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The Legal Distinction in the United States Between a Cosmetic and a Drug

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The Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes substantially different regulatory requirements in the United States for cosmetics and drugs. This chapter traces the history of U.S. regulatory policy for these two categories of products, discusses the application of U.S. law to products that fall within both categories at the same time (i.e., cosmetic drugs†), and considers potential strategies for resolving the long-standing concern that the drug provisions of the Act impose overly stringent requirements on cosmetic drugs.

HISTORICAL OVERVIEW

Cosmetic products have been used by humans since before recorded history. Archeologists date the earliest discovered cosmetics to about 10,000 B.C. (1). By the height of the ancient Roman civilization, virtually all types of cosmetics that

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† The term ''cosmeceutical'' has no legal or regulatory meaning and no other accepted definition, and therefore is not used in this chapter.

are available today were in widespread use. In his landmark *Natural History*, Pliny the Elder (23–79 A.D.) described such cosmetic products as hair dye, eyelash dye, eyebrow dye, freckle removers, rouge, deodorants and antiperspirants, depilatories, wrinkle removers, hair preservatives and restorers, bust firmers, sunburn products, complexion aids, moisturizers, mouthwashes and breath fresheners, toothpaste, face powder, and perfume (2). Cosmetics have continued to be widely used from these ancient times to the present.

During the 19th century, virtually all government regulation of private enterprise in the United States was conducted at the city, county, and state levels. Because of the Supreme Court's narrow interpretation of the power of the federal government to regulate interstate commerce, federal laws regulating consumer products did not emerge until the first decade of the 20th century. Thus, the first laws explicitly regulating cosmetics were enacted by the states. The earliest known state regulatory law explicitly mentioning cosmetics was enacted by Massachusetts in 1886. That law included all cosmetics within the statutory definition of a drug, thus imposing the same regulatory requirements on both cosmetics and drugs (3).

From 1879 through 1906, Congress held hearings and debated the enactment of a federal food and drug law (4). Although bills introduced in Congress during 1898–1900 explicitly defined the term ''drug'' to include all cosmetics (5), the inclusion of cosmetics was deleted from the drug definition in 1900 as part of a legislative compromise (6). As a result, cosmetics were not included when the legislation was finally enacted as the Federal Food and Drugs Act of 1906 (7).

Implementation of the 1906 Act was delegated by Congress to the U.S. Department of Agriculture (USDA). Subsequently, it was redelegated to the Federal Security Agency (FSA), then the Department of Health, Education, and Welfare (DHEW), and now the Department of Health and Human Services (DHHS). Since 1930, the specific agency responsible for the 1906 Act and its successor statute, the Federal Food, Drug, and Cosmetic Act of 1938 (8) has been the Food and Drug Administration (FDA) (9). For editorial purposes, throughout this chapter all references to the agencies and departments responsible for implementing federal food and drug laws shall be to the FDA.

Not long after enactment of the 1906 Act, the FDA concluded that its jurisdiction should be expanded to include both cosmetics and medical devices (10). When the Roosevelt Administration introduced a bill to replace the 1906 Act (11), cosmetics were included (12) through a separate definition and separate regulatory requirements. Although the provisions relating to cosmetics were revised periodically during the 5 years of congressional consideration, the separate definition and separate regulatory requirements were retained in the final FD&C Act when it was enacted in 1938 (13). In the intervening 62 years, these provisions have not been amended.

LEGISLATIVE HISTORY OF THE COSMETIC AND DRUG PROVISIONS OF THE 1938 ACT

The 1906 Act had defined a drug to include:

> . . . all medicine and preparations recognized in United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals (14).

From the time that the legislation that ultimately became the FD&C Act was initially introduced until it was finally enacted, substantial attention was focused on the specific definitions of food, drug, and cosmetics, and the interaction among these three definitions. Out of these deliberations, the following important principles and policies emerged.

First, the 1938 Act, like the 1906 Act, classified products according to their intended use. In a paragraph from the 1935 Senate Report on the legislation, Congress established the policy that the representations of the sellers with respect to a product would determine its classification:

> The use to which the product is to be put will determine the category into which it will fall. If it is to be used only as food it will come within the definition of food and none other. If it contains nutritive ingredients but is sold for drug use only, as clearly shown by the labeling and advertising, it will come within the definition of drug, but not that of food. If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both. The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product (15).

This principle remains the touchstone for product classification under the 1938 Act.

Second, from the outset, the FDA sought to expand the definition of a drug from the narrow definition included in the 1906 Act. The 1906 Act limited the drug definition to products intended to prevent or treat disease. The FDA was concerned that, although it was able to regulate food products represented for use in weight reduction, it could not exert jurisdiction over nonfood chemicals represented for the same purpose because obesity was not regarded as a disease. Accordingly, from the initial bill to the final law, the drug definition was expanded to include articles ‘‘intended to affect the structure or any function of the body of man or other animals’’ (16).

Third, Congress determined that the definitions of food, drugs, and cosmetics should not be mutually exclusive. Because the representations made for the product would determine the proper classification of the product, and thus classification was within the sole control of the seller, Congress concluded that the product should be subject to whatever statutory requirements are established for whatever product classifications applied, based upon those representations:

> It has not been considered necessary to specify that the definitions of food, drug, and cosmetic shall not be construed, other than to the extent expressly provided, as mutually exclusive. The present law does not have such a clause relating to the definitions of food and drug and there has never been a court decision to the effect that these definitions are mutually exclusive, despite the fact that repeated actions have been brought, for example, against filthy foods bearing unwarranted therapeutic claims, alleging these products to be adulterated as food because of their filth, and misbranded as drugs because of their false and fraudulent therapeutic claims (17).

Thus, dual and even triple classification of a product as a food, drug, and cosmetic was contemplated by Congress under the 1938 Act.

