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June 13, 2008

David Mallory
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Stationary Sources Division
California Air Resources Board
1001 I Street, 6th Floor
Sacramento, California 95812

Re: Consumer Product Rulemaking; Astringents/Toners

Dear CARB Staff,

As you know, I have met with you and with members of the CARB Board on a number of occasions over the last two years in the hope of persuading CARB to allow a full range of non-OTC alcohol astringents and toners to remain on the market. In the course of those meetings, I have stressed my strong medical opinion that this range of products includes high levels of alcohol needed by certain affected groups. Rather than describe those affected groups here again, I am enclosing the letter that Janellen Smith, M.D. (University of California, Irvine) and I sent to you on January 4, 2008, which outlines those various groups of patients.

I have been asked to specifically opine on whether there is a technical basis for the establishment of a 40% alcohol/VOC cap rather than the 35% level recommended by CARB staff. There is indeed a technical and experiential basis for maintaining the availability of the higher alcohol levels due to dose response and to the medical necessity of these products for certain categories of patients.

The fact that certain brands of products with low levels of alcohol make marketing claims that they can be used for "oily skin" does not make them medically appropriate or accurate. In my experience, and that of my colleagues

with whom I have discussed this issue, astringents with high levels of alcohol are practically and medically necessary. The necessity for higher levels of alcohol in these products has long been recognized by medical experts. See *Principles of Cosmetics for the Dermatologist*, Frost & Horowitz, C.V. Mosby & Company, 1982, p. 300, which describes the category of fresheners, toners, pore lotions and astringents for oily skin:

> These products are generally applied after cleansing with soap and water or some other form of cleanser or as interim sebum removers without prior cleansing.... These preparations are basically hydroalcoholic solutions.... The alcohol (usually SD alcohol 40) content may be as high as 95%, but for the most part it is just under 50% to minimize stinging and burning (emphasis supplied).

As I have discussed during my presentations, there is a direct dose response relationship between the amount of alcohol in the astringent product and the degree of effect. Enclosed is a slide I have highlighted in our meetings which shows that a 60% alcohol product (a level of non-OTC product I continue to recommend to patients) removes two times what a 40% alcohol product removes. In my medical opinion even though higher would be better, 40% represents a bare minimum level of an effective product for the affected groups described in my previous letter.

I will be away in Washington, DC for the next few days but would be happy to speak with you or other interested parties if you require additional information.

Sincerely,

/s/ Ruby Ghadially

Ruby Ghadially, M.D.

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January 4, 2008

David Mallory
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Stationary Sources Division
California Air Resources Board
1001 I Street, 6th Floor
Sacramento, California 95812

RE: Consumer Product Rulemaking; Astringents/Toners

Dear CARB Staff:

As we stated in our remarks in CTFA's meeting with you on November 15, 2007, we believe it is critically important for the current range of non-OTC alcohol astringents and toners to remain on the market, including higher-alcohol products. These products serve a wide range of skincare needs.

The universe of astringents and toners falls on a continuum. At one end, there are the OTC anti-acne treatments. The primary active ingredients in these products are salicylic acid and benzoyl peroxide. These products, as their name indicates, are intended to treat patients with acne. At the other end of the continuum are low- or no-alcohol products. These products are generally intended to treat those with drier and/or sensitive skin.

Between these two categories lie the vast majority of astringents and toners on the market – i.e., those with alcohol levels ranging anywhere from 10% to upwards of 50%. This subcategory embraces a wide range of skincare needs, namely for patients who have normal/combination skin, or have oily skin with no acne. For these skin types, the astringent functions as a pre-acne preventative treat or as a post-acne treatment, for use after a flare-up. In some cases, the astringent can be a concomitant therapy used in conjunction with a prescription drug (depending on the specifics of the prescribed drug and condition of patient's skin).

The subcategory in question also serves those consumers who have difficulty tolerating the active ingredients in salicylic acid or benzoyl peroxide, whether due to allergies, irritation, or other sensitivities.

Another affected group of major concern is the roughly 85% of teenagers with acne. Teenagers have special needs, such as acne on the back, chest and other parts of the body, in addition to the face. Acne on the back and chest generally requires and

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tolerates stronger concentrations of alcohol. Benzoyl peroxide has limitations in that it is intended as a spot treatment and is not practical for application on large areas. Given the scarring and psychosocial issues associated with teenage acne, we believe the health implications flowing from the current proposal would have a greater impact on the teenage population, particularly for those who lack regular access to dermatologists and health care.

