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Deborah E. Mason

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# NOTE

## KISS AND MAKE-UP: A NEED FOR CONSOLIDATION OF FDA AND COSMETIC INDUSTRY REGULATION PROGRAMS

*Deborah E. Mason*<sup>†</sup>

### INTRODUCTION

The Food and Drug Administration (FDA) protects all consumers in the U.S. “with a broad umbrella of safeguards that enables them to go about their daily business without worries about the safety of the myriad products FDA regulates.”<sup>1</sup> Cosmetics are among the products regulated by the FDA.<sup>2</sup> The Federal Food, Drug, and Cosmetic Act (the FDA Act) is the law regulating food and drug safety in the U.S. This law is intended to “assure consumers . . . that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.”<sup>3</sup> Despite the law’s intended assurances, John E. Bailey, director of the FDA’s Division of Color and Cosmetics, said, “[m]ost cosmetics contain ingredients that are promoted with exaggerated claims of beauty or long-lasting effects to create an image . . . . Image is what the cosmetic industry sells through its products, and it’s up to the consumer to believe it or not.”<sup>4</sup>

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<sup>†</sup> J.D. Candidate 2008, Case Western Reserve University School of Law

<sup>1</sup> U.S. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., FDA’S GROWING RESPONSIBILITIES FOR THE YEAR 2001 AND BEYOND I (2001), <http://www.fda.gov/oc/opacom/budgetbro/budgetbro.html> [hereinafter FDA’S GROWING RESPONSIBILITIES].

<sup>2</sup> *Id.* at 2.

<sup>3</sup> Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., Regulations and Policies and Procedures for Postmarketing Surveillance Programs <http://www.fda.gov/cder/regulatory/applications/Postmarketing/regpostmarket.htm> (last visited Sept. 28, 2007).

<sup>4</sup> Judith E. Foulke, *Cosmetic Ingredients: Understanding the Puffery*, FDA CONSUMER, May 1992, <http://www.fda.gov/fdac/reprints/puffery.html> (quotations omitted).

A survey conducted in 2004 by the National Consumers League revealed that six out of ten adults believe that the FDA tests anti-aging [one form of cosmetic product] for safety and efficacy, when in reality, this is untrue.<sup>5</sup> By inadequately regulating the cosmetic industry, the FDA, a body whose mission statement proclaims responsibility for, “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,”<sup>6</sup> is failing the American public by its inadequate regulation of the cosmetic industry.

The FDA requires drugs undergo thorough testing before the agency will consider approving them and placing them on the market.<sup>7</sup> Cosmetic products, on the other hand, do not require extensive testing or pre-market approval by the FDA.<sup>8</sup> As such, “many cosmetic companies avoid testing the ingredients in their products,” or avoid publicizing the results of these tests in an effort to avoid the labeling requirements for products meeting the definition of a “drug.”<sup>9</sup> This is especially problematic since some scientists believe “that some of the chemicals found in commonly used health and beauty products can, in sufficient quantity, cause cancer, birth defects or disrupt hormone function.”<sup>10</sup> Dibutyl phthalates, for example, a chemical used to soften plastics and found in nail polish and other cosmetic products, have been linked to development problems in the male genitals of humans and rats.<sup>11</sup> The drug versus cosmetic controversy has led some scientists and researchers to call for the creation of a new category, “cosmeceuticals,” “to allow the necessary testing of the products for patient use, while at the same time protecting the interests of the cosmetic companies.”<sup>12</sup>

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<sup>5</sup> Erika Kawalek, *Artfully Made-Up*, LEGAL AFF., Nov.–Dec. 2005, at 54, 55.

<sup>6</sup> U.S. Food & Drug Admin., FDA’s Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Sept. 28, 2007).

<sup>7</sup> Melissa C. Lazarus & Leslie S. Baumann, *The Use of Cosmeceutical Moisturizers*, 14 DERMATOLOGIC THERAPY 200, 200 (2001).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> Lisa Stiffler, *Putting on Your Face Can Become Pretty Ugly: Chemicals in Cosmetics Linked to Cancer, Birth Defects*, SEATTLE POST-INTELLIGENCER, Nov. 6, 2006, at A1, available at [http://seattlepi.nwsource.com/health/291217\\_cosmetics06.html](http://seattlepi.nwsource.com/health/291217_cosmetics06.html).

<sup>11</sup> *See id.* (explaining that some nail polish companies have agreed to phase out dibutyl phthalate, a chemical that may be a human reproductive toxin).

<sup>12</sup> Lazarus & Baumann, *supra* note 7 at 200.

Those calling for the new category cite drugs on the market that are also available in cosmetic form, including lactic acid (known as Lac Hydrin in prescription form), and the drug Regranex.<sup>13</sup> Both drugs are in over the counter cosmetic products.<sup>14</sup> The call for the creation of this hybrid category by various consumer groups claims that in order to learn more about the healing powers of these ingredients, “[c]osmetic companies should be encouraged to perform these studies on their products, despite the fact that it may cause them to lose their product’s *cosmetic* label.”<sup>15</sup> The FDA has not recognized the cosmeceutical category, therefore no FDA-approved definition exists; however, the industry defines cosmeceuticals as “a cosmetic product that claims to or has been found to have biologic activity.”<sup>16</sup>

In January, 2005, FDA District Director B. Belinda Collins issued a warning letter to Basic Research, the marketer and distributor of numerous cosmetic products including StriVectin-SD.<sup>17</sup> Collins wrote the letter in reference to Basic Research’s marketing and distribution of StriVectin-SD, StriVectin-SD Eye Cream, Dermalin-Apg, MarmalinAra, and TestroGel; the letter described some of the claims made by Basic Research about these products, including: “‘Clinically Proven to Dramatically Reduce the Appearance of Existing Stretch Mark Length, Depth, Texture, and Discoloration’; ‘Optimum Glycosaminoglycan and Collagen Synthesis’; ‘Better than Botox®?’; and ‘Superior wrinkle-reducing properties of a patented oligo-peptide.’”<sup>18</sup> The letter lists nearly 40 other claims made for Basic Research products which would rightfully categorize the products as drugs.<sup>19</sup> Because of these claims, StriVectin-SD and the other Basic Research Products were wrongfully labeled cosmetics.<sup>20</sup> However, by the time Collins issued a warning letter, StriVectin-SD’s 2005 earnings were already on their way to the \$100 million mark, “a sign of FDA inaction and consumer confusion.”<sup>21</sup>

FDA warning letters are effective in curtailing FDA Act violations once discovered. However, the FDA does not have the re-

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<sup>13</sup> *Id.* at 206.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* (emphasis added).

<sup>16</sup> *Id.* at 200.

<sup>17</sup> Kawalek, *supra* note 5, at 57.

<sup>18</sup> *Id.* (quoting Letter from B. Belinda Collins, District Director, U.S. Food & Drug Admin., to Dennis Gay, Chief Executive Officer, Basic Research (Jan. 20, 2005), available at [http://www.fda.gov/foi/warning\\_letters/archive/g5195d.htm](http://www.fda.gov/foi/warning_letters/archive/g5195d.htm)).

<sup>19</sup> *Id.*

<sup>20</sup> *See id.* (reporting that Basic Research’s questionable marketing practices caused the FDA to issue a warning letter).