Fourth, Congress realized that there must be one exception to the general rule of nonexclusive definitions. All food is intended to affect the structure or function of the human body. Accordingly, Congress explicitly excluded food from the structure/function prong of the drug definition, but not from the disease prong.

In the Senate debate on the legislation in April 1935, the exclusion of food from the structure/function prong of the drug definition was expanded, without discussion, to include cosmetics (18). That bill was not passed by the House of Representatives, however, and no subsequent legislation retained the cosmetic exclusion. Accordingly, any cosmetic represented to affect the structure or function of the human body is classified as a drug as well as a cosmetic and must meet the statutory requirements for both categories of products.

Fifth, Congress also included in the 1938 Act, as it had in the 1906 Act, a third prong of the drug definition to include articles recognized in specified pharmacopeias. This was intended, however, to include pharmacopeial articles only when they are in fact represented for disease or structure/function purposes (19). Accordingly, this prong of the definition may be excluded from further consideration in this chapter.

With these principles and policies established, Congress enacted the FD&C Act in 1938 with the following two pertinent definitions. A drug was defined in section 201(g) to mean:

> . . . (1) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in

> the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . .

A cosmetic was defined in section 201(i) to mean:

> . . . articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance . . . .

Parts of the drug definition not pertinent here have been revised since 1938, but the central core of the definition has not been altered. No part of the cosmetic definition has been changed. Thus, the controlling definitions have remained in place for the entire 62-year history of the FD&C Act.

IMPLEMENTATION OF THE FD&C ACT

The regulatory consequences of classifying a product as a drug rather than as a cosmetic are substantial. A drug will almost invariably be determined by the FDA to be a ''new drug'' that required substantial preclinical toxicological testing, clinical testing under an investigational new drug (IND) application, submission of a new drug application (NDA) requesting FDA approval, and ultimately marketing under substantial FDA postapproval requirements, including drug good manufacturing practices (GMP) regulations (20). New drugs typically require a decade or more for research and development prior to FDA approval and require the investment of hundreds of millions of dollars. In short, it is only the very rare cosmetic product that could justify this level of investment. It is therefore essential that cosmetic products be formulated and labeled in such a way as to avoid the drug definition.

Initial FDA Action Under the FD&C Act

FDA scientists recognized very early that all cosmetics penetrate the skin and thus inherently affect the structure or function of the body:

> . . . there are few if any substances which are not absorbed through the intact skin, even though the idea is prevalent that the skin is a relatively effective barrier to its environment (21).

Nonetheless, the FDA recognized that Congress fully intended a separate category of cosmetic products regardless of their inherent effect on the structure or function of the body, as long as no structure/function or disease claims were made for them.

The FDA sought to establish policy on the distinction between a cosmetic and a drug in three ways. First, FDA issued formal trade correspondence that set forth advisory opinions on the classification of products. Second, the agency published pamphlets and other educational materials with examples of product classification. Third, it brought court action to contest the legality of cosmetic products with labeling that contained what the agency concluded to be drug claims. From this body of literature and precedent has emerged, over six decades, a number of well-developed examples:

A suntan product is a cosmetic but a sunscreen product is a drug.
A deodorant is a cosmetic but an antiperspirant is a drug.
A shampoo is a cosmetic but an antidandruff shampoo is a drug.
A toothpaste is a cosmetic but an anticaries toothpaste is a drug.
A skin exfoliant is a cosmetic but a skin peel is a drug.
A mouthwash is a cosmetic but an antigingivitis mouthwash is a drug.
A hair bulking product is a cosmetic but a hair growth product is a drug.
A skin product to hide acne is a cosmetic but an antiacne product is a drug.
An antibacterial deodorant soap is a cosmetic but an antibacterial anti-infective soap is a drug.
A skin moisturizer is a cosmetic but a wrinkle remover is a drug.
A lip softener is a cosmetic but a product for chapped lips is a drug.

This list is illustrative, not exhaustive.

Products that are represented only to change the structure or function of the hair or nails are regarded as cosmetics and not drugs. For example, permanent waves and cuticle removers are cosmetics, not drugs (22). Products that are represented to affect the hair or nails systemically, on the other hand, are regarded as drugs.

Cosmetic products represented as ''hypoallergenic,'' and thus with reduced allergic potential, remain classified as cosmetics and not as drugs (23). Only if these products are represented to treat specific reactions or diseases would they be classified as drugs.

Inclusion of an active ingredient in a cosmetic does not automatically classify it as a drug, unless the active ingredient is so closely identified with therapeutic properties that the mere use of the term would connote a drug claim. For example, use of the term ''penicillin'' or ''AZT'' would preclude classification of the product solely as a cosmetic because of their well-recognized therapeutic purposes (24). In many instances, however, ingredients can be used in both cosmetic and drug products. When the FDA banned all topical nonprescription drug products containing hormones, the agency stated that cosmetics could continue to contain hormones without becoming drugs if the chemical name of the specific hormone was included in the ingredient statement and the word ''hormone'' was not used in the labeling or advertising (25).

In many instances, the context of a word or phrase must be considered before a determination can be made about proper classification of the product as a drug or cosmetic. A product represented as a treatment for disease is a drug, but a product represented as a beauty treatment is a cosmetic. A product represented to kill germs that cause infection is a drug but a product tht is represented to kill germs that cause odor is a cosmetic.

These examples illustrate the difficulty in drawing a clear and definitive distinction between these two categories of products. Nonetheless, these distinctions have come to be understood both by FDA and by industry and serve the extremely useful purpose of guiding decisions in this area.

