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An In-Depth Look At The Personal Care Products Safety Act

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Personal care products, which include cosmetics, are a large, profitable growth industry.[1] In the United States, cosmetics are regulated by the U.S. Food and Drug Administration under the Federal Food, Drug & Cosmetic Act. In general, the FDA regulates cosmetics to ensure they are not adulterated[2] or misbranded.[3][4] However, the FDA does not currently have the authority to order cosmetic recalls. Manufacturers are also currently not legally required to disclose consumer-reported, cosmetic-associated adverse effects and manufacturer facility registration with the FDA is voluntary.

The Personal Care Products Safety Act

On April 20, 2015, Sens. Dianne Feinstein, D-Calif. and Susan Collins, R-Maine, introduced a bipartisan bill, the Personal Care Products Safety Act,[5] which aims "to protect consumers and streamline industry compliance by strengthening the [FDA's] authority to regulate ingredients in personal care products."[6] The act, which is supported by the Personal Care Products Council (a 600+ member company trade association) and industry leaders such as Johnson & Johnson, Proctor & Gamble, Revlon, Unilever and L'Oreal, and consumer groups including the Environmental Working Group[7] and the Society for Women's Health Research,[8] would appear to have a reasonable chance of becoming law. If enacted, the act will be the most significant change in FDA cosmetic regulation in over 70 years.

The act is divided into two titles: Title I addresses cosmetic safety and Title II sets forth fees related to cosmetic safety. This article highlights provisions from Titles I and II deemed of highest import to cosmetics manufacturers.

The Act - Title I

Registration

Pharmaceutical and medical device manufacturers have long had mandatory FDA registration requirements. Cosmetics manufacturers currently have voluntary registration requirements. If the act becomes law, manufacturers and processors of cosmetic products and formulations distributed in the U.S. will be required to register their facilities with the FDA.[9][10] If the registering entity has average gross annual sales (for the previous three-year period) of greater than $500,000, a user fee must also be paid or registration will not be considered complete.[11] After the act becomes law, new manufacturers and processors of cosmetic products and formulations will have 60 days to register.[12] Registration must be submitted electronically using an FDA provided registration form, which will specify required content.[13] At the time of registration, the FDA will assign a unique identifier to the manufacturing or processing facility.[14]

Cosmetic Ingredient Statement

A cosmetic ingredient statement (CIS) must also be submitted to the FDA.[15] CISs are to be submitted electronically, using an FDA provided form. Required information includes:

- the facility's cosmetic product listing number (assigned by the FDA);
- the brand name and full name for the cosmetic product as it appears on the label;
- applicable cosmetic product category;
- a list of ingredients in the cosmetic product, including a range of possible amounts of each ingredient;
- title and full contact information of each individual submitting the statement; and
- such additional information pertaining to the cosmetic product as the [FDA] may require, including "an attestation that the safety of the product, including the individual ingredients of such product and the product as a whole, has been substantiated ..."[16]

The act also requires FDA notification should certain information related to the CIS change.[17] At submission, the FDA will assign a unique cosmetic product listing number to the CIS and shall make this information available to any state upon request. The act notes that information "disclosed to a state that is exempt from disclosure under [5 U.S.C. § 552(b)(4)], shall be treated as a trade secret and confidential information by the state."[18]

Notice and Suspension

If the FDA determines that a cosmetic formulation or product "manufactured, processed, packed, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans,"[19] and there is a reasonable probability to believe that other cosmetic formulations or products from the same facility may carry the same risk, the FDA can suspend the

facility's registration, the CIS, or both, after providing notice indicating specific actions to avoid suspension. If within two business days of notice the reasons for suspension are not addressed, the suspension can take effect.[20]

Suspension Effect

If a registration is suspended, the act mandates that "no person shall import or export cosmetics or otherwise distribute cosmetics from such facility."[21] If a CIS is suspended, "no person shall import or export or otherwise distribute in the United States such cosmetic product ..."[22]

FDA Review of Cosmetic Ingredients and Non-Functional Constituents

With the exception of color additives, there is currently no mandatory FDA review of cosmetic ingredients and nonfunctional constituents (collectively ingredients for purposes of this alert section). In contrast to the current state of affairs, the act also requires that starting in fiscal year 2016, the FDA will begin reviewing, on an annual basis, ingredients for safety. During fiscal year 2016, the act requires the FDA to review for safety:

1. Diazolidinyl urea;
2. Lead acetate;
3. Methylene glycol/methanediol/formaldehyde;
4. Propyl paraben; and
5. Quaternium-15.[23][24]

Starting in fiscal year 2017, the act requires the FDA to "annually select and complete review of at least five cosmetic ingredients that were not reviewed in the prior three years from a list determined in consultation with industry and consumer groups for review of safety."[25] The FDA will solicit public feedback on the ingredients to be reviewed, and if it determines there is adequate evidence to make an initial finding of ingredient safety, the FDA shall issue a proposed administrative order on the FDA's website. After providing 30 days for public comment and considering public comment, if the FDA determines there is adequate evidence to make a final finding on ingredient safety, the FDA will issue a final administrative order. If the ingredient is found to be safe under specified conditions of use, the order shall include: 1) limits on the amount or concentration of ingredient, 2) warnings that are necessary or appropriate (*e.g.*, for children, pregnant women, high risk populations) and 3) such other conditions as are necessary for the safety of cosmetic products containing the ingredient.[26]