<sup>21</sup> *Id.*

sources to seek out every violation, issue a warning letter, and subsequently protect consumers from the misleading advertisements and potentially unsafe products. "For every FDA warning letter [sent], thousands of misbranded cosmetics... slip by."<sup>22</sup> Had Basic Research identified these products as drugs, the FDA would have required product and ingredient testing, for both safety and efficacy, prior to approving the products. By labeling the items as cosmetic products, however, Basic Research was able to sell them across the U.S., making unsubstantiated claims about both safety and efficacy, without any FDA oversight or regulation. Consumers purchased StriVectin-SD and other Basic Research Products, relying on the statements made about these product. They were misled and unprotected. As a result of the issues exemplified by this type of violation, an improved system of oversight is necessary to adequately protect American consumers.

This Note identifies the dichotomy between drug and cosmetic products and calls attention to the cosmetic industry's current self-regulation programs. This Note also explores more stringent systems of review in countries outside the U.S., as well as in individual U.S. states while identifying the need for more stringent safety regulations in the U.S. on cosmetic products and the ingredients used in those products.

The purpose of this Note is to suggest possible regulatory changes which, if enacted, would increase the safety testing of cosmetic ingredients and products. This Note will also outline the roles of both the FDA and the cosmetic industry following these changes to the regulatory systems. Finally, this Note strives to increase public awareness as to the current level of FDA regulation of cosmetic products and ingredients, as well as the cosmetic industry's role in establishing additional regulatory methods.

## I. BACKGROUND OF THE FDA

The FDA enforces three laws: the FDA Act, the FDA Modernization Act of 1997, and the Bioterrorism Act of 2002.<sup>23</sup> These laws establish the spectrum of oversight granted to the FDA on products ranging from drugs to cosmetics. Prescription drugs (New Drug Applications) are the most regulated of all products the FDA oversees,

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<sup>22</sup> *Id.*

<sup>23</sup> See generally Paul Hyman, *U.S. Food and Drug Law and FDA – A Historical Background*, in *A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION* 15, 15-45 (Kenneth R. Piña & Wayne L. Pines eds., 2d ed. 2002) (outlining the jurisdiction and the legislation governing the FDA's actions).

requiring: “(1) preclinical investigation (laboratory and animal testing); (2) clinical investigation (human testing); (3) FDA review of the application; [and] post-marketing[,] [with] each of these phases involv[ing] varying levels of FDA oversight.”<sup>24</sup> Medical devices follow closely behind prescription drugs in their level of FDA regulation.<sup>25</sup> Three classes of medical devices exist, and regulation varies depending on the class, however, at its most lenient, the FDA regulates Class I devices by applying “general controls,”<sup>26</sup> which include “requirements for facility registration and product listing with [the] FDA, pre-market notification ... maintenance of records and filing reports with respect to device marketing experience, adherence to good manufacturing practices, ... and any distribution and use limitations [the] FDA may impose.”<sup>27</sup> Additionally, the FDA has the authority to ban Class I devices “that present substantial deception or significant risks, and/or to detain devices that are alleged to violate the FDA Act, pending legal action.”<sup>28</sup> Class I, this least regulated category of devices, includes elastic bandages, examination gloves and handheld surgical instruments.<sup>29</sup> Class II devices are subject to more stringent requirements, including performance standards, post-market surveillance and patient registries, whereas Class III devices require pre-market approval.<sup>30</sup>

The FDA moderately regulates animal drugs and food additives, with approval required before a company can introduce the products into the U.S. market.<sup>31</sup> General food products are regulated slightly less than additives, while cosmetic products are the least regulated,

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<sup>24</sup> Geoffrey M. Levitt, *The Drugs/Biologics Approval Process*, in A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 89, 89 (Kenneth R. Piña & Wayne L. Pines eds., 2d ed. 2002).

<sup>25</sup> See Edward C. Wilson, Jr. & Laurie A. Clarke, *The Medical Device Approval Process*, in A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 127, 128 (Kenneth R. Piña & Wayne L. Pines eds., 2d ed. 2002) (explaining that medical devices that present a significant risk are subjected to strict review before the FDA approves them for use).

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 128-29.

<sup>31</sup> See Levitt, *supra* note 24, at 122 (explaining the required showing of safety and efficacy for animal drugs to be approved and that they are subjected to post-approval regulatory oversight as well); see also Megan L. Foster & Daniel R. Dwyer, *The Regulation of Dietary Supplements*, in A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 215, 215 (Kenneth R. Piña & Wayne L. Pines eds., 2d ed. 2002) (describing specific legislation that was enacted to regulate the niche area of dietary supplements).

requiring no independent review of safety studies, or any FDA approval prior to market introduction.<sup>32</sup>

### A. Drugs vs. Cosmetics

Currently, a typical cosmetic product making its way to the U.S. market, for example a face cream, may be classified by the FDA as either a cosmetic or a drug. The product is appropriately classified as a drug if it is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . . and [if it is an] article[] (other than food) intended to affect the structure or any function of the body of man or other animals.”<sup>33</sup> The FDA is involved in examining drugs through both preclinical and clinical investigation.<sup>34</sup> The preclinical phase is subject to good laboratory practices (GLPs), a specific FDA regulation, published in the Code of Federal Regulations, which establishes specific requirements for certain aspects of laboratory practice, subjects the laboratory to FDA inspectional oversight, and assigns penalties for noncompliance.<sup>35</sup> “The primary purpose of the preclinical investigation is to gather sufficient evidence about the proposed new drug to proceed to the next regulatory stage” – clinical testing of the product on humans.<sup>36</sup> Prior to the commencement of clinical trials, the producer must give the FDA formal notification, typically called an Investigational New Drug (IND), in addition to submitting other information, about the drug itself as well as the proposed clinical trials.<sup>37</sup> Clinical trials may begin only if the FDA does not object to the information provided by the producing company. If the FDA finds a problem with the application or IND, it can impose a “hold” on

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<sup>32</sup> See Foster & Dwyer, *supra* note 31, at 215 (explaining that food regulations are less stringent than those enacted for dietary supplements); see also Thomas J. Donegan, Jr. & Catherine C. Beckley, *The Cosmetics Regulatory Process, in A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION* 149, 152-54 (Kenneth R. Piña & Wayne L. Pines eds., 2d ed. 2002) (describing the FDA’s approach to regulating the cosmetic industry and explaining that it is mostly a self-regulating industry).

<sup>33</sup> OFFICE OF COSMETICS & COLORS, U.S. FOOD & DRUG ADMIN., IS IT A COSMETIC, A DRUG, OR BOTH? (OR IS IT SOAP?) (2002), <http://www.cfsan.fda.gov/~dms/cos-218.html> [hereinafter IS IT A COSMETIC] (citation omitted).

<sup>34</sup> See Levitt, *supra* note 24, at 90-91 (describing the process and FDA oversight involved in preclinical and human clinical drug investigation).

<sup>35</sup> *Id.* at 90.

<sup>36</sup> *Id.* at 91.

