient or NFC.

The industry draft fundamentally alters three key features of this provision. It:

- Weakens the safety standard, forcing the agency to find ingredients and NFCs safe even where we know they pose substantial harm to consumers;

- Creates a lengthy and burdensome new process before FDA can find an ingredient or NFC to be unsafe and take action; and

- Preempts the States from taking action on any of the thousands of cosmetic ingredients or NFCs, whether or not FDA has conducted a safety review.

The overall effect of the industry changes is to make it more difficult to take action against unsafe cosmetic ingredients than under the current weak system.

(1) Safety standard lowered (p. 19)

Although it is difficult to follow the new safety standard adopted by the industry bill, it is clearly intended to prevent FDA from finding a cosmetic ingredient or NFC unsafe unless it poses grave risks to consumers. For example, the draft states that FDA may not consider an ingredient or NFC to be harmful if it causes a "non-serious" adverse health reaction. That is, FDA is prohibited from finding an ingredient or NFC unsafe unless it causes "serious" adverse events. Under the draft, only the following grave adverse health reactions are "serious": (1) death, (2) a life-threatening experience, (3) inpatient hospitalization, (4) persistent and significant disability or incapacity, (5) a congenital anomaly or birth defect, or (6) permanent disfigurement (or a medical or surgical intervention that is necessary to prevent one of the six listed serious events).

Taken together, these provisions in the industry draft mean that an ingredient or NFC that causes damaging but less grave illnesses or injuries must be found "safe."

Box 2. Examples of "acceptable" harms from cosmetic ingredients under the draft

- A baby shampoo ingredient that causes severe skin and eye irritation to infants must be considered safe for use in infant products, unless it causes blindness or permanent scarring.

- A hair care ingredient that causes the user's hair to fall out must be considered safe, as long as the hair eventually grows back.

- A facial moisturizer ingredient that causes burning and blistering must be considered safe for that use, unless it causes permanent disfigurement.

- An ingredient in make-up that causes frequent allergic reactions must be considered safe, unless the reactions are so severe that they are life-threatening, require hospitalization, or result in permanent disfigurement.

In FDA's view, none of these reactions should be considered acceptable risks for cosmetic ingredients, yet the draft bill requires FDA (and American consumers) to accept them as reasonable.

(2) Process before FDA can act against unsafe chemicals made longer and more difficult (pp. 14-20).

Under the July agreement, FDA would conduct a safety review of an ingredient or NFC and issue a final order in a process that could be undertaken in approximately 15 months.[1] Under the industry draft, the review process has been substantially revised to require two separate rulemakings, with proposed and final regulations issued for each, before the agency could enforce its safety findings. The draft includes provisions to allow stakeholders to sue FDA if these rulemakings are not completed within ridiculously short timeframes, but offers no explanation of where FDA would find the unprecedented resources necessary to meet those deadlines. The reality of federal rulemaking on complex, contested scientific issues is that such a process would take FDA several years to complete. During that period, it would be extremely difficult for FDA to take action against products containing these ingredients or NFCs, even if mounting evidence strongly suggested harm. And the States would be completely barred from taking action.

The industry draft also weakens FDA's existing authority. Under current section 601(a), FDA could issue a regulation restricting use of a cosmetic ingredient or NFC if the ingredient or NFC "may render [a cosmetic] injurious to users."[2] There is no limitation in the current law on the types of injuries that can be the basis for FDA action and the agency can currently take enforcement actions and issue regulatory restrictions on ingredients if they cause injuries of the type in Box 2. This authority would apparently be eliminated by the industry draft.

(3) State action against *any* cosmetic ingredients preempted (pp. 12-13).