The Wrinkle Remover Cases of the 1960s

In the early 1960s, the cosmetic industry developed a line of products, broadly characterized as ''wrinkle remover'' products, containing ingredients intended to smooth, firm, and tighten the skin temporarily and thus to make wrinkles less obvious. In 1964, the FDA seized several of these products, alleging that they were drugs under the FD&C Act. The resulting litigation produced three decisions by U.S. District Courts and two decisions by U.S. Courts of Appeals involving three products: Line Away, Sudden Change, and Magic Secret.

The District Court in the Line Away case took the position that, by intending to smooth and tighten the skin, Line Away had as its objective affecting the structure of the skin and thus was a drug (26). The Court of Appeals agreed, citing the ''strong therapeutic implications'' of the promotional material (27).

The District Court in the Sudden Change case concluded that the product was represented merely to alter the appearance of the skin and thus was a cosmetic (28). The Court of Appeals, however, reversed the District Court in a split decision. The majority held that the claims that that product would give a ''face lift without surgery'' and would ''lift out puffs'' had ''physiological connotations'' (29). The majority went out of its way, however, to state that all of the traditional cosmetic claims (e.g., that a product will soften or moisturize the skin) remain within the cosmetic category. One judge dissented on the ground that the two claims cited by the majority as drug claims were indistinguishable from such cosmetic claims as smooths, firms, tones, and moisturizes the skin.

Finally, the District Court in the Magic Secret case determined that the product was a cosmetic, not a drug, based on the conclusion that the claims were less exaggerated than in the other two cases. The court held that the claim that the product caused an ''astringent sensation'' would not be regarded by consumers as doing anything other than altering their appearance (30).

By this time, it was apparent both to the FDA and to the regulated industry that further litigation would be unproductive. Industry sought to modify its claims in order to bring them within the cosmetic boundaries established by the FDA

administrative precedent and the judicial decisions. The FDA concluded to provide any further guidance with respect to the distinction between a drug and a cosmetic through the OTC Drug Review, which was initiated in the early 1970s.

The OTC Drug Review

Under the Drug Amendments of 1962 (31), which were enacted following the thalidomide disaster in order to strengthen drug regulation in the United States, the FDA was required to review every new drug application (NDA) that had become effective on the basis of an agency safety review between 1938 and 1962 in order to determine whether the drug was effective as well as safe. For prescription drugs, FDA submitted the pre-1962 NDAs for review by the National Academy of Sciences, under the Drug Efficacy Study Implementation (DESI) program. For nonprescription drugs (also called over-the-counter or OTC drugs), the FDA chose a different approach. Under procedures promulgated in 1972 (32), the FDA established advisory committees to review all of the pharmacological categories of OTC drugs and to prepare reports on the safety, effectiveness, and labeling for all existing OTC drugs. The advisory committee reports, together with a proposed monograph, were published in the Federal Register for public comment. After reviewing the public comment, the FDA published its own conclusions together with a tentative final monograph for further public comment. Following its consideration of the second round of public comments, the FDA promulgated a final monograph establishing the conditions for safe and effective use including required and permitted labeling of the OTC drugs that fell within that drug category. An OTC drug ingredient that was not included in a final monograph could no longer be used as an active ingredient in an OTC drug following the effective date of the final monograph, but could be used as an inactive ingredient or as a cosmetic ingredient.

The OTC Drug Review inherently raised issues relating to the distinction between a cosmetic and a drug. All of the traditional cosmetic drug products—sunscreens, antiperspirants, antidandruff shampoos, anticaries toothpaste, skin protectants, hormone creams, acne products, and so forth—were reviewed under the OTC Drug Review. The FDA made clear that only the drug and not the cosmetic aspects of cosmetic drugs were subject to review and evaluation, and ultimately a final monograph, under this program. Thus, in many of the advisory committee meetings and subsequent reports (33), as well as in the preambles to the tentative final (34) and final (35) monographs, there has been substantial discussion about the dividing line between a drug claim and a cosmetic claim for a cosmetic drug. In several instances, the FDA has explicitly stated that a final monograph covered only products making drug claims and did not cover cosmetic claims for the product or products making only cosmetic claims.

The distinction between a cosmetic and a drug became important early in the OTC Drug Review process. Based on an advisory committee recommendation, FDA published regulations banning three substances as unsafe for use: hexachlorophene (36), TBS (37), and zirconium (38). Recognizing that these substances could properly be used both in drugs and in cosmetics, the FDH published parallel regulations to assure that both types of uses would be banned.

For the most part, the OTC Drug Review has proceeded without major controversy with respect to the classification of cosmetic and drug claims. In general, the FDA has followed the traditional cosmetic/drug distinctions described earlier in this chapter. In a few remaining monographs, however, the FDA has proposed to change its policy with respect to important products. It has proposed to reclassify ''kills germs that cause odor'' from the cosmetic category to drug status (39). It has proposed to set a limit on cosmetic use of hormone ingredients, above which they would automatically become drugs (40). The resolution of these matters remains uncertain. Although the FDA had previously stated that suntan products are cosmetics (41), it proposed to reclassify them as drugs, but then retained them as cosmetics (with a required sunburn warning) in the final regulations (42). Industry, in turn, has asked the FDA to classify sunscreen ingredients when used in nonbeach traditional cosmetic formulations as cosmetic ingredients rather than as drugs, in order to encourage the cosmetic industry to include sunscreen ingredients in skin-care products for public health protection wherever feasible, but the FDA rejected this approach.

The Warning Letters of the Late 1980s

For a period of 15 years following the conclusion of the wrinkle remover cases, the FDA pursued cosmetic/drug issues largely through the OTC Drug Review and seldom, if ever, through Regulatory Letters or direct court action. Based upon new product technology and the conclusion that the consuming public was becoming increasingly sophisticated about skin-care products and their claims, the cosmetic industry gradually became more aggressive with cell rejuvenation and other antiaging promotional claims. As a result of research and development in the intervening years, new and more effective products were now on the market.