<sup>37</sup> See *id.* at 91-92 (outlining the specific steps to be taken and information to be provided to the FDA prior to beginning a human clinical investigation).

the clinical trials, halting testing until the problem is resolved.<sup>38</sup> The application, among other things, must include:

[A] detailed “investigative plan” addressing ... the rationale behind the planned clinical research, an outline of the proposed approach, the types of clinical trials to be conducted, an estimate as to the number of patients involved ... a discussion of any significant anticipated patient risks based on toxicological data ... [and] a commitment from the sponsor to conduct clinical trials under the supervision of an Institutional Review Board (IRB), and to follow all applicable rules and regulations.<sup>39</sup>

In contrast, a product intended “to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance,” is a cosmetic.<sup>40</sup> Currently, the FDA does not mandate any pre-market regulation of cosmetics.<sup>41</sup> While manufacturers must test products and ingredients for safety, color additives are the only cosmetic ingredients requiring pre-approval by the FDA.<sup>42</sup> Because pre-approval is not required for other ingredients, the “FDA enacted a labeling requirement for products where safety has not been substantiated before marketing.”<sup>43</sup> Cosmetic products with unsubstantiated safety claims must label their products with the proper warning: “[t]he safety of this product has not been determined.”<sup>44</sup>

Under its limited authority, the FDA may regulate “adulterated” and “misbranded” cosmetics after they have been sold in the U.S. market. The federal government deems a cosmetic “adulterated” if:

“it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual” [with an exception made for hair dyes]; “it consists in whole or in part of any filthy putrid, or decomposed substance”; “it has been prepared, packed, or held under insanitary conditions whereby it may have become

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<sup>38</sup> *Id.* at 92.

<sup>39</sup> *Id.*

<sup>40</sup> IS IT A COSMETIC, *supra* note 33.

<sup>41</sup> Donegan & Beckley, *supra* note 32, at 149.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 150.

<sup>44</sup> *Id.*



contaminated with filth, or whereby it may have been rendered injurious to health"; "its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health"; or except for hair dyes, "it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a)" of the FD&C Act.<sup>45</sup>

The federal government considers a cosmetic "misbranded" if: (1) its labeling is false or misleading; (2) in package form it does not bear a label containing identification of its manufacturer, and an accurate statement of the contents; or (3) its container is made to be misleading.<sup>46</sup> The FDA justifies its "consumer choice" theory of protection by mandating "an ingredient declaration to enable consumers to make informed purchasing decisions."<sup>47</sup>

Unfortunately, the labeling of a product as a drug rather than a cosmetic, and the increased regulatory compliance such a label requires provides an incentive for producers to avoid this categorization. The resulting side-effect is an abundance of cosmetic products which would be more appropriately labeled drugs. The incentive to avoid the drug category, and its accompanying regulations, shows a failure of the FDA's system of regulation, while doing a disservice to consumers.

Even more problematic, some products, especially those with more than one intended use, can meet both definitions and therefore may actually be both a drug and a cosmetic product. Anti-dandruff shampoo, which both cleans hair and treats dandruff, is an example of drug/cosmetic hybrid product.<sup>48</sup> The FDA determines a product's intended use in three primary ways: (1) through claims made by the product's producer; (2) through consumer perception of the product's purpose; and (3) through ingredients in the product.<sup>49</sup> If the producer makes claims while advertising, labeling, or promoting the product that show the intended use of the product is to "treat or prevent disease or otherwise affect the structure or functions of the human body," despite the fact that the product is marketed as a cosmetic, that prod-

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<sup>45</sup> OFFICE OF COSMETICS & COLORS, U.S. FOOD & DRUG ADMIN., FDA AUTHORITY OVER COSMETICS: WHAT DOES THE LAW SAY ABOUT COSMETIC SAFETY AND LABELING? (2005), <http://vn.cfsan.fda.gov/~dms/cos-206.html> [hereinafter FDA AUTHORITY OVER COSMETICS] (citation omitted).

<sup>46</sup> *See id.*

<sup>47</sup> *Id.*

<sup>48</sup> IS IT A COSMETIC, *supra* note 33.

<sup>49</sup> *Id.*

uct should be labeled as a drug.<sup>50</sup> Further, if consumers purchase the product because they perceive (either through advertising or through the product's reputation) that it will "treat or prevent disease or otherwise affect the structure or functions of the human body," the product should be labeled as a drug.<sup>51</sup>

### B. Fair Packaging and Labeling Act

The Fair Packaging and Labeling Act (FPLA) was enacted to help inform consumers and enable them to obtain accurate information as to the contents of the products they purchase, keeping in mind that informed consumers are essential to efficient functioning of a free market economy.<sup>52</sup> FPLA requires cosmetic labels to contain: the identity of the commodity, the name and place of business of the manufacturer, packer or distributor of the product, and the net quantity of the product's contents, "separately and accurately stated in a uniform location upon the principal display panel of that label."<sup>53</sup> FPLA makes it unlawful to distribute (or cause to be distributed) in commerce any commodity if it is contained in a package which does not conform to the act's provisions. Unfortunately, many consumers do not inspect their purchases for unsafe ingredients, and for an untrained consumer, labeling products for the presence of unsafe contents does not protect against the contents' risk.

The "FDA is not authorized to require recalls of cosmetics but does monitor companies that conduct a product recall and may request a product recall if the firm is not willing to remove dangerous products from the market without [the] FDA's written request."<sup>54</sup> While domestically produced cosmetics are not subject to FDA pre-market approval, the FDA may inspect production facilities and product samples *after* receiving complaints of adverse reactions.<sup>55</sup>

### C. Industry Self-Regulation

The cosmetic industry has made engaged in efforts to self-regulate through programs established by both FDA and Cosmetic Toiletry and Fragrance Association (CTFA). Currently, two programs exist to regulate the cosmetic industry.

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<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> Fair Packaging and Labeling Act, 15 U.S.C. § 1451 (2000).

<sup>53</sup> *Id.* § 1453(a)(1)-(2).

<sup>54</sup> FDA AUTHORITY OVER COSMETICS, *supra* note 45.

<sup>55</sup> *See id.*

### 1. Voluntary Cosmetics Registration Program

In the early 1970s the FDA established the Voluntary Cosmetics Registration Program (VCRP) at the request of the cosmetics industry.<sup>56</sup> At its inception, the VCRP created a system through which companies could report post-market data to the FDA “on cosmetic products being sold to consumers in the United States.”<sup>57</sup> Originally VCRP registration was comprised of three parts: (1) registration of the location of the cosmetic manufacturing or packing establishment; (2) filing of both the ingredient formulation of a cosmetic product already on the market in the U.S. and any raw materials used in the product; and (3) annual reporting of the number and type of adverse reaction complaints from consumers or physicians.<sup>58</sup> Since its creation, the VCRP has been modified by the FDA.<sup>59</sup> The current VCRP registration requires only: (1) registration of the location of the cosmetic manufacturing or packing establishment; and (2) filing of the ingredient formulation of a cosmetic product already on the market in the U.S.<sup>60</sup> Raw material use and the annual reporting of adverse reactions are no longer included in the VCRP.<sup>61</sup>

Registration in the VCRP does not equate to FDA approval or endorsement of a cosmetic producer, product, or materials used.<sup>62</sup> Further, only about 35 percent of eligible companies participate in VCRP,<sup>63</sup> meaning that nearly 65 percent of producing companies are unregulated.