Under the industry draft, the preemptive effect of the review process has been expanded beyond that of any federal statute known to FDA. Not only would States be barred from regulating ingredients or NFCs on which FDA has made a final determination, they would not be able to regulate any cosmetics ingredients or NFCs at all, whether or not they ever have been reviewed by FDA, or are even known to FDA.[3] Under our agreement, FDA was to receive user fees that would permit the agency to review only five ingredients or NFCs per year, of over 19,000 cosmetic ingredients listed in the International Cosmetic Ingredient Dictionary and Handbook, and an untold number of potential NFCs. FDA would have no expectation of resources to review more than five, and the States would have been permitted to regulate any ingredient or NFC until FDA had reviewed it. We are unaware of any public health rationale for the complete elimination of State authority over ingredients and NFCs that FDA has not reviewed. Nor does the industry offer one.

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[1] Under this procedure, FDA would receive a petition containing safety data, solicit public comment on the submitted data and argument in the petition, review the data and comments, then issue an order setting out the agency's determination on safety.

[2] Section 601(a) states that a cosmetic is adulterated if it contains "any poisonous or deleterious substance, which may render it injurious to users under the conditions of use in the labeling thereof, or, under such conditions of use which are customary or usual." 21 USC §361(a).

[3] This provision also appears to preempt action by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Although there is an additional preemption provision under section 612 that includes an exemption for Proposition 65, there is no comparable exemption under section 606(b).

Although the industry draft allows the States to petition for exemption from preemption, this is a virtually meaningless provision, because, for the vast majority of ingredients and NFCs (those not specifically listed in the bill), even if the petition was granted, the State still couldn't act. The only action permitted by the bill upon the granting of a petition is for FDA itself to begin a review of the chemical. Sec. 606(b)(2). Given the enormous number of ingredients in cosmetics, with new ones entering the market every year without any premarket review, together with the minimal resources available to FDA to review all of these ingredients after marketing, FDA believes that there is a valuable role for the States in protecting their citizens against unsafe ingredients that have not undergone FDA review.

Moreover, the industry draft requires the petition to be issued by a vote of the State legislature and signed by the Governor. This provision illustrates the remarkable overreach of the draft bill. Not only is it clear that the provision is intended to prevent the State's executive branch from exercising its public health responsibilities under State law, the industry draft would have Congress dictate how a State governs itself by requiring action by the legislature and Governor.

2. Registration and Ingredient Statements (Sec. 102, pp. 3-11)

a. The draft weakens FDA's ability to learn of cosmetic manufacturers and ingredients and to collect user fees.

Under the July agreement, each owner or operator of a cosmetic facility would be required to register with FDA annually and pay any applicable user fee. Each brand owner would have to provide the agency with a list of the products and their ingredients annually. If there was a reasonable probability of serious adverse health consequences or death FDA would be able to suspend the registration or ingredient statement and then hold a hearing.

Under the industry draft, companies would no longer register or file ingredients statements annually unless there was a change in their information. Without a regular date for registration or filing, FDA would lose track of many companies and products. In addition, FDA would have no practical way of ensuring payment of user fees.

The industry draft also weakens FDA's ability to suspend a registration or ingredient statement despite the very high level of harm involved, by forcing the agency to hold a hearing before the suspension and giving the company additional opportunities to delay the suspension.

3. Safety Substantiation (Sec. 104, pp. 21-23)

a. FDA could no longer verify safety substantiation of most finished products

Under the July agreement, companies would be required to substantiate the safety of the products they manufacture and maintain files of the substantiation. Companies would not be required to submit that substantiation to FDA except upon a specific request. This was not a burdensome requirement—rather than require companies to test each of their ingredients, companies would have been allowed to rely on authoritative safety findings by recognized expert bodies, if the findings were supported by adequate data. Under the July agreement, the company would lose the ability to rely on an expert finding if (1) FDA had reached a different conclusion in a rulemaking on the safety of that ingredient, or (2) FDA notified the company that it had information raising "significant questions about safety of the product or its ingredients."