Two defining events served to initiate a new round of FDA enforcement activities against skin-care claims in the late 1980s (43). First, in 1986 the well-known South African heart surgeon, Christiaan Barnard, made a tour of the United States on behalf of a cosmetic company to promote its skin care product, Glycel. Barnard made extravagant claims for Glycel on the television program, Nightline, with FDA Commissioner Frank Young participating on the same program. Second, an attorney for a major cosmetic company wrote Dr. Young to protest the claims being made for Glycel. As a result, the FDA began to issue Regulatory Letters not only to the manufacturer of Glycel but also to other leading

members of the industry (44). More than 20 Regulatory Letters were sent in the first wave, and when the FDA concluded that the response was unsatisfactory the agency sent another 20. Complex negotiations ensued among the FDA, individual companies, and a consortium of companies. The FDA established the agency position on the matter with a letter from the FDA Associate Commissioner for Regulatory Affairs, John Taylor:

> We consider a claim that a product will affect the body in some physiological way to be a drug claim, even if the claim is that the effect is only temporary. Such a claim constitutes a representation that the product is intended to affect the structure or function of the body and thus makes the product a drug under 21 U.S.C. 321(g)(1)(C). Therefore, we consider most of the anti-aging and skin physiology claims that you outline in your letter to be drug claims. For example, claims that a product ''counteracts,'' ''retards,'' or ''controls'' aging or the aging process, as well as claims that a product will ''rejuvenate,'' ''repair,'' or ''renew'' the skin, are drug claims because they can be fairly understood as claims that a function of the body, or that the structure of the body, will be affected by the product. For this reason also, all of the examples that you use to allege an effect within the epidermis as the basis for a temporary beneficial effect on wrinkles, lines, or fine lines are unacceptable. A claim such as ''molecules absorb'' . . . and expand, exerting upward pressure to ''lift'' wrinkles ''upward'' is a claim for an inner, structural change (45).

The Associate Commissioner did offer some guidelines for cosmetic claims:

> While we agree with your statements that wrinkles will not be reversed or removed by these products . . . we would not object to claims that products will temporarily improve the appearance of such outward signs of aging. The label of such products should state that the product is intended to cover up the signs of aging, to improve the appearance by adding color or a luster to skin, or otherwise to affect the appearance through physical means . . . .
>
> However, we would consider a product that claims to improve or to maintain temporarily the appearance or the feel of the skin to be a cosmetic. For example, a product that claims to moisturize or soften the skin is a cosmetic.

Following the FDA letter, one company brought court action to obtain a declaratory judgment that its product was a cosmetic rather than a drug, but the court ruled that a Regulatory Letter could not be contested in this way, and thus the issue remained unresolved (46). Individual companies eventually worked out their issues with the FDA and thus the agency was not required to bring formal court action against even one product.

The Alpha-Hydroxy Acid (AHA) Products of the 1990s

In the early 1990s, the cosmetic industry developed and marketed a line of products containing alpha-hydroxy acids such as glycolic, lactic, and citric acid that

occurred in natural food products, to cleanse dead cells from the surface of the skin and assist moisturization. The AHAs have been used in consumer products at relatively modest levels, usually at 10% or lower, in contrast with very high levels used in professional skin peeling products (47). It is universally accepted that the AHA products are the most effective skin-care beauty products that the industry has ever developed. As a result, they have become extremely popular with consumers and gained substantial media and regulatory attention.

The FDA has raised two questions about the AHA products. First, the agency has questioned the claims being made. The FDA has sought to adhere to the guidelines established in the November 1987 letter on the antiaging and cell rejuvenation products. Second, the FDA has also questioned the safety of these products, not on the ground that there are known toxicological concerns but rather on the ground that their safety is unproven. In contrast with the cell rejuvenation claims of the 1980s, however, the FDA has not launched another wave of Warning Letters. A company that had obtained FDA approval of NDAs for antiaging drugs, frustrated by this lack of FDA action, brought a private false advertising case under section 43(a) of the Lanham Act (48) against a competitor making aggressive claims for a cosmetic product, but lost in both the District Court (49) and the Court of Appeals (50).

Use of Foreign Marketing Experience

As noted above, the cosmetic industry has been forced to stay within the confines of traditional cosmetic claims for skin-care products that could potentially justify stronger promotion, because the only other alternative is the bottomless pit of the IND/NDA process for drugs. To create a more realistic alternative, the FDA has sought to modify its position on OTC drugs.

When the OTC Drug Review was initiated in 1972, the FDA announced two policies that were designed to confine the scope of the Review. First, the Review included only those products on the market prior to the final procedural regulations, published in June 1972. This date was later extended to December 1975. Second, the Review included only products marketed in the United States, and excluded those marketed abroad. As a result, it was impossible to market in the United States any nonprescription drug that had been sold abroad before the cutoff date or that was developed at any time, anywhere in the world, after the cutoff date.

These two policies were adopted for management, not legal, reasons. The OTC Drug Review was an enormous undertaking, and the FDA concluded that it was essential to establish limitations in order to avoid a perpetual process. Nonetheless, these two policies had a major adverse impact. Some products marketed abroad have important public health benefits. For example, sunscreen products providing protection against both ultraviolet A (UVA) radiation and ultravio-

let B (UVB) radiation were available in Europe for at least 15 years before they became available in the United States. The FDA refused to bring these products within the OTC Drug Review until it finally relented in 1997 (51). In the interim, U.S. residents were denied important public health protection solely because of this policy.

Recognizing the adverse public health consequence of its policy, and in light of a court decision invalidating a parallel policy for food ingredients (52), the FDA has now opened up the issue of expanding the OTC Drug Review to include new conditions under the OTC drug monograph system based upon foreign marketing experience (53). The FDA has thus far published an advance notice of proposed rulemaking on this issue, and an actual proposed change in the current regulations, but it may be some years before final action is taken on it.