### 2. Cosmetic Ingredient Review

In the early 1970s, Congress considered legislation to amend the FDA Act, which would have required pre-market safety testing for cosmetic products similar to that currently required for drugs.<sup>64</sup> Since the FDA lacked the resources necessary to inspect facilities and re-

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<sup>56</sup> M.V. Waleski, L.K. Parker & D.C. Havery, Abstract to *History of FDA's Voluntary Cosmetics Registration Program*, FDA SCI. F., available at [http://www.accessdata.fda.gov/scripts/oc/scienceforum/sf2006/Search/preview.cfm?abstract\\_id=1102&backto=author](http://www.accessdata.fda.gov/scripts/oc/scienceforum/sf2006/Search/preview.cfm?abstract_id=1102&backto=author).

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> Foulke, *supra* note 4.

<sup>63</sup> *Id.*

<sup>64</sup> Wilma F. Bergfeld et al., *Safety of Ingredients Used in Cosmetics*, 52 J. AM. ACAD. DERMATOLOGY 125, 125 (2005).

view safety data, Congress did not institute this legislation.<sup>65</sup> Instead, the cosmetic industry established their own industry-wide self-regulatory program.<sup>66</sup>

The Cosmetic Ingredient Review (CIR) program sponsored by the Cosmetic, Toiletry and Fragrance Association<sup>67</sup> (CTFA), is an industry sponsored self-regulation program implemented by a panel of scientific and medical experts who evaluate cosmetic ingredients for safety.<sup>68</sup> “The CIR mission statement calls for the thorough review and assessment of the safety of ingredients used in cosmetics in an open, unbiased, and expert manner . . .”<sup>69</sup> with results and detailed reviews of available safety data published in “peer-reviewed scientific literature.”<sup>70</sup>

The CIR catalogues cosmetic ingredients in an International Cosmetic Ingredient Dictionary and Handbook, and reviews the ingredients based on a priority system determined by the frequency of use and potential biologic activity.<sup>71</sup> The CIR Expert Panel reviews cosmetic ingredients regularly, and classifies the ingredients into categories, including: “safe as used, safe with qualifications, unsafe, and insufficient data.”<sup>72</sup> The ingredients as well as the Expert Panel’s findings are listed on the CIR website.<sup>73</sup>

Out of nearly 1200 individual cosmetic ingredients reviewed, the cosmetic industry through the CIR Expert Panel, has identified limitations on 33 percent of ingredients reviewed, and has placed an alert on another 9 percent.<sup>74</sup> Further, “a handful of ingredients have been identified [by the Expert Panel] as unsafe for use in cosmetics.”<sup>75</sup>

Unfortunately, the CIR is unable to review every cosmetic product on the market. CIR review is voluntary and as such only regulates

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<sup>65</sup> *See id.*

<sup>66</sup> *Id.* at 126; *see also* Donegan & Beckley, *supra* note 32, at 150 (noting that the cosmetic industry works alongside the FDA to ensure the safety of their products).

<sup>67</sup> The Cosmetic, Toiletry and Fragrance Association is also referred to by some as the Personal Care Products Council.

*See* <http://www.personalcarecouncil.org/> (last visited March 31, 2008).

<sup>68</sup> Foulke, *supra* note 4.

<sup>69</sup> Bergfeld et al., *supra* note 64, at 126.

<sup>70</sup> *Id.*; *see also* Foulke, *supra* note 4.

<sup>71</sup> Bergfeld et al., *supra* note 64, at 126.

<sup>72</sup> *Id.* at 128.

<sup>73</sup> *Id.*; *see also* Cosmetic Ingredient Review, Cosmetic Ingredient Findings: 1976 – Current, <http://www.cir-safety.org/findings.shtml> (last visited Sept. 16, 2007) (listing the CIR’s findings with respect to investigations on cosmetic ingredient safety).

<sup>74</sup> Bergfeld et al., *supra* note 64, at 131.

<sup>75</sup> *Id.*

products submitted by their manufacturers for review.<sup>76</sup> “The Environmental Working Group’s report *Skin Deep* states that 89 [percent] of ingredients used in personal care products have not been evaluated for safety by the CIR, the FDA, nor any other publicly accountable institution.”<sup>77</sup> Without the CIR, however, no systematic examination of the safety of individual cosmetic ingredients would exist, as the FDA currently has no statutory authority to require that products be submitted for any type of pre-market review.<sup>78</sup> This industry instituted program is currently the only safety testing of its kind for U.S. cosmetic products.

## II. MORE STRINGENT REVIEW NEEDED

The level of review currently in place in the U.S. is much more lenient than that of other countries, and as a result, some U.S. states have enacted their own more stringent standards. Products from an array of categories also regulated by the FDA are subject to much stronger, mandatory testing, leading U.S. consumers to assume that cosmetic products are regulated in a similar fashion.<sup>79</sup> The discrepancy between the perception of American consumers and the level of regulation currently in place for cosmetic producers necessitates the development of a stronger U.S. regulatory system.

### A. International Regulation

Countries outside the U.S. have recognized the inherent risk in cosmetic ingredients, and as such established stringent review requirements for cosmetic products. The EU banned the sale of cosmetics or personal care products that contain any ingredients on a list of more than one-thousand chemicals known or suspected of causing cancer, genetic mutations, or birth defects;<sup>80</sup> in the U.S., the FDA has banned only nine such ingredients.<sup>81</sup> The EU also mandates, “[A] compilation of information on each cosmetic product (dossier) must be kept readily accessible for inspection by the competent authorities

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<sup>76</sup> *Id.* at 126.

<sup>77</sup> Think Before You Pink, Corporate Cover-Up: The Regulation of Our Cosmetics, <http://www.thinkbeforeyoupink.org/Pages/CorporateCoverUp.html> (last visited Sept. 29, 2007) (citation omitted).

<sup>78</sup> See Foulke, *supra* note 4; see also Kawalek, *supra* note 5, at 56.

<sup>79</sup> See Kawalek, *supra* note 5, at 56 (reporting that many similar products are FDA tested, while cosmetics are not).

<sup>80</sup> See Stiffler, *supra* note 10; Walgreen Co., SEC No-Action Letter, 2006 SEC No-Act. LEXIS 638, at \*9 (Oct. 13, 2006) (citation omitted).