As we further noted in our discussion, another affected group concerns darker-skinned persons. We are concerned about persons of color for two reasons. First, black people have been shown to have more sebum (Rawlings 2006), and the key reason for using astringents is to control sebum. Second, the prevalence of hyperpigmentation (i.e., increased pigmentation) in persons with darker skin caused by irritation associated with acne highlights the critical importance of proper pre- and post-acne treatment for this population. Clearly, individuals with darker skin comprise a significant portion of the underserved populations in California. These individuals should not be denied ready access to the range of affordable products that are currently on the market.

Sincerely,

Ruby Ghadially

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Principles of cosmetics for the dermatologist

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with **184** illustrations including **6** color plates

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CHAPTER 37

Cosmetic products for people with dry or oily skin

Frances Pascher

DRY SKIN

Not all dry skin is alike. It is important to distinguish between xerosis (simple dryness) and ichthyosiform eruptions, atopic skin, and dry skin caused by a wide variety of endogenous factors.[2,3] Simple dryness, which may be familial but is more often induced by improper or excessive cleansing, climate, and aging, in contrast to other forms of dryness, can be managed by appropriate cosmetic care.

Cleansers

Exposure to soap, detergents, lipid solvents, and water, especially hot water, should be curtailed.[17] Alternatives to conventional toilet soaps, which may be too drying, are superfatted emollient soaps, soapless soaps, cleansing creams, and cleansing lotions for dry skin.

There are any number of superfatted (emollient) soaps to choose from. Some examples are Cold Cream Soap,* Basis Soap,† Neutrogena Dry Skin Soap,‡ and Oilatum.§ These and Dove Bar,‖ a detergent/soap mixture, contain unsaponified fatty materials to prevent excessive "stripping" of the skin surface lipids (SSL); they deposit an emollient film to replace some of the natural lipids removed in the cleansing process.

Soapless soaps, that is, synthetic detergent cleansers (syndets), are free of organic and inorganic soaps (true soaps) formed by the interaction of triethanolamine and sodium and potassium salts, respectively, with fatty acids. Some examples are Lowila Cake¶ and Emulave Bar.#

According to Shelmire[17] and others,[15] there is no evidence that anionic surfactants, which are generally used in the preparation of syndets, are milder to the skin than true soaps because they are less alkaline.

Cleansing lotions and creams for dry facial skin to be used in lieu of soap are offered by many cosmetic companies and pharmaceutical manufacturers of skin care products. These cleansers vary considerably in composition; they are produced as lotions and creams, which may be "tissued off" or rinsed off with cool water, depending on the nature of the formulation. The core formula is a surfactant or a diluted soap emulsifier combined with oleaginous materials to minimize "stripping" of SSL and to provide a "protective" emollient film. The following examples have been selected to emphasize the chemical diversity of these formulations. It should be noted that formulae are subject to change.

Deep Mist Cleanser*

Mineral oil, water, petrolatum, propylene glycol, stearyl alcohol, oleic acid, cetyl alcohol, triethanolamine, lanolin alcohol, glyceryl stearate, magnesium aluminum silicate, methylparaben, propylparaben, FD & C Blue No. 1, and D & C Red No. 19

This is an unscented O/W emulsion containing approximately 5% organic soap emulsifier formed by the interaction of oleic acid and triethanolamine to form triethanolamine oleate. The emollients are mineral oil, petrolatum, and lanolin alcohol.

Combination Skin Cleanser (Allercreme†)

Water, cetyl alcohol, propylene glycol, sodium lauryl sulfate, stearyl alcohol, fragrance, sodium citrate, methylparaben, propylparaben, butylparaben, and citric acid

*Almay, Inc., Apex, N.C.
†Beiersdorf, Inc., South Norwalk, Conn.
‡Neutrogena Corp., Los Angeles, Calif.
§Stiefel Laboratories, Inc., Coral Gables, Fla.
‖Lever Brothers Co., New York, N.Y.
¶Westwood Parmaceuticals, Buffalo, N.Y.
#Cooper Labs, Wayne, N.J.

*Almay, Inc., Apex, N.C.
†Owen Laboratories, Ft. Worth, Tex.