In the interim, additional pressure is being placed on the FDA to change its policy in order to achieve international harmonization in the regulation of cosmetics and nonprescription drugs. It is difficult, if not impossible, to reconcile the FDA policy that excludes foreign marketing experience with the requirements of the General Agreement on Tariffs and Trade (GATT) (54). The recently enacted Food and Drug Administration Modernization Act of 1997 also requires the FDA to work toward international harmonization and mutual recognition agreements relating to drugs between the European Union and the United States (55). The combination of all of these efforts may well produce a more flexible approach toward FDA approval of nonprescription cosmetic drugs.

If the FDA were to recognize foreign marketing experience and engage in international harmonization, the distinction between a cosmetic and a drug in the United States could become less crucial. A number of products that are marketed as cosmetic drugs in the United States are classified solely as cosmetics in Europe. Cosmetic drugs can also be marketed in Europe with less restrictions than apply in the United States. Once a cosmetic drug is on the market in Europe, entry into the United States could become easier based upon international harmonization and mutual recognition principles.

The Rationale of the Tobacco Initiative

In August 1995, the FDA published two notices in the Federal Register relating to the proposed regulation of tobacco (56). The first notice set forth the proposed regulation governing cigarettes. The second notice consisted of an analysis supporting the agency's decision on the matter. Normally, regulation of cigarettes would have little or nothing to do with regulation of cosmetics. The rationale provided by the FDA for asserting its jurisdiction over cigarettes, however, as

well as some of the specific discussion in the Federal Register preambles, are of substantial importance to the cosmetic/drug distinction.

As discussed above, the FD&C Act provides that a drug includes articles ''intended to affect the structure or any function of the body.'' In its analysis relating to cigarettes, the FDA took the position that the ''intent'' required under this definition means the ''objective'' intent of the manufacturer, not the ''subjective'' intent (i.e., the manufacturer's representation for the product). The FDA contended that ''objective'' intent requires a ''reasonable person'' test, and that a manufacturer is charged with the reasonable foreseeability—the natural and foreseeable consequences—of its action. Thus, the FDA asserted that it has authority under the FD&C Act to classify products as drugs where they inherently result in nontherapeutic but pharmacological effects even though no pharmacological or therapeutic claims are made for the products. The following examples were given by the FDA: topical hormones and sunscreens. The FDA analysis stated, however, that courts have distinguished between ''remote physical effects'' that would not make a product inherently a drug and ''significant effects on structure or function'' which the agency concluded clearly fall within the drug definition (57).

In its final regulation published in August 1996 (58), the FDA adhered to this position. The FDA categorically rejected the contention that the intended use of a product must be derived solely from the manufacturer's subjective intent (i.e., promotional claims for the product). The FDA did, however, reiterate that the structure/function provision would not extend to products that have a ''remote physical effect on the body'' (59).

The U.S. District Court that reviewed this matter upheld the FDA position on ''intended use'' (60). On appeal, however, the U.S. Court of Appeals overturned the District Court and declared the FDA regulations unlawful (61). In a divided decision, the majority of the Court of Appeals agreed with the District Court that ''no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use,'' but then went on to decide the case on completely different grounds. The majority concluded, as a matter of statutory construction, that the FDA has no jurisdiction over tobacco products under the FD&C Act, and thus it was unnecessary to determine the scope of the ''intended use'' provision in the structure/function prong of the drug definition. The dissenting judge agreed with the FDA interpretation of intended use.

As a result, we are left with an FDA interpretation, a District Court agreement with that interpretation, two judges on the Court of Appeals who questioned the FDA interpretation but determined it was irrelevant, and one judge on the Court of Appeals who also agreed with the FDA interpretation. In short, the state of the law remains quite uncertain in this area. Even if the FDA interpretation

were upheld, however, it would still exclude all cosmetics with structure/function effects that are remote or insignificnat.

Labeling and Manufacturing Difficulties for Cosmetic Drugs

Compliance with the combined cosmetic and drug provisions of the FD&C Act can be difficult and aggravating. FDA regulations have in the past sought to accommodate cosmetic drug labeling requirements (62), however, and the FDA Modernization Act specifically reconciled the two different approaches to ingredient labeling (63). To the extent that FDA continues to ignore the labeling complexities of cosmetic drugs—as it did, for example, in promulgating the final regulations for nonprescription sunscreen drugs (64) and for the new labeling requirements for all nonprescription drugs (65)—concerns about the dividing line between a cosmetic and a drug will be greatly aggravated. Although the FDA has declined formally to acknowledge different good manufacturing practice standards for cosmetic drugs (66), in practice cosmetic drugs are usually not held to the identical requirements.

Budgetary Impact on the FDA

The ability of the FDA to monitor and bring regulatory action with respect to claims for cosmetic products must take into account the resources available to the agency for this purpose. During the past several years, the FDA has experienced a flat budget. Because of the inexorable impact of inflation, this has been tantamount to a substantial reduction in available resources. At the same time, the FDA has been pursuing its tobacco initiative and a presidential initiative on food safety. As a result of all of these budgetary factors, the FDA announced in 1998 that it was reducing the staff of the Office of Cosmetics and Colors by 50% and cutting back or eliminating many cosmetic regulatory programs (67). This reduction is so substantial that it propelled the cosmetic industry to request and obtain restoration by Congress of adequate funds to assure that the FDA has a credible cosmetic regulatory program. FDA cosmetic officials are also reaching out to FDA drug officials for cooperation and assistance in discharging their duties.