<sup>81</sup> Walgreen Co., SEC No-Action Letter, 2006 SEC No-Act. LEXIS 638, at \*11; Stiffler, *supra* note 10.

of the Member State concerned at the address specified on the cosmetic package.”<sup>82</sup> This dossier:

should contain information on the qualitative and quantitative composition of the products, its physico-chemical and microbiological specifications, the method of manufacture, evaluation of its safety for human health, the name, address and qualifications of the safety assessor, existing data on undesirable effects on human health, proof of the effect(s) claimed and data on any animal testing performed relating to the development or safety evaluation of the product or its ingredients.<sup>83</sup>

The dossier is called a Technical Information File (TIF) and usually consists of four parts:

(1) An administrative dossier: [t]rade name of the product and responsible company, manufacturer or distributor[;] [p]roduct category[;] [i]ntegral composition of the product[;] [and] identification of persons with ultimate responsibility [for the product]. (2) An ingredients dossier: [i]dentify(ies), supplier(s) and composition(s) of the ingredients[;] [d]etails on manufacturer(s) and supplier(s) of the ingredients[;] [p]hysico-chemistry and microbiology of the ingredients . . . [;] [t]oxicity data . . . [;] [f]irst aid measures[;] [r]isk and safety instructions . . . [;] [l]ist of animal tests performed with the ingredient. (3) A finished product dossier: [f]abrication of the product with place(s) of manufacturing, methodology, identification of person responsible for manufacturing[;] [s]tability of the product including physical and microbiological stability[;] [p]hysico-chemical properties and microbiological data on the finished product including examinations[;] [s]afety data concerning the finished product including an overview of the toxicological data of the ingredients; the communication done with the national competent authorities and the poison control centres [sic.]; toxicological animal testing performed on the finished product; toxicological tests using alternative methods; human tests performed on the finished product; an undersigned safety evaluation with the iden-

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<sup>82</sup> Marleen Pauwels & Vera Rogiers, *Safety Evaluation of Cosmetics in the EU Reality and Challenges for the Toxicologist*, 151 TOXICOLOGY LETTERS 7, 9 (2004).

<sup>83</sup> *Id.*

tification of the safety assessor and the appropriate credentials[;] [e]fficacy of the finished product . . . [;] [p]ackaging and labeling . . . (4) Follow-up dossier of the market: a good functioning post-market complaint system, where consumers can communicate eventual complaints must be installed. All undesirable effects on human health reported during use of the product and their follow-up by the responsible manufacturer or marketer, must be added to the dossier.<sup>84</sup>

Although the EU has established a more in depth system of regulation than that currently existing in the U.S., compiling a list of unsafe ingredients is an imperfect, and temporary, solution to a larger problem. A list format is effective only when the list contains every possible dangerous cosmetic ingredient. With the passage of time, however, lists become out of date, and as such, the system of regulation is ineffective.

The EU's TIF dossier program is a more effective regulatory mechanism than the U.S.'s ingredient list or, post-market complaint system. This information, however, is only effective if consumers know of its existence and can easily access and understand it. If consumers are unaware of data identifying undesirable health effects surfacing after a product's use in the market, they are unable to protect themselves, thereby making the data irrelevant as a consumer protection device. Currently in the U.S., the CTFA is in the process of initiating a new program, the Consumer Commitment Code (CCC).<sup>85</sup> CCC, which will include a dossier program similar to that established by the EU, will make safety information more easily accessible to the FDA. To participate in the program, companies must provide a safety information summary to the FDA upon request. This summary will list information including raw material specifications, particle size, and "a statement that the product's safety has been substantiated."<sup>86</sup>

While CCC is a step in the right direction, the CTFA has no regulatory authority to mandate FDA inspection, pre-market approval, or cosmetic manufacturer participation in the program. The EU TIF dossier program mandates participation by all cosmetic producers in a program which already outlaws the use of over one-thousand harmful, or potentially harmful ingredients. Although the EU program is not

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<sup>84</sup> *Id.* at 9-10.

<sup>85</sup> Comment from Env'tl. Working Group, to U.S. Food & Drug Admin., A Survey of Ingredients in 25,000 Personal Care Products Reveals Widespread Use of Nano-Scale Materials, Not Assessed for Safety, in Everyday Products (Oct. 10, 2007), <http://www.ewg.org/node/21738>.

<sup>86</sup> *Id.*

the ideal method of regulation, at the very least, the EU has the authority to mandate compliance. The CTFA can not require cosmetic producers to participate in the CCC program.

Voluntary systems in the U.S. like CCC, VCRP and CIR will not create the level of effective regulation necessary to effectively protect consumers. One main problem with the current FDA regulatory scheme is that U.S. consumers believe that products are approved by the FDA prior to market introduction. John Bailey, director of FDA's Office of Cosmetics and Colors has said, "[c]onsumers believe that 'if it's on the market, it can't hurt me' . . . [a]nd this belief is sometimes wrong."<sup>87</sup> In fact, "[t]he ingredient list on a cosmetic container is the only place where a consumer can readily find out the truth about what he or she is buying."<sup>88</sup> Consumers can check the listing to identify substances they wish to avoid, however, if they do not know which substances they should avoid, the ingredient list provides only an illusory protection against the risk cosmetic ingredients pose.

### B. Individual State Regulation

In the absence of strong FDA regulations, some U.S. states have heightened their rules, enacting stronger regulations than those of the FDA. California lawmakers, for example, adopted the Safe Cosmetics Act of 2005 (SCA).<sup>89</sup> SCA is a response to independent testing in the U.S. and the EU, both of which determined that some cosmetic products contain substances known or suspected to cause cancer and reproductive toxicity.<sup>90</sup> Further, because neither the FDA nor the State Department of Health Services required pre-market safety testing, review, or approval of cosmetic products, California legislators created the SCA to fill this gap. The SCA requires cosmetic manufacturers to provide the state with a list of product ingredients which can cause cancer or reproductive harm.<sup>91</sup> SCA concludes:

[g]iven the presence of substances in cosmetic products that cause cancer and reproductive toxicity, the heavy use of these products by women of childbearing age, the significant exposure to these products in occupational settings such as nail and beauty salons, the adverse impacts of these substances on hu-

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<sup>87</sup> Carol Lewis, *Clearing Up Cosmetic Confusion*, FDA CONSUMER, May-June 1998, [http://www.fda.gov/fdac/features/1998/398\\_cosm.html](http://www.fda.gov/fdac/features/1998/398_cosm.html).

<sup>88</sup> *Id.*

<sup>89</sup> Stiffler, *supra* note 10.

<sup>90</sup> California Safe Cosmetics Act of 2005, 2005 Cal. Legis. Serv. ch. 729, § 1(a) (West).

<sup>91</sup> *Id.* § 1(b).



man health, the inadequate information about the presence of these substances in products or the extent of their impacts, and the availability of alternatives to the use of these substances, it is in the interest of the people of the State of California to take steps to ensure that cosmetic products sold and used in the state can be used safely.<sup>92</sup>

This heightened regulation by the California legislature is another step in the right direction, however, SCA only requires that companies provide the state with a list of potentially harmful ingredients. SCA does not require any form of testing prior to market introduction. As explained above, lists of prohibited ingredients do not regulate effectively. When new, yet harmful, ingredients are developed, consumers will not be protected against them simply because they were not included on an already developed list of harmful ingredients. Instead, a system which requires testing and post-market reporting of complications is more effective.

The SCA legislation is, however, beneficial because in mandating disclosure of ingredients which can cause cancer or reproductive harm, the legislation encourages cosmetic producers to test and learn more about their ingredients. Such testing is beneficial to the industry and to consumers, and it has been a priority of scientists and researchers calling for the creation of a “cosmeceutical” category,<sup>93</sup> yet it has frequently been avoided by cosmetic producers aiming to avoid a “drug” label for their products.<sup>94</sup>

### III. PROPOSED REGULATORY CHANGES

The level of regulation currently provided by the FDA is inadequate. A purely reactive system of product regulation, like the one currently in place, is ineffective because it necessitates the existence of a problem before producers are sufficiently incentivized to find a solution. Although the FDA definition of a cosmetic product clearly differs from the FDA definition of a drug, the actual distinction between cosmetic products and drugs has blurred over time and many products could fall into a hybrid category of “cosmeceuticals.”<sup>95</sup> These products may have multiple purposes, however the current incentive for producers to categorize products as cosmetics puts Ameri-

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<sup>92</sup> *Id.* § 1(j).