This is a scented O/W emulsion with an anionic surfactant, sodium lauryl sulfate, and fatty alcohols.

Cold cream (USP XX)[19]

Cetyl esters wax, white wax, mineral oil, sodium borate, and purified water

Cold cream, generally classified as an all purpose cream, is often used as a cleansing cream. Countless modifications of this W/O emulsion are extant. Conversion to an O/W formulation is readily achieved by the use of an emulsifier such as glyceryl stearate and by increasing the water content.

The major types of bath oils (dispersible bath oils, floating bath oils, and bath oil beads) are reviewed by Goldemberg.[7] Dispersible bath oils are the most widely used. Some examples are Alpha Keri Bath Oil,* Ar-ex Bath Oil,† and Jeri-Bath.‡

Most manufacturers recommend immersion for a period of 15 to 20 minutes in a comfortable warm bath to which the bath oil has been added; others advise immersion for a similar period prior to adding the bath oil for preliminary hydration of the skin to enhance absorption.

Oilated baths are not advisable for the elderly because of the slipperiness and because prolonged immersion may be debilitating. Moreover, people who cannot or will not take the time required for maximum benefit may do as well by taking a quick bath or shower, followed by the liberal application of a body oil or a moisturizing body lotion.

Fresheners, toners, and pore lotions

These products, also sometimes referred to as *purifiers* or *clarifiers*, are applied after cleansing to "freshen" and "tone" and to prepare the skin for the application of makeup by removing exogenous oils, including emollients deposited by superfatted soaps and/or cleansing lotions and creams for dry skin. They may also be used as interim quick cleansers or fresheners before reapplying makeup.

These products for dry skin are usually mild and differ from their counterparts for oily skin in having a low concentration of alcohol. If surfactants and astringents are incorporated, they are generally present in low concentration. A humectant such as sorbitol or glycerin may be added to counteract dryness. Some examples follow.

Deep Mist Mild Skin Freshener*

Water, SD alcohol 40, sorbitol, methylparaben, propylparaben, tetrasodium EDTA, FD & C Yellow No. 5, and R & C Red No. 33

Allercreme Freshener†

Water, SD alcohol 40, propylene glycol, and imidazolidinyl urea

Skin Freshener‡

Water, alcohol, glycerin, and aluminum chloride

Moisturizing creams and lotions, day creams, night creams, hand and body lotions, and hand creams

The efficacy of the countless preparations in the marketplace can only be judged by improvement in feeling and appearance of the skin. A number of in vitro and in vivo techniques have been devised in recent years to objectively measure the effectiveness of moisturizers. Unfortunately, these methods are not sufficiently reliable or feasible for general use. Consequently, the claims made for the superiority of some humectants and emollients cannot be substantiated quantitatively.

Suffice it to say that most preparations contain one or more humectants, such as sorbitol, glycerin, propylene glycol, lactic acid or sodium lactate, sodium pyrrolidone carboxylate (NaPCa), and urea, and a combination of emollients (mineral oil, petrolatum, polybutene, fatty alcohols and esters, and lanolin or lanolin derivatives). Night creams, as a rule, are "greasier" and "heavier" than day creams because of a higher concentration of more occlusive emollients.

The search for the ideal moisturizer continues. Because of the variability of human responsiveness and the sensitizing and irritancy potential of some of the ingredients in moisturizers, it is reasonable to predict that no single product or combination of components will satisfy all needs.

Hellgren and Larson's[9] studies indicate that the prolonged use of high concentrations of urea

*Westwood Pharmaceuticals, Inc., Buffalo, N.Y.
†Ar-ex Products Co., Chicago, Ill.
‡Dermik Laboratories, Inc., Blue Bell, Pa.

*Almay, Inc., Apex, N.C.
†Owen Laboratories, Ft. Worth, Tex.
‡Marcelle, Plattsburgh, N.Y.

may reduce and damage the horny layer of the skin. It would seem advisable, therefore, to confine the use of creams and lotions with more than 2% to 5% urea (e.g., Aquacare/HP Dry Skin Cream and Lotion* and Elaqua X,XX†) to the hyperkeratotic areas on the elbows, knees, and ankles, which are associated with simple dryness. One should also be mindful of the fact that the concentration of urea increases with the evaporation of water from these products,[9] making general body use for prolonged periods questionable.