POTENTIAL FUTURE APPROACHES

For more than 30 years, there has been widespread debate about whether, and how, the current statutory definitions of cosmetic and drug should be changed. Virtually every option has been considered, from making no change at all to modest or even substantial legislative changes.

Advocates of leaving the statute unchanged contend that, in general, there is already sufficient flexibility in the law to permit valid cosmetic claims and that any attempt to change the legislation might well result in a worse situation rather than a better one. Even the November 1987 FDA guidelines provide industry with a great deal of flexibility. Creative marketing has found a way to convey the benefit of innovative new cosmetic products to consumers, as shown by experience with the AHA products. Thus, there is little to be gained, and potentially a great deal to be lost, by Congress considering changes in the cosmetic provisions of the FD&C Act that have stood the test of 60 years of experience without a single amendment.

Advocates of moderate change contend that all that would be needed is to insert the two words ''and cosmetics'' in the parenthetical exclusion that currently exists in the structure/function prong of the drug definition—the approach taken by the Senate in April 1935 (68)—with the result that both food and cosmetics would be excluded from this portion of the definition. This would allow cosmetics to make structure/function claims comparable to the structure/function claims available to dietary supplements and conventional food (69). It would be necessary to obtain clear legislative history that a structure/function claim is not an implied disease claim, as the FDA once contended for food products (70). Advocates of this minimalist legislative approach acknowledge, however, that they can offer no assurance that Congress would not reexamine other portions of the cosmetic provisions of the FD&C Act and perhaps make additional changes.

Advocates for a more extensive legislative approach offer a wide variety of potential statutory changes. Some advocate creating an entire new category of cosmetic drugs that would have its own separate regulatory requirements and prohibitions, halfway between those for drugs and those for cosmetics. Others argue for imposing the same premarket safety requirements for cosmetic drugs as for other drugs, but excluding claims from premarket review or approval. Once again, these advocates acknowledge that Congress could, in the process of establishing any such new statutory scheme, also review and change the existing cosmetic provisions of the FD&C Act.

In the more than 30 years that this subject has been debated, no new legislation has been proposed to address the matter. Over the same period of time, industry has found ways to accommodate the existing FDA requirements and to reconcile advances in technology with current regulatory policy.

CONCLUSION

The history set forth in this chapter reflects the inherent uncertainty in attempting to formulate any bright line between a cosmetic and a drug. Even with legislation, whatever new statutory definitions or standards that might be enacted would inev-

itably raise close questions of judgment that would continue to evolve over time. Accordingly, legislation will not eliminate the uncertainty inherent in the cosmetic/drug distinction and thus is not the only or even the preferred solution to this matter.

The FDA has substantial administrative discretion to determine the line between a cosmetic and a drug. By assuring the safety of cosmetic ingredients through the Cosmetic Ingredient Review program (71), the cosmetic industry has substantially reduced concern about the safety of marketed cosmetic products. International harmonization activities have already led the FDA to explore opening U.S. requirements to include foreign marketing experience, and the FDA Modernization Act requirements with respect to international harmonization and mutual recognition will accelerate this approach. It is thus more likely that a reasonable approach to the cosmetic/drug distinction will be found through administrative and international action rather than through legislation.

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16
Drugs Versus Cosmetics: Cosmeceuticals?

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REGULATORY: JAPAN

Regulatory Environment

The legal classification of topical products in Japan is different from that in the United States and Europe, where they are classified into only two categories—drugs and cosmetics. In Japan, there are also regulations covering cosmetic products with pharmacological action, called quasidrugs, which are ranked between cosmetics and drugs (1). Each definition of drugs, cosmetics, and quasidrugs in the regulations of The Pharmaceutical Affairs Law (2) reads as follows:

Drugs are articles as defined below.

1. Articles recognized in the official Japanese pharmacopoeia.
2. Articles (other than quasidrugs) that are intended for use in the diagnosis, cure, or prevention of disease in humans or animals, and that are not equipment or instruments (including dental materials, medical supplies, and sanitary materials).
3. Articles (other than quasidrugs and cosmetics) that are intended to affect the structure or any function of the body of humans or animals, and that are not equipment or instruments (paragraph 1, article 2 of the law).

Quasidrugs are articles that have the purposes given below and exert mild actions on the human body, or similar articles designated by the Minister of Health and Welfare. They exclude not only equipment and instruments but also any article intended, in addition to the following purposes, for the use of drugs described in 2 and 3 above.

1. Prevention of nausea or other discomfort, or prevention of foul breath or body odor.
2. Prevention of prickly heat, sores, and the like.
3. Prevention of falling hair, or hair restoration or depilation.
4. Killing or prevention of rats, flies, mosquitoes, fleas, etc., for maintaining the health of humans or animals (paragraph 2, article 2 of the law).

Examples of quasidrugs, as designated by the Minister of Health and Welfare (MHW Notification No. 14, 1961) include: (1) cotton products intended for sanitary purpose (including paper cotton); (2) products with a mild action on the human body [i.e., hair dyes; agents for permanent waving; products that combine the purposes of use as stipulated in paragraph 3, article 2 of the law (on cosmetics), with the purpose of prevention of acne, chapping, itchy skin rash, chilblain, etc., as well as disinfection of the skin and mouth (so-called medicated cosmetics) and bath preparations].

The term ''cosmetic'' means any article intended to be used by means of rubbing, sprinkling, or by similar application to the human body for cleaning, beautifying, promoting attractiveness, altering the appearance of the human body, and for keeping the skin and hair healthy, provided that the action of the article on the human body is mild. Such articles exclude the articles intended, besides the above purposes, for the use of drugs described in 2 or 3 above, and quasidrugs (paragraph 3, article 2 of the law).