<sup>93</sup> Lazarus & Baumann, *supra* note 7.

<sup>94</sup> *Id.*

<sup>95</sup> See Natasha Singer, *A Word from Our Sponsor*, N.Y. TIMES, Jan. 25, 2007, at G1.

can consumers at risk by avoiding the pre-market testing and FDA approval required of drug products.

“The public at large and a wide array of interest groups in American society demand the presence of FDA in the marketplace . . . .”<sup>96</sup> FDA experts argue that “changes in FDA’s external environment and in the demands placed on [it] to protect and promote public health will require [the] FDA to re-examine the way it works in relation to individuals and private institutions in society.”<sup>97</sup> The time for re-examination is upon us. Despite demands for FDA presence in the marketplace, the FDA may be required to partner with industry leaders in order to fund any regulatory improvements it makes. A number of potential solutions exist with varying levels of FDA involvement. Investigation into the FDA regulatory process of prescription drugs as well as the dental industry’s self-regulatory practices may lead to an appropriate regulatory solution for cosmetic products.

#### A. Creation of A “Cosmeceutical” Category Under the FDA

One potential change the FDA could institute would be to formally create a category for “cosmeceutical,” products. The FDA could adopt the current industry definition of “cosmeceutical,” and classify cosmetic products which possess the appropriate characteristics under this title.<sup>98</sup> In doing so, the FDA should not require pre-market testing and FDA approval for all cosmetic products similar to the process currently required for drug products. Instead, the FDA should mandate this more stringent level of testing only for products falling under the new “cosmeceutical” classification.

The positive effect of this policy is that development of a “cosmeceutical” category would ensure protection of consumers against products possessing properties similar to some drugs, products which currently require no pre-market safety testing. The negative effect of creating this category is the cost to the FDA; as already stated, the FDA’s budget leaves very little room for new obligations. While the creation of a “cosmeceutical” category would cost less to implement than full-scale testing and pre-market approval of all cosmetic products, the additional cost to the FDA of regulating “cosmeceutical” products may still be unmanageable.

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<sup>96</sup> Michael R. Taylor, *Fundamental Issues Facing 21st Century Regulation*, in A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION 323, 324 (Kenneth R. Piña & Wayne L. Pines eds., 2d ed. 2002).

<sup>97</sup> *Id.* at 325.

<sup>98</sup> See Lazarus & Baumann, *supra* note 7 (defining “cosmeceutical” as “a cosmetic product that claims to or has been found to have biologic activity”).

Another negative effect of this policy change is the fact that creation of a “cosmeceutical” category on its own does nothing to protect consumers who purchase and use the products still classified as cosmetics. These cosmetic products would receive no additional safety testing, and thus would remain minimally regulated. Despite these negative aspects, the creation of a hybrid, “cosmeceutical” category would provide a higher level of testing for products containing “cosmeceutical” properties, thereby providing a higher level of safety to the American public.

#### B. Requirement of FDA Testing and Pre-Market Approval

Another regulatory change the FDA could enact for all cosmetic products would be mandatory testing and pre-market approval similar to that currently required of drugs. Mandating this level of testing for cosmetic products would ensure that every ingredient and product is tested for safety and efficacy prior to its entrance into the U.S. market. This option would protect consumers from ingredients which may cause physical harm, or products which fail to perform as their producers claim.

Mandating testing and pre-market approval would be a perfect solution if the FDA had adequate funding to oversee such research. Unfortunately, the FDA has seen its budget dwindle in recent years.<sup>99</sup> “[F]unding for drug safety is ‘especially inadequate,’” and the “FDA’s food division budget . . . is ‘even more dire’ . . . .”<sup>100</sup> The funding situation has become so strained that the FDA’s food division, the department “which tries to keep tainted foodstuffs from supermarket shelves” cut its headquarter workforce from 950 to 850 employees in 2006.<sup>101</sup> This funding situation led Food Division director Robert Brackett to state, “[the FDA] has been presented with unique challenges, and we will not be able to take on the same large number of objectives we have identified in previous years.”<sup>102</sup> As a result of the changing economy, including the expansion of global trade, “the number of shipments of foreign-produced regulated products [increased] from about 1.5 million in 1992 to 6 million in 2000.”<sup>103</sup> As such, the “FDA’s investigators are now able to sample less than 1

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<sup>99</sup> See *Los Angeles Times Examines FDA Funding Levels*, MED. NEWS TODAY, Oct. 12, 2006, <http://www.medicalnewstoday.com/articles/53845.php>.

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> See FDA’S GROWING RESPONSIBILITIES, *supra* note 1, at 5-6.

percent of all food offered for imports.”<sup>104</sup> The FDA funding situation is worse now than it has ever been before.<sup>105</sup>

With FDA funding in short supply, implementation of mandatory testing and pre-market approval for all cosmetic products is simply not feasible. The FDA cannot mandate and adequately implement such testing at the levels currently in place for drug products. As such, the FDA should consider less costly methods of regulating the cosmetic industry.

### C. FDA Promotion of Current Regulatory Practices to the American Public

Consumers believe that the cosmetic products currently on the market are adequately regulated and approved by the FDA as safe and effective, yet this belief is unfounded.<sup>106</sup> Therefore, if the regulatory system is not strengthened, at the very least, the FDA must adequately inform American consumers of the current lack of oversight and approval in the cosmetic industry. While the FDA may effectively pass on regulation and other responsibilities to the cosmetic industry, ultimately, the responsibility for oversight rests with the FDA itself.<sup>107</sup>

One potential method for informing consumers of the current lack of regulation of cosmetic products would be to display warning information in all places those products are sold. Such information should clearly state a message to the effect of:

The FDA prohibits misbranded and adulterated cosmetics, however, the FDA does not subject cosmetics to pre-market testing or approval. Cosmetic products—and the ingredients used in their formulation—should be tested by their manufacturer for safety, however, the safety of some products cannot be substantiated. As such, any product whose safety cannot be substantiated by its manufacturer will display a warning on

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<sup>104</sup> *Id.*

<sup>105</sup> See *Los Angeles Times Examines FDA Funding Levels*, *supra* note 98.

<sup>106</sup> See Lewis, *supra* note 87 (reporting that confused cosmetic consumers wrongfully believe that they are protected by the FDA); see generally Kawalek, *supra* note 5 (discussing consumers' mistaken beliefs in the safety of marketed cosmetic products).

<sup>107</sup> See Taylor, *supra* note 96 (describing the general public's expectation that the products and devices made available for use and purchase are safe).

its label stating this fact. Please read all cosmetic product labels carefully and thoroughly.<sup>108</sup>

The FDA could also communicate a similar message through television and radio commercials, newspaper, magazine and billboard advertisements.

Additionally, if the FDA utilizes this method to inform the American public of the current lack of oversight in the cosmetic industry, it should require manufacturers of products with unsubstantiated safety to include in their packaging a warning insert containing the message above, as well as a message to the effect of the following.