The industry draft makes three significant changes, each of which undercuts FDA's ability to make sure that marketed cosmetics are safe. First, the draft eliminates the requirement that an expert finding be supported by adequate data. As long as the finding is supported by "information" of any kind, FDA must accept the finding as sound. FDA is already aware of a number of expert findings that are not supported by adequate data to establish safety. FDA would be unable to challenge those findings until it had completed lengthy rulemakings on each ingredient (using resources not provided under the user fee amount discussed).

Second, the draft eliminates FDA's ability to challenge a company's reliance on an expert finding even when FDA has information raising significant safety questions about the ingredient. This change in particular puts consumers at risk, by immunizing companies from responsibility for product safety even where there is evidence of risk.

Finally, the draft virtually eliminates FDA's ability to require submission of a company's safety substantiation file. This change is contained in the Records Inspection provision (Sec. 107). Under the draft, FDA may not request submission of safety substantiation unless it has one of three types of evidence it will almost never have. The first two of these are: (1) evidence of harm from "serious" adverse event reports, which as described in section 1.B.(i), are limited to reports of grave harm, such as death and permanent disability, and (2) prohibition by a foreign country of use of an ingredient because it poses a threat of imminent harm or adverse health consequences. Both of these describe very rare events, and most of the adverse events that occur with cosmetics (severe skin irritation, burning, hair loss) that might warrant review of the safety substantiation file will not meet these tests. Finally, FDA can request the file if it has documented reasons to believe the responsible person has not even tried to substantiate safety. It is difficult to imagine how FDA would "document" this belief without first asking for submission of the file.

4. Good Manufacturing Practices (Sec 105, p. 23)

a. GMP requirements would be unenforceable

"Good manufacturing practice" (GMP) requirements ensure that products are manufactured with appropriate quality controls and that finished products meet standards for safety, identity, purity, and other important product characteristics. GMPs are minimum standards for safe production, whose requirements are tailored to each type of product and are designed to prevent contamination and other production errors that can result in unsafe products. Under the July agreement, FDA would have been given explicit authority to issue and enforce GMP requirements for cosmetics, using the language of the standard GMP statutory provisions for dietary supplements, devices, and drugs, but with the clear understanding that the specific GMP requirements for cosmetics would have been based on the current cosmetic GMP guidance document and not on the specific requirements for drugs or dietary supplements.

The industry draft revises the agreed-upon GMP authority so as to render the cosmetic GMP requirement unenforceable, by imposing an unprecedented requirement that violations of cosmetic GMP regulations can be enforced only if FDA can prove that the violation "creates a significant risk of serious adverse health consequences to humans." The GMP language for dietary supplements, drugs, and devices, on which the July agreement was based does not require proof that any individual violation would create a risk of harm. A successful quality control system operates as a whole, and prevents

safety problems consistently only when all of its component parts are being implemented consistently. Each specific requirement in the system is there because it is necessary to prevent safety problems, even if harm cannot be proven in every case. Requiring FDA to prove a risk of harm for each violation removes the incentive to implement quality control procedures consistently and will put consumers at risk.

Not only does this revision require proof of risk in each individual case, it requires proof of grave risk. As noted above, "serious adverse health consequences" include only risks of the highest order, such as death, hospitalization, or permanent disability. Many of the risks that GMPs are designed to prevent would not meet this standard. For example, if FDA investigators discovered that the company was not taking necessary steps to clean its equipment or ensure the identity or purity of its ingredients, the agency would probably be unable to take any action to correct the problem because it would not have proof of a significant risk of serious adverse health consequences. Nevertheless, such quality control failures could result in unsafe products.