In assessing the safety of an ingredient, the act directs the FDA to consider factors including:

- the probable human exposure to the ingredient;
- the probable cumulative and aggregate effect in humans of relevant exposure to the ingredient or to any chemically or pharmacologically related substances for use in cosmetics or other products with similar routes of exposure under recommended or suggested conditions for use;
- whether warnings would be necessary and appropriate;
- published and nonpublished studies;
- adverse event reports;
- findings from state, federal, national, and international entities and other bodies composed of scientific and medical experts;
- if the ingredient is lawfully used or present in other products regulated by the FDA and the scientific basis for such use; and
- experience with the ingredient in products distributed in the U.S. and other countries.[27]

Cosmetics Good Manufacturing Practices

Medical devices and pharmaceuticals have long been subject to current good manufacturing practices regulations (QSRs in the case of medical devices). In contrast, the FDA has issued draft guidance for cosmetic good manufacturing practices (GMPs).[28] The act changes the FDA's level of regulatory oversight by requiring that the FDA "shall develop and implement, through regulations, United States standards ... to ensure that the requirements of this chapter with respect to the manufacturer of cosmetic products are in harmony ... and shall publish a proposed rule ... not later than 18 months after the date of enactment ... and shall publish a final ... rule not later than three years after such enactment."[29] The act states that for large businesses, the GMPs "shall take effect beginning 180 days after ..." the final rule becomes effective and for small businesses, shall take effect "beginning two years after [this] date ..."[30]

Adverse Event Reporting

Adverse event reporting is currently encouraged, but not required, for cosmetic manufacturers. The act changes this, requiring serious adverse event reports to be filed with the FDA not later than 15 days "after information concerning the adverse event is received."[31] A serious adverse event for a cosmetic product is one that results in:

- death;
- a life-threatening experience;

- inpatient hospitalization;
- a persistent or significant disability or incapacity;
- congenital anomaly or birth defect; or
- significant disfigurement, including serious and persistent rashes and infections; or
- requires, based on appropriate medical judgment, a medical or surgical intervention to prevent an outcome described [above].[32]

The act also requires annual report submission to the FDA no later than March 1 of each year. The annual report is required to contain "a summary of all adverse events received during the reporting period, a complete list of the individual reports and an estimate of the total number of product units estimated to have been distributed to consumers during such period."[33]

Mandatory Recall Authority

The FDA currently lacks the authority to order mandatory recalls of cosmetic products and must seek court intervention if a manufacturer refuses to initiate a voluntary recall. The act changes this, setting up a two tiered process. If the FDA "determines that there is a reasonable probability that a cosmetic is adulterated ... or misbranded ... and the use of or exposure to such cosmetic is likely to cause serious adverse health consequences or death, the FDA shall provide ... an opportunity to voluntarily cease distribution and recall such article."[34] If the manufacturer declines voluntary cessation of distribution and recall, the FDA may order the manufacturer to "(A) immediately cease distribution of such cosmetic; and (B) as applicable, immediately notify all persons — (i) manufacturing, processing, packing, transporting, holding, receiving, distributing, or importing and selling such cosmetic; and (ii) to which such cosmetic has been distributed, transported, or sold, to immediately cease distribution of such cosmetic."[35]

Labeling

The act gives the FDA expanded labeling oversight. Specifically, the act recites that when a review of cosmetic ingredients "determines that warnings are required to help ensure safe use of cosmetic products ... the [FDA] shall require labeling of the cosmetics that are not appropriate for use in the entire population, including warnings that vulnerable populations, such as children or pregnant women, should limit or avoid using the product."[36] The act also stipulates that the warning "shall be prominently displayed — (1) in the primary language used on the label; and (2) in conspicuous and legible type in contrast by typography, layout, or color with other material printed or displayed on the label."[37]

In the case of internet sales, the act requires that "each Internet website offering cosmetic products for sale to consumers shall provide the same information that is included on the packaging of the cosmetic products as regularly available and the warnings and statements ... shall be conspicuously displayed."[38]

The act also requires that the cosmetic's label "shall bear the domestic telephone number or electronic contact information and it is encouraged that the label include both ... [so] that consumers may use [it] to contact [the manufacturer] with respect to adverse events."[39]

Animal Testing Alternatives

The act is concerned with growing sensitivity surrounding animal testing. To "minimize the use of animal testing for safety of cosmetic ingredients, non-functional constituents, and finished cosmetic products, the FDA shall — (1) encourage the use of alternative testing methods that provide information that is equivalent or superior in scientific quality to the animal testing method ..."[40] The act specifies that the FDA shall encourage tests that minimize the use of an animal, or that use fewer animals than conventional animal-based tests and that the FDA shall encourage the sharing of data across companies and organizations to avoid duplication of animal tests.[41]