Cosmeceuticals in Japan

A current definition of cosmeceuticals would cover those products ''that will achieve cosmetic results by means of some degree of physiological action'' (3). This product category is ranked between cosmetics and drugs. It is a well-known fact that Japan is ahead of most other countries in coping with the legal issues. A category of pseudodrugs that are what we now refer to as cosmeceuticals has already been established in the Pharmaceutical Affairs Law (4). The phrase pseudodrugs corresponds to the legal category of quasidrugs. Actually, many of the topical products corresponding to the cosmeceuticals fall into the category of quasidrugs. In the Pharmaceutical Affairs Law, quasidrugs are defined as articles having ''a fixed purpose of use'' and ''a mild action on the body'' or similar articles designated by the Minister of Health and Welfare. Their types, purpose of use, principal product form, indications, and effects are described in Tables 1 and 2 (2,5).

The manufacturers of quasidrugs are required to obtain government approval before marketing. Approval of a product under application for manufacturing (import) is contingent upon a judgment by the Ministry of Health and Welfare

regarding its adequacy as a quasidrug in view of its effectiveness, safety, etc. It should be noted, therefore, that the examination procedures for approval, as well as the data and documentation required to be submitted upon filing differ according to indications and effects of the products (2). The following data must be submitted, depending on the kind of ingredients, etc.: (1) data on origin, background of discovery, use in foreign countries; (2) data on physicochemical properties, specifications, testing methods; (3) data on stability; (4) data on safety; and (5) data on indications or effects.

The scope of data actually to be attached to the application depends on the type of quasidrug: (1) new quasidrugs that obviously differ from any one of previously approved products with regard to active ingredient, usage, and dosage and/or indications or effects; (2) quasidrugs identical with previously approved quasidrug(s); or (3) other quasidrugs that are other than those specified in (1) and (2) above (2).

For a product under application to be approved as a quasidrug, it is prerequisite that the purpose of its use is within the scope stipulated by the Pharmaceutical Affairs Law. Thus, approval of a product as a quasidrug is determined by an integrated judgment of various factors such as its ingredients, quantity (composition), indications and effects, usage and dosage, and dosage form. For example, those products whose effects are not mild and thus come under the category of poisons or deleterious drugs are *not* approved, even if their indications, effects, and dosage forms are within the scope of quasidrug legislation. Likewise, products for which the purpose of use deviates from the scope of quasidrug are not approved either, even if their effects are mild (2).

When viewed taking into account the essential characteristics of quasidrugs for example, it is inappropriate for products such as mouth refreshers to include any medicinal indications and effects relevant to ''treatment,'' such as morning sickness and sterilization and disinfection of the mouth (2).

Since a quasidrug under the law may be sold and used by any person without specific restriction, it should be a product that, in principle, can be easily and directly used by any person without involving any complex process (2). An active ingredient used in a chemically pure (bulk drug) form is usually considered a drug and not suitable for over-the-counter use. Therefore, such a product is not acceptable as a quasidrug. Generally, simplicity in handling and usage constitutes another potent factor (2).

Cosmeceuticals in the Future

With respect to cosmetic requirements, the demand for fashion has strengthened, but, at the same time, a tendency to place importance on efficacy has also emerged (6). This trend has become increasingly strong with the transition toward a gerontocracy, who wish to delay the biological process of aging and remain young as

Table 1 Types, Purposes of Use, Indications, and Effects of Quasidrugs

Type of quasidrugs	Scope of purpose of use and principal product forms		Scope of indications and effects
	Purpose of use	Principal product form	Indications and effects
1. Mouth refreshers	Oral preps for prevention of nausea or other indisposition	Pill, plate, troche, liquid	Heartburn, nausea and vomiting, motion sickness, hangover, dizziness, foul breath, choking, indisposition, sunstroke
2. Body deodorants	External agents to prevent body odor	Liquid, ointment, aerosol, powder, stick	Body odor, perspiration odor, suppression of perspiration
3. Talcum powders	Agents to prevent prickly heat, sores, etc.	Powder for external application	Prickly heat, diaper rash, sores, razor burn
4. Hair growers (hair nutrients)	External agents to prevent loss of hair and to grow hair	Liquid, aerosol	Hair growth, prevention of thinning hair, itching and falling hair, promotion of hair growth, dandruff, loss of hair after illness or childbirth, hair nutrition
5. Depilatories	External agents for hair removal	Ointment, aerosol	Hair removal
6. Hair dyes (including color and dye removers)	External agents for dying hair, removing hair or dye colors. Excluding agents for physical hair dying	Powder, tablet, liquid, cream, aerosol	Hair dying, hair decoloring, removal of hair color dye
7. Permanent waving agents	External agents for waves in the hair etc.	Liquid, cream, powder, paste, aerosol, tablet	Creation and retention of waves in the hair, straightening frizzy, curly or wavy hair, and retaining that condition
8. Sanitary cotton products	Cotton (including paper cotton) used for sanitary purposes	Cotton products, gauze	Sanitary napkins for absorbing and managing menses; cotton for cleaning, for wiping clean the skin and cavities of babies, for wiping clean the breasts and nipples when nursing, for wiping clean the eyes, genitals, and anus