The safety and/or efficacy of the product you have purchased has not been substantiated by the product's producer, or by the FDA. Please take caution in using this product. If unused, you may return this product to the store where it was purchased, or to its manufacturer for a full refund.<sup>109</sup>

One benefit of this option—informing the American public of the current lack of oversight, or approval of the cosmetic industry—is that the cost to the FDA is far less than in the options discussed above. Further, this option would be beneficial if used in conjunction with a unified regulatory program adopted by the cosmetic industry. Although there would be some cost associated with advertisements and warning inserts, the FDA could share this cost with the cosmetic industry, while working with producers of cosmetic products to develop and distribute informational materials. Considering current FDA budgetary constraints, this would benefit the agency and would give cosmetic producers input in creating the warning advertisements and inserts.

#### D. Industry Sponsored Seal of Approval Program

In light of the FDA's current budgetary constraints, it is appropriate, and necessary, for the FDA to look to the cosmetic industry to assist in formulating and sponsoring a new review process. The FDA could join forces with the cosmetic industry to develop a new regulatory system, or the industry could independently create a program similar to those in use in other industries.

The American Dental Association (ADA) established a Seal of Acceptance (Seal) program in 1930.<sup>110</sup> The Seal program formulated

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<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> Am. Dental Ass'n, ADA Seal of Acceptance: Frequently Asked Questions

rigorous guidelines for testing and advertising dental products.<sup>111</sup> A manufacturer applying for the Seal must supply the ADA with objective data from “clinical and/or laboratory studies that support the product’s safety, effectiveness and promotional claims.”<sup>112</sup> A manufacturer must also conduct clinical trials as required in strict compliance with ADA guidelines.<sup>113</sup> A manufacturer must also “[p]rovide evidence that manufacturing and laboratory facilities are properly supervised and adequate to assure purity and uniformity of the product, and that the product is manufactured in compliance with Good Manufacturing Practices.”<sup>114</sup> Finally, a manufacturer must submit all advertising and promotional claims, all patient education materials for review and approval by the ADA, be in compliance with the ADA’s standards for accuracy and truthfulness in advertising and submit ingredient lists and other pertinent product information for review and approval.<sup>115</sup>

Over 100 consultants, ADA staff scientists, and members of the ADA’s Council on Scientific Affairs review the safety and efficacy oral care products seeking the ADA Seal.<sup>116</sup> The ADA may conduct or request additional product testing, and will only award a product the ADA Seal after it has been proven safe and effective.<sup>117</sup> Over 400 products carry the mark of this voluntary Seal program.<sup>118</sup> Participating manufacturers contribute significant resources to evaluate, test, and market products eventually receiving the Seal.<sup>119</sup>

The ADA Seal of Acceptance is typically awarded for a five-year period, after which manufacturers must reapply in order to continue using the Seal.<sup>120</sup> If “the composition of an [a]ccepted product changes, the company must resubmit the product for review and approval before it is marketed with the Seal.”<sup>121</sup> A product must continue to meet these requirements “as long as [it] bears the ADA Seal.”<sup>122</sup>

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(FAQ), <http://www.ada.org/ada/seal/faq.asp> (last visited Oct. 5, 2007).

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

As stated above, the ADA reviews all advertising claims for products bearing the Seal.<sup>123</sup> The ADA permits only those claims that can be supported by appropriate clinical and/or laboratory studies and scientific data.<sup>124</sup> The ADA Seal was designed to assist the public (as well as dental professionals) in making informed decisions regarding the safety and efficacy of dental products.<sup>125</sup> "Market research has shown that the ADA seal on a product directly affects the purchase decisions of consumers."<sup>126</sup>

The cosmetic industry should consider instituting its own endorsed approval program. The CTFA should establish oversight for the cosmetic industry's approval program, drawing from its involvement in CIR review. Similar to CIR review, a cosmetic industry approval program should be purely voluntary. Involvement by major cosmetic producers should, as it has with the ADA Seal program, motivate other producers to participate. Unlike the CIR program, which lists results and reviews of safety data in peer-reviewed scientific literature,<sup>127</sup> a cosmetic industry approval program should ensure the mark of approval appears prominently on all packaging so that it is visible to consumers. Further, a cosmetic industry approval program would differ from CIR review in that the approval program should conduct a safety and efficacy review of cosmetic products in the order they were submitted to the overseeing body. Additionally, unlike CIR review, the application for a cosmetic industry Seal of Approval should result in either approval or disapproval. This would avoid a confusing rating system thereby helping consumers remain informed about their cosmetic purchases. Finally, cosmetic producers must be free to sell their products to consumers prior to, or without receiving, the cosmetic industry's Seal of Approval. As with the ADA Seal program, participation must be voluntary, but consumers are likely make purchasing decisions based on whether a product has industry approval.<sup>128</sup>

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<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> Bergfeld et al., *supra* note 64, at 126.

<sup>128</sup> *See* Am. Dental Ass'n, *supra* note 110.

### E. FDA Institution of Shared-Fee Practices Similar to the Prescription Drug User Fee Act

As stated above, the current state of the FDA's budget is such that the agency cannot adequately fund new regulations.<sup>129</sup> As such, the FDA could consider instituting a shared-fee practice, requiring industry assistance in funding any heightened level of regulation.

The FDA has had shared-fee programs in the past, most notably after Congresses' 1992 passage of the Prescription Drug User Fee Act.<sup>130</sup> Prior to 1992, taxpayers alone supported the costs of prescription drug review by the FDA.<sup>131</sup> At this level of funding, it took the FDA an average of 30 months to review a new medication.<sup>132</sup> After the 1992 passage of the Prescription Drug User Fee Act (PUDFA), the FDA collected fees from drug producers to support review.<sup>133</sup> Companies seeking FDA approval of a new drug or biologic must now submit an application along with a fee to the FDA.<sup>134</sup> In the years since PUDFA was implemented, the FDA has been "able to hire additional reviewers and support staff who have helped reduce the median review time for drugs to 12 months[,] . . . [and] breakthrough products are now reviewed in 6 months or less."<sup>135</sup> This shortened review has increased "the number of new drugs approved in a year . . . [to] almost 40 percent . . ."<sup>136</sup>

"The combination of efficient reviews and high product standards have made the United States the country of choice for the world's leading drug manufacturers who want to introduce new medicines."<sup>137</sup> Prescription drug companies pay annual fees "for each manufacturing establishment and for each prescription drug marketed."<sup>138</sup> The FDA also assesses user fees for producers of animal drugs<sup>139</sup> and medical devices to support those respective review processes.<sup>140</sup>

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<sup>129</sup> See *Los Angeles Times Examines FDA Funding Levels*, *supra* note 99.

<sup>130</sup> U.S. Food & Drug Admin., Prescription Drug User Fees – Overview, <http://www.fda.gov/oc/pdufa/overview.html> (last visited Sept. 29, 2007) [hereinafter Prescription Drug User Fees].

<sup>131</sup> *Id.*

<sup>132</sup> FDA'S GROWING RESPONSIBILITIES, *supra* note 1, at 3.

<sup>133</sup> Prescription Drug User Fees, *supra* note 130.

<sup>134</sup> *Id.*

<sup>135</sup> FDA'S GROWING RESPONSIBILITIES, *supra* note 1, at 4.