5. Adverse Event Reporting (Sec. 106, pp. 24-27)

a. FDA would not receive reports of most adverse events and would be prevented from detecting signals of harm

The purpose of adverse event reporting is to allow FDA to detect safety concerns with products that cannot be detected at the individual level. When, for example, a child develops a rash, there can be many causes, only one of which is that her shampoo contains an irritating ingredient. When a single consumer develops an eye infection, there can again be many causes, only one of which is that her eye make-up is contaminated with bacteria. When one baby is born with a birth defect, it is almost impossible to know whether the cause is a product used by his mother during pregnancy. In most cases, there is no evidence of a causal connection between a cosmetic product and a medical event until many consumers develop similar problems and report a possible association with a product. Adverse event reporting allows FDA to pick up "signals" of harm through a pattern of similar reports, and confirm causation through further testing.

Under the July agreement, a cosmetic manufacturer would be required to send FDA reports it had received of "serious" and certain non-serious but unexpected adverse events associated with their cosmetic products. The non-serious events included: (1) an unexpected rise in reports of non-serious adverse reactions; and (2) adverse events requiring repeated medical or surgical interventions. Many of the types of adverse reactions seen for cosmetics (irritation, burning, infection, hair loss) may not meet the definition of "serious", and yet an unexpected rise in such reactions could signal a safety problem with these products. As with all adverse event reporting, no evidence of causation was required before the company had to make a report.

The industry draft makes two key changes which render the provision almost useless for detecting cosmetics safety problems. First, the draft eliminates reporting of non-serious adverse events. Second, it exempts a company from reporting any adverse event unless the company believes it has "evidence to suggest a causal relationship between the cosmetic product and the adverse event." The first change means that companies will **not** be required to report the vast majority of meaningful adverse events of which they are aware. The second means that companies will be the sole arbiters of which events are caused by their products, a role that many companies have neither the evidence nor expertise to fulfill, and that FDA will never learn of many significant product-related adverse events.

6. Records Inspection (Sec. 107, pp. 27-29)

a. The draft undercuts FDA's access to records relevant to product safety

The industry draft reduces FDA's ability to review company safety records in three ways.

First, it makes it much harder to gain access to certain safety records, such as safety substantiation records, during an FDA inspection. Under the July agreement, FDA would have had immediate access to such records during an inspection if the agency reasonably believed that a cosmetic (1) was adulterated, (2) had caused a reportable adverse event (which included non-serious but unexpected events), or (3) contained an ingredient or NFC for which there was reliable scientific information showing that it "may be unsafe." Under the draft, these standards have been substantially raised so that FDA may only access certain safety records when FDA has a reasonable belief that the product is adulterated or contains an unsafe ingredient, has "caused" a "serious" adverse event report, or contains an ingredient that has been prohibited by a foreign government because it threatens "imminent" harm or adverse health consequences. The draft also restricts the information that the inspectors can look at concerning a cosmetic they have reason to believe is adulterated.

Second, FDA must provide a written notice explaining the basis for the reasonable belief "signed by the Associate Commissioner of Food and Drugs for Regulatory Affairs," one of the highest ranking officials at FDA. This is an unprecedented limitation on FDA's access to records.

Finally, as described above in section 3, the industry draft virtually eliminates FDA's ability to require a company to submit its safety substantiation file to the agency. Taken together with the restrictions on FDA's ability to review these documents during an inspection, only in the most unusual cases will FDA be able to verify a company's safety substantiation.

7. National Uniformity (Sec. 110, pp. 32-33)

a. Additional State preemption provision eliminates virtually all remaining State authority

Beyond the sweeping preemption of State regulation of cosmetic ingredients and NFCs in section 103, the industry bill contains a separate provision that also preempts (1) any State order or requirement related to the safety of any cosmetic ingredient, NFC, or finished product, unless the requirement is "identical" to an FDA safety finding or confirms that a "deemed safe" ingredient is in fact safe; and (2) any requirements related to registration of cosmetic companies, disclosure of ingredients, adverse event reporting, good manufacturing practices, records inspection, recalls or registration fees.