Because cosmetic[5,12] acne may be induced by the repeated and prolonged use of moisturizers, they should be tested for potential comedogenicity by the rabbit ear assay for comedogenicity.[11] Products found to be noncomedogenic by this assay are now available.[5,12,14] Although the relevancy of the animal assay to the human is questioned by some and divergent results are sometimes obtained by different observers (Kligman and Mills[12] disagree with Fulton et al.[5] as to the comedogenicity of precipitated sulfur and sodium lauryl sulfate), the rabbit ear assay is nevertheless an excellent screen for potential comedogens. Moreover, the potential comedogenicity of a product cannot be reliably predicted from its ingredients. A formulation containing a low concentration of an ingredient (e.g., isopropyl myristate, which was rated strongly comedogenic in the animal assay because of a variance in concentration among other factors) may nevertheless prove to be noncomedogenic. Conversely, products containing a number of ingredients, each rated noncomedogenic by assay, may indeed prove to be comedogenic because of the additive effect of each. It is the total formulation that is important.

Makeup for dry skin

Makeup is comprised of foundation lotions and bases, blushers, and face powders. Products for dry skin generally contain emollients to counteract existing dryness and the drying effect of sorbent ingredients (talc, silica, iron oxides) present in most of these products. Noncomedogenic products should be selected to avoid induction of cosmetic acne. Almay* and Dermage† cosmetics have been shown to be noncomedogenic by the rabbit ear assay.[5,11]

Summary

Uncomplicated xerosis (simple dryness) can be successfully managed by the appropriate selection of skin care products and cosmetics. Products for dry skin include cleansers (superfatted soaps, oilated bath products, cleansing creams and lotions), fresheners and toners, moisturizing creams and lotions, and makeup (foundation lotions, blushers, and face powders). The recognition of the disparate needs of different skin types has led to the development of these highly specialized formulations.

OILY SKIN

Oily skin and its associated "shine" are distressful to those who suffer from this physiologic aberration. Although gloss and sheen are often sought as a feature of cosmetics, such is the nature of humans that a shiny nose must be avoided at all cost. Perhaps this is so because oiliness is a reminder of a physiologic function that has gone awry.[10]

At the present time there is no generally acceptable method for reducing sebum synthesis. The benefit/risk ratio excludes the use of superficial x-ray therapy,[6] which at best achieves only a temporary reduction in sebum output. The adverse effects of anovulatory drugs and oral retinoids[18] likewise preclude their use for uncomplicated seborrhea. Other potential inhibitors of sebum synthesis such as antiandrogens,[1,16] cimetidine,[13] and zinc[4,8] are under investigation. Thus far none has been found to be uniformly effective and without systemic toxicity. Consequently, the removal of sebum is the only method currently available for the management of seborrhea.

The appropriate combination of selected skin care products and cosmetics is required for clinical effectiveness. The following measures, applied in the following steps, are suggested: (1) cleansing two or three times a day with soap and water or a facial cleanser for oily skin; (2) appli-

*Herbert Laboratories, Irvine, Calif.
†Elder Pharmaceuticals, Bryan, Ohio.

*Almay, Inc., Apex, N.C.
†Cosmedice Research Laboratories, Inc., New Orleans, La.

cation of a freshener/toner/pore lotion or astringent; (3) application of a noncomedogenic moisturizer to dry, chapped, or overtreated areas; and (4) use of noncomedogenic makeup (foundation lotion, blusher, and/or face powder) for oily skin for those who wear makeup.

Cleansers

Most toilet soaps are adequate for the emulsification and removal of SSL and exogenous lipids. Cleansers expressly formulated for oily skin, mainly acne cleansers, are said to have a greater "stripping" effect than conventional soaps. Superfatted soaps should, of course, be avoided because they are inferior cleansers and leave an oily residue.

Facial cleansers for oily skin are indicated for individuals who are adverse to the use of soap and water and for those who do not tolerate soap well. Tolerance of facial cleansers for oily skin may be attributed to the lower concentration of soap emulsifiers or surfactant than found in soap and detergent bars and to the lower pH of these products. These cleansers are also more effective removers of "heavy" makeup (theatrical makeup, extra-cover makeup, other covering agents) applied for the masking of a wide variety of cutaneous imperfections. The core formula is composed of a soap emulsifier or surfactant combined with one or more lipid solvents. Two examples follow.