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> Prescription Drug User Fees, *supra* note 130.

<sup>139</sup> Animal Drug User Fee Act of 2003, 21 U.S.C.S. § 379j-12 (LexisNexis 2006).

<sup>140</sup> Medical Device User Fee and Modernization Act of 2002, 21 U.S.C.S. § 379j (LexisNexis 2006).



The FDA should consider instituting a shared-fee practice among cosmetic producers in order to fund an expanded safety review program. Such a program would require cosmetic producers to pay annual fees for each manufacturing establishment, as well as submit an application and new product fee for each new product they wish to add to the U.S. market. With these fees, the FDA would have ample resources to hire cosmetic product reviewers and support staff. These reviewers would test the safety and efficacy of each product for which a company applied for market admission.

Negative aspects of this program include prolonged delays in the entrance of products into the U.S. market. In the current system, products can enter into the U.S. market as soon as producing companies decide they are ready to sell the product. With an FDA run system of review like the one described above, however, producers must wait until FDA reviewers have approved each product before marketing and selling the cosmetic to the public. The positive effect of this delay is that American consumers would be able to select cosmetic products knowing that the ingredients and the product passed safety and efficacy review.

#### F. Industry Consolidation of Review Programs

The most practical, and potentially the most effective regulatory change would include several of the options discussed above. The cosmetic industry should create an industry-wide Seal of Approval program with a fee-sharing element, to fund the program. To maintain involvement, the FDA should participate in the approval program, either by providing a representative to serve as a reviewer, or by publicizing the level of current regulatory practices to the American public. The FDA could promote the level of regulation through advertisements on television and in print media, as well as through cosmetic package inserts and in-store advertising.

The cosmetic industry's approval program should be organized by the CTFA, and should be voluntary. The approval program should consist of an application process, where cosmetic producers submit product ingredients, specifications, and advertising to a review board. The board would examine testing completed by the producer, and would re-test to the extent necessary. After testing and evaluating the product, the review board would either approve or reject the product. If a product is approved, the industry's stamp of approval can appear on the packaging and advertising for that product.

As with the ADA Seal program, involvement by major cosmetic producers should motivate smaller producers to participate.<sup>141</sup> After gaining familiarity with the program, consumers are likely to begin looking for the approval marking on cosmetic products. Meanwhile, producers who choose not to participate in the approval program will still be able to sell and market their products. Consumers will simply know that their products have not been approved by the industry's review board.

The CTFA should institute a shared-fee practice similar to that used by the FDA with prescription drug manufacturers, in order to fund this expanded safety review program. Cosmetic producers should be required to pay annual fees for each manufacturing establishment, and should be required to submit an application and new product fee for each new product they wish to add to the U.S. market. The CTFA could then use these fees to hire cosmetic product reviewers and support staff, and may additionally choose to contribute some of the revenue to the FDA for use in promoting the regulatory system.

As discussed previously, negative aspects of this program include prolonged delays in the entrance of products into the U.S. market. Without regulation, products can currently enter the U.S. market as soon as companies decide they are ready to sell a product. However, with an industry run system of review like the one described above., producers must wait until the industry panel approves each product before marketing and selling the cosmetic to the public. A positive result is that American consumers will be able to select cosmetic products knowing that they and their component ingredients have been tested for safety and efficacy.

If the cosmetic industry does not institute a Seal of Approval program, the next option to consider is the consolidation of industry-regulated review programs. The cosmetic industry, through sponsorship by the CTFA and endorsement by the FDA, should consolidate the original VCRP<sup>142</sup> established by the FDA in the early 1970's, the CIR currently in place, and the CCC currently under development by the CTFA.

The original VCRP, which included three parts: registration information for the manufacturing or packing establishment, information regarding the ingredient formulation and raw material usage in cosmetic products, and annual reporting of adverse reactions, would have to be re-adopted by the cosmetic industry to replace the abbrevi-

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<sup>141</sup> See Bergfeld et al., *supra* note 64, at 131 (stating that personal care product companies are committed to the CIR program).

<sup>142</sup> Voluntary Cosmetics Review Program, discussed *infra* section I.C.1.

ated version currently in operation. Further, this program would have to be consolidated with two other programs; the CIR currently in practice, which through its Expert Panel provides review and assessment of the safety of ingredients used in cosmetics, and the CCC currently under development by the CTFA, which will include a dossier program similar to that established by the EU. The compilation of these three programs would maximize the amount of information gathered from cosmetics producers, and will in-turn maximize the amount of information available to consumers.

It is not necessary for the FDA to run the consolidated review program, especially considering budgetary constraints which might make such involvement impossible. As such, registration for the combined program would not be mandatory unless Congress passes legislation requiring all cosmetic producers to participate. Absent such legislation, registration should be encouraged of all cosmetic producers. To incentivize cosmetic producers to register and participate in the combined review program, products having successfully completed review must have a specific designation or logo on their packaging. This designation would inform consumers that the product has undergone safety testing and received industry approval.

The FDA should, however, maintain the oversight of cosmetic regulation as mandated by the FDA Act.<sup>143</sup> The best way for the FDA to fulfill its duty to regulate cosmetics is by endorsing the new program and promoting the new regulatory practices to the American public. In conjunction with a unified cosmetics industry and combined review program, the FDA should enact the promotion and advertisement changes analyzed above. The FDA should create a warning message for display in stores selling cosmetic products, in order to inform consumers about the current state of the regulatory system. The FDA should also write a warning message for inclusion in the packaging of products producers have not submitted for testing through the consolidated review program. Finally, the FDA should create advertisements for television, radio, newspapers and magazines, to inform the American public about the new consolidated review program, its requirements and protections. Together these practices should inform American consumers of the safety regulations currently in effect, allowing consumers to make informed decisions about cosmetic purchases.

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<sup>143</sup> See Hyman, *supra* note 23, at 21-25 (describing the enactment of the Federal Food, Drug, and Cosmetic Act in 1938 that brought regulation of cosmetics and therapeutic devices under the FDA's jurisdiction).

## CONCLUSION

American consumers have a heightened sense of FDA regulation generally because they are aware of drug recalls and food source contaminations, which take center stage on the nightly news. As a result of this awareness, many American consumers mistakenly assume that the FDA, regulates all products in a uniform fashion.<sup>144</sup> This is clearly not the case. As such, the FDA has a responsibility to inform American consumers about the actual level of regulation of cosmetic products.

Additionally, the cosmetic industry, through the CTFA, has assumed a great deal of responsibility for providing safety testing and strengthened review of products, particularly where the FDA has fallen short. The industry should be commended for their efforts, however, the system of regulation currently in place is imperfect. To make the regulation they offer as effective as possible, one of the two options described above must be implemented. The industry must either create a Seal of Acceptance program similar to that created by the ADA, or the industry-sponsored review systems currently in effect should be consolidated as explained above. The selection of one of these two options, coupled with endorsement and advertising provided by the FDA, the cosmetic industry will be able to provide the American public with the increased level of safety testing they expect. Further, the FDA's advertising and promotion of the selected review system and the testing methods in existence will further inform American consumers as they make purchasing decisions. To leave consumers without such testing and information subjects them to the mercy of a system that currently leaves them uninformed and unprotected.

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<sup>144</sup> *See id.*