9. Bath preparations	External agents to be dissolved, as a rule, in the bath (excluding bath soaps)	Powder, granule, tablet, soft capsule, liquid, etc.	Prickly heat, roughness, ringworm, bruises, stiff shoulder, sprains, neuralgia, eczema, frostbite, hemorrhoids, tinea, chills, athlete's foot, scabies, itch, lumbago, rheumatism, fatigue recovery, chaps, cracks, chills before and after childbirth, acne
10. Medicated cosmetics (including medicated soaps)	External agents combining cosmetic purposes and resembling cosmetics in forms	Liquid, cream, jelly, solid, aerosol	See Table 2
11. Medicated dentifrices	External agents combining cosmetic purposes and resembling ordinary dentifrices in forms	Paste, liquid, powder, solid, tooth wet-powder	Making the teeth white, cleaning and refreshing the mouth, prevention of pyorrhea, prevention of gingivitis, prevention of tartar, prevention of dental caries, prevention of occurrence and progress of dental caries, prevention of foul breath, removal of tobacco stains
12. Repellents	Agents for repelling insects such as flies, mosquitoes, fleas, etc.	Liquid, stick, cream, aerosol	Repelling mosquitoes, gnats, stinging flies, fleas, house ticks, bedbugs, etc.
13. Insecticides	Agents for killing and eliminating insects such as flies, mosquitoes, fleas, etc.	Mat, stick-incense, powder, liquid, aerosol, paste	Killing of insects; exterminating and preventing sanitary insect pests such as flies, mosquitoes, fleas, etc.
14. Rodenticides	Agents for killing and eliminating rats and mice		Killing of rats and mice; expelling, exterminating, or preventing rats and mice
15. Soft contact lens disinfectants	Agents to disinfect soft contact lens		Disinfectant for soft contact lenses

Source: Modified from Refs. 2 and 5.

Table 2 Types of Medicated Cosmetics

Type	Indications and effects
1. Shampoos	Prevention of dandruff and itching Prevention of perspiration odors in the hair and on the scalp Cleaning of the hair and scalp a. Keeping the hair and scalp healthy b. Making the hair supple (Choose either a or b)
2. Rinses	Prevention of dandruff and itching Prevention of perspiration odors in the hair and on the scalp Supplementing and maintaining moisture and fat of the hair Prevention of split, broken, or branched hairs a. Keeping the hair and scalp healthy b. Making the hair supple (Choose either a or b)
3. Skin lotions	Chapping and roughness of the skin Prevention of prickly heat, frostbite, chaps, cracks, acne Oily skin Prevention of razor burn Prevention of spots and freckles due to sunburn Burning sensation after sunburn or snow burn Bracing, cleaning, and conditioning the skin Keeping the skin healthy; supplying the skin with moisture
4. Creams, milky lotions, hand creams, cosmetic oils	Chapping and roughness of the skin Prevention of prickly heat, frostbite, chaps, cracks, acne Oily skin Prevention of razor burn Prevention of spots and freckles due to sunburn Burning sensation after sunburn or snow burn Bracing, cleaning and conditioning the skin Keeping the skin healthy; supplying the skin with moisture Protection of the skin; prevention of dry skin
5. Shaving agents	Prevention of razor burn Protection of the skin for smoother shave
6. Sunburn prevention agents	Prevention of chapping due to sunburn and snow burn Prevention of sunburn and snow burn Prevention of spots and freckles due to sunburn Protection of the skin
7. Packs	Chapping and roughness of the skin Prevention of acne Oily skin Prevention of spots and freckles due to sunburn Burning sensation after sunburn or snow burn Making the skin smooth Cleaning the skin
8. Medicated soaps (including face cleaning agents)	Soaps which are mainly bactericides Cleaning, sterilizing and disinfecting the skin Prevention of body odor, perspiration odor, and acne Soaps mainly containing anti-inflammatory agents Cleaning of the skin; prevention of acne, razor burn, and chapping

Source: Refs. 2 and 5.

long as possible. However, the desire to look young and beautiful is shifting to a desire to protect the health of the skin (6).

In addition, with the increasingly sophisticated research into the skin, technology has been generating new active ingredients for antiaging skin-care products. However, some of them, such as antiwrinkle products, fall into neither of the three categories—drugs, quasidrugs, or cosmetics. No existing specifications (Tables 1,2) (2,5) of quasidrug are suitable for such products. How, then, should these products be categorized?

In the United States, a drug is defined as ''an article intended for the use in the diagnosis, mitigation, treatment or prevention of disease or intended to affect the structure or any function of the body.'' According to the current federal Food, Drug and Cosmetic Act, written in 1938, cosmetics are defined as ''articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance'' without affecting structure or function (7–9). If, for example, a nonmedicated shampoo is designated ''dandruff'' shampoo, simply by virtue of the fact that it removes loose dandruff flakes as part of the cleansing process, then it would be classified as a cosmetic shampoo (8). However, a shampoo that controls dandruff flaking would be categorized as a drug, and known as an ''antidandruff'' shampoo (8). On the other hand, an antidandruff shampoo would be regarded as a quasidrug in Japan if its action on the human body was mild.

Generally, topically applied quasidrugs are intended to mollify flaws of the skin and have a mild action on the human body, while drugs are intended to treat diseases (10). Therefore, hair-growing products having mild action on male pattern baldness, which is not a disease (1), and are considered quasidrugs; on the other hand, products intended for alopecia areata, which is a kind of disease, are regarded as drugs. Aging of skin, as in wrinkling, for example, is not a disease. We should also keep in mind that ''high efficacy'' would not always involve ''strong action.'' There will probably be many cosmeceutical products with mild action showing good efficacy. Accordingly, those new cosmeceutical products intended for antiaging of the skin could be categorized as quasidrugs. Legally, the Minister of Health and Welfare can add new or novel types of product to the current list of quasidrugs (10).

Regarding this matter, a review ''. . . of the scope of efficacy by adding new effects, will increase incentives toward research and developments in the technological standards and quality of cosmetics'' was included in the policy for promoting the Japanese cosmetic industry (6,11) published in May, 1984 by the Pharmaceutical Industry Policy Council, a consulting body of the Director of Pharmaceutical Affairs Bureau, the Ministry of Health and Welfare. The Japan Cosmetic Industry Association has set up an ad hoc subcommittee within its

technical committee to review the scope of indications and effects of cosmetics and quasidrugs (12). We hope this effort will be successful.

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