Counter Balance Fluffy Facial Cleanser*

Water, stearic acid, propylene glycol, oleic acid, potassium hydroxide, methylparaben, propylparaben, and imidazolidinyl urea

Cleansing is effected by the presence of a soap emulsifier (interaction of potassium hydroxide with oleic and stearic acids) and the solvent action of propylene glycol.

Marcelle Cleanser for Oily Skin†

Water, sodium *N*-lauroyl sarcosinate, propylene glycol, lauramide DEA, PEG 8 distearate, ceteareth-5, lactic acid, spermaceti, glycol stearate, candelilla wax, methylparaben, cetyl alcohol, allantoin, propylparaben, benzophenone-4, and D & C Red No. 33

Cleansing is effected primarily by the combination of surfactants, sodium N-lauroyl sarcosinate and lauramide DEA, and the solvency of propylene glycol.

*Almay, Inc., Apex, N.C.
†Marcelle, Plattsburgh, N.Y.

Fresheners, toners, pore lotions, and astringents

These products are generally applied after cleansing with soap and water or some other form of cleanser or as interim sebum removers without prior cleansing. The terms noted earlier for this group of skin care formulations are used more or less interchangeably and are not to be taken as indicative of their drying action. These preparations are basically hydroalcoholic solutions combined with a surfactant and/or astringent such as alum, acetone, or an aluminum salt. The alcohol (usually SD alcohol 40) content may be as high as 95%, but for the most part it is just under 50% to minimize stinging and burning.

Noncomedogenic moisturizers

Moisturizers are commonly contraindicated in the management of oily skin because of their oiliness and an anticipated comedogenic effect. The interdiction may now be waived because of the availability of noncomedogenic moisturizers as determined by the rabbit ear assay for comedogenicity.[11] Patients with oily skin may now enjoy the luxury of using such a product for the alleviation of extremely dry or scaly areas caused by excessive cleansing, topical medication, or adverse climatic conditions. Other benefits are the enhanced appearance of the skin and the smooth finish imparted to makeup. These moisturizers should be applied sparingly and should be limited to dry or peeling surfaces so as not to add to the general oiliness. A noncomedogenic moisturizer for normal to dry skin may be used, or a so-called oil-free moisturizer advocated for oily skin may be selected. By definition an oil-free moisturizer contains no mineral oil, vegetable oil, or animal fat per se, but it may contain modified (acetylated, esterified, or ethoxylated) mineral, vegetable, and animal fats. An example follows.

Almay's Counter Balance Oil-Free Moisturizer*

Water, propylene glycol, PEG #40 stearate, propylene glycol dicaprylate/dicaprate, talc, laneth-10 acetate, titanium dioxide, imidazolidinyl urea, methylparaben, triethanolamine, propylparaben, carbomer-941, myristyl alcohol, sodium polymethacrylate, disodium EDTA, simethicone, FD & C Yellow No. 5, FD & C Blue No. 1

Makeup

Makeup foundations, blushers, and face powders for oily skin can be helpful in the manage-

ment of seborrhea. Foundation lotions for oily skin are generally totally lipid-free. They are water-based vehicles (e.g., Almay Pure Beauty Foundation Lotion for Oily Skin*) or hydro-alcoholic vehicles (e.g., Clinique's Pore Minimize Makeup†) in which powders and pigments are suspended to provide coverage and a sorptive surface for natural and exogenous lipids. Generally speaking, powder and gel blushers are preferable to cream blushers for oily skin. Face powders for oily skin contain large quantities of sorptive materials such as talcs, kaolin, Fuller's earth, silica, and iron oxides for blotting up sebum.

Summary

Skin care products and cosmetics designed for oily skin are the only safe measures now available for the management of seborrhea. The benefits far outweigh the risks, which are principally irritation and contact dermatitis. These are usually localized and readily reversible. In my judgment cosmetic care will continue to play a significant role in the management of seborrhea even when safe systemic measures become available for the suppression of sebum synthesis.

*Almay, Inc., Apex, N.J.
†Clinique, New York, N.Y.

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Average Stratum Corneum Lipid Removal as a Function of Increasing Ethanol Concentration

60% Alcohol removes 2 times what 40% Alcohol removes