Together, these provisions appear to preempt all State regulation of cosmetics based on human health concerns, as well as removing States' key investigation and enforcement powers. If a State's only authority is to issue a regulation identical to a final determination by FDA, or to confirm a "deemed safe" finding in federal law, all State power over cosmetic ingredients and products that are not covered by such a determination or law has been eliminated. The sweep of this provision is unprecedented, and is particularly inappropriate because FDA's authority over cosmetics would still be quite limited by

comparison to other regulated products. The only exceptions to complete preemption in the industry draft appear to be for certain State requirements under California's Proposition 65 (although sections 103 and 112 may have already preempted virtually all actions under Proposition 65), and product liability actions.

Even with the user fees under the July agreement, FDA would have very limited resources to investigate and take action based on safety issues arising across the cosmetic marketplace. Given FDA's limited resources, there is a long history of complementary State and local government actions to protect their citizens against unsafe cosmetics, which would be undermined or terminated by these provisions. Many of these actions involve rapid State action responding to local problems that FDA could not act against quickly.

Box 3. Examples of past State actions that would be preempted

California action against formaldehyde in Brazilian Blowout. Brazilian Blowout is a hair straightening product whose use without adequate ventilation can expose users and salon workers to dangerous levels of formaldehyde, a known carcinogen. Such exposure can also cause difficulty breathing, eye irritation, nose bleeds, nausea, headache, dizziness, and fainting. In 2010, before FDA could act against the product, California filed suit under the California Safe Cosmetics Act and Proposition 65 for falsely advertising the product as "formaldehyde-free" and for containing hazardous substances above legal limits. As a result of this lawsuit, the product label now includes a warning that its use releases formaldehyde, and provides new instructions for use. Under the draft, any State attempt to regulate formaldehyde in Brazilian Blowout, including this action, would have been preempted until FDA completed a rulemaking on the safety of formaldehyde in cosmetics.

Rhode Island and NYC actions against lead in imported deodorant. Litargirio is a deodorant powder imported from the Dominican Republic and used in the Hispanic community. In 2003, Rhode Island discovered that litargirio contained high lead levels and issued a statewide health alert warning the public to stop using litargirio and advising pregnant and nursing women and children who used this product to obtain a test for lead poisoning. New York City followed up with a warning to its citizens and ordered a recall of litargirio from the city's many Hispanic groceries. FDA issued a warning 3 months after Rhode Island's action. Under the draft, it appears that Rhode Island and NYC would have been barred from recalling litargirio, unless and until FDA could complete a multi-year rulemaking on lead in cosmetics.

California and Nevada embargoes of Rio Hair Naturalizer. Rio Hair Naturalizer was an imported hair relaxer marketed to African Americans. In the mid 1990s, FDA received over 3,000 reports of hair loss, discoloration, and breakage, as well as burning of the scalp. After FDA investigated and identified large storehouses of the product in California and Nevada, both States embargoed the products, preventing their sale. This gave FDA, which does not have immediate embargo authority, the longer time necessary to initiate lawsuits and require destruction of the products under its own authority. The State embargo orders would have been preempted under the industry draft.

This framework represents the views of individual FDA employees and has not been approved or cleared by the Agency. The elements below were negotiated as a package and are not severable.

Cosmetic User Fee Legislation: Overview of Possible Framework

FDA, the cosmetic industry, and the American public have begun to call for a more modern regulatory framework to help ensure the safety of cosmetic products. Over the last several months, FDA staff and the cosmetic industry have been working together to develop for the consideration of agency and industry leadership a possible framework for a more comprehensive cosmetics safety program that would protect and promote the public health. Although consumer groups have not been part of these discussions, the agency is separately consulting with them and their eventual support will be important to getting any legislation passed. The key elements of the framework are summarized below. These elements of the framework are intended to be considered together, and if one part of the framework changes, the remaining provisions would no longer have the support of those FDA staff involved in their negotiation.