The Act - Title II

Fees

The act contemplates that its requirements will necessitate an increase in FDA resources devoted to regulating cosmetics. Therefore, the act authorizes the FDA to collect annual user fees to be applied for this purpose.[42] The fees are tiered and for fiscal year 2016, look to generate an estimated revenue amount of $20.6 million.[43] For example, for a registrant that has gross annual sales of $5 billion or more in 2015, the user fee would be $1.1 million.[44] The act also contemplates user fee inflation adjustment.[45]

Analysis

If the act becomes law, cosmetics companies will face increased regulatory and financial burdens. Some companies will need to hire regulatory professionals. Companies will also need to implement changes to conform to the act. For example, companies will need to ensure that they timely and properly register facilities with the FDA and timely and properly submit CISs. Also, cosmetics companies will need to develop expertise in GMPs, make sure their manufacturing processes conform to the FDA's GMPs and

become adept at handling FDA inspections and audits. Companies will also need to track and timely pay fees, review their product labels to ensure that they are regulation compliant, implement adverse event reporting and monitor ingredients to ensure that they remain classified as safe for use. Finally, companies will need to put recall protocols in place in the event that a recall is required by the FDA.

Companies will be faced with the hard choice of passing along the increased costs to consumers or squeezing profit margins. Implementation of the act may result in consumer pushback to lawmakers because of increased cosmetics costs.

Conclusion

If it becomes law, the act will be the most significant change in FDA cosmetic regulation in over 70 years. The act is bipartisan and is broadly supported by industry and consumer groups. Thus, the act is likely to become law and companies should start preparing now for enactment.

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[1] U.S. 2015 personal care product revenues are estimated to exceed $60 billion.

[2] *See* 21 U.S.C. § 361.

[3] *See* 21 U.S.C. § 362.

[4] The U.S. Federal Trade Commission (FTC) also regulates cosmetic advertising under the FTC Act.

[5] Personal Care Products Safety Act, S. 1014, 114th Cong. (2015), available electronically at: http://www.feinstein.senate.gov/public/index.cfm/files/serve/?File_id=445a9268-4964-4de0-89f9-4caf577099f2, last accessed April 22, 2015.

[6] Press Announcement from the Office of Senator Dianne Feinstein, April 20, 2015, available electronically at: http://www.feinstein.senate.gov/public/index.cfm/press-

releases?ContentRecord_id=89ff88b8-5fb1-4617-b96a-c46547ca14ef, last accessed April 22, 2015.

[7] The Environmental Working Group maintains a database that rates the safety of over 68,000 cosmetic products. The database is electronically available at:http://www.ewg.org/skindeep/, last accessed April 22, 2015.

[8] Press Announcement from the Office of Senator Dianne Feinstein, April 20, 2015, available electronically at: http://www.feinstein.senate.gov/public/index.cfm/press-releases?ContentRecord_id=89ff88b8-5fb1-4617-b96a-c46547ca14ef, last accessed April 22, 2015.

[9] The act at pages 5-6. Registration must be completed not later than December 1, 2015.

[10] The act contains exemptions, based, *e.g.*, on type of business. Companies looking to understand if they qualify for an exemption should consult legal counsel.

[11] The act at page 6.

[12] *Id*.

[13] *Id*. at pages 7-8.

[14] *Id*. at page 10.

[15] *Id*. at page 11. Existing cosmetic products will require CIS submission no later than December 1, 2015. New cosmetic products, and reformulated cosmetic products first marketed after the act becomes law, will require CIS submission within 60 days of first marketing. Small businesses may have a longer submission window.

[16] *Id*. at page 18.

[17] *Id*. at page 19.

[18] *Id*. at page 21.

[19] *Id*.

[20] *Id*. at page 22.

[21] *Id*. at page 23.

[22] *Id*.

[23] *Id*. at pages 24-25.

[24] Diazolidinyl urea is a preservative used in cosmetics which is known to release formaldehyde. Lead acetate is an ingredient in some men's hair colorings. Lead is a neurotoxic metal. Methylene glycol, methanediol, and formaldehyde are used in hair treatments. Methylene glycol and methanediol are known to release formaldehyde. Propylparaben is a common cosmetic preservative and a known estrogen mimetic. Quaternium-15 is a surfactant and preservative, and a formaldehyde releaser that can cause contact dermatitis.

[25] The act at page 25.

[26] *Id*. at pages 28-31.

[27] *Id*. at pages 34-37.

[28] *See* "Guidance for Industry: Cosmetic Good Manufacturing Practices - Draft Guidance",*FDA*, last revised June 2013, available electronically at:http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM358287.pdf, last accessed April 22, 2015.

[29] *Id*. at pages 44-45.

[30] *Id*. at page 45.

[31] *Id*. at pages 47-48.

[32] *Id*. at page 47.

[33] *Id*. at pages 48-49.

[34] *Id*. at page 55.

[35] *Id*. at page 56.

[36] *Id*. at pages 60-61.

[37] *Id*. at page 62.

[38] *Id*.

[39] *Id*.

[40] *Id*. at pages 64-65.

[41] *Id*. at pages 64-65.

[42] *Id*. at pages 77-78.

[43] *Id*. at page 80.

[44] *Id*. at page 81.

[45] *Id*. at page 87.