Ingredient and Non-functional Constituent (NFC) Review

- FDA's goal will be to review 5 ingredients and NFCs/year, after an initial phase-in period.
- About 20 ingredients of concern to industry and consumers will be listed in the law, and FDA may add high priority ingredients to the list, as needed.
- FDA will review ingredients under a "reasonable certainty of no harm" standard. Safety evidence does not need to establish proof beyond any possible doubt that no harm will result under any conceivable circumstances. Minor, transient reactions will not be considered "harm."
- FDA's final findings will preempt state regulation of those cosmetic ingredients for human health purposes over which FDA has jurisdiction.

Substantiation of Safety for Each Finished Product

- Brand owners must keep records that provide scientific substantiation of product safety, as currently required.
- Ordinarily, FDA will presume that safety substantiation is adequate if the brand owner has:
  - A safety finding of CIR, or another expert body, on each ingredient, and
  - Appropriate finished product testing.
- The owner may lose the presumption if FDA's safety findings conflict with those of CIR or other expert body or if FDA provides notice that substantiation is inadequate.

- No pre-market submissions will be required, but when appropriate, FDA may require a manufacturer to submit its substantiation file for a marketed product. Manufacturers would have at least 30 days to respond to FDA.

Basic Oversight Provisions

- Registration and Listing
  - Brand owners and manufacturing facilities must register electronically with FDA on an annual basis.
  - Brand owners must provide FDA a list of products and their ingredients (with use level ranges) annually, but do not need to identify fragrances and colors specifically.
  - Significant modifications to the products and discontinuations will be reported within 60 days. Modifications in colors or fragrances would be reported on an annual basis.
- Good Manufacturing Practices (GMPs)
  - FDA will issue GMP regulations after receiving public comments from industry and other interested groups.
  - GMPs will be appropriate for cosmetics, modeled on the FDA's current guidance. They will not be based on the GMPs for drugs or dietary supplements (specified in side letter agreement).
- Adverse Event Reports
  - 15 day reports: brand owners must report serious adverse events in 15 days, including death, hospitalization, and disfigurement.
  - 60 day reports: brand owners must report within 60 days: unexpected spikes in non-serious adverse events within 60 days of determining that the spike is product-related; serious adverse events that are covered by product warnings and verified; and adverse events that require repeated medical or surgical intervention.
  - Brand owners must report annual summaries of all adverse events.
- Mandatory Recall
  - Only used if there is a reasonable probability of a serious adverse event or death, and the manufacturer refuses to conduct a voluntary recall (same standard as for food).
- Records Access

- FDA will have access to GMP and AER records during an inspection.
- FDA will have access to other records, including safety substantiation files, during an inspection if it has reasonable belief that that there is a safety concern, based on (1) serious or unexpected adverse events, (2) new scientific information suggesting that the product is unsafe, or (3) a reasonable belief that the product is contaminated or contains an ingredient that is unsafe under the conditions of use. The basis for FDA's reasonable belief must be provided in writing.
- FDA will not have access to most business records (same as other regulated products).

Penalties

- Ordinarily, manufacturers that violate any new cosmetic provisions will be subject to the usual penalties for FDA-regulated products. Failure to comply with GMPs or to adequately substantiate safety also will subject manufacturers to product seizure, which is typical for similarly adulterated or misbranded FDA-regulated products.
- Suspension of registration or ingredient statement for cosmetics that present serious risks to human health (similar to foods).

Small Business Relief

- FDA will consider phase-ins for small business, exemptions consistent with product safety, and the use of third-party certification of ingredient validation.
- Phase-in of fee amounts, as the program grows, to a maximum of $20.2 million.

Preemption

- FDA's ingredient findings will preempt state regulation of those cosmetic ingredients for human health purposes over which FDA has jurisdiction.
- States cannot have different specific regulatory requirements for: registration/listing, GMPs, or adverse event reporting.
- This would not preempt: product liability lawsuits, Proposition 65), or state environmental programs.

User Fees

- $20.2 million over base Congressional funding.