

# **Cosmeceuticals**

## **Drugs vs. Cosmetics**

**edited by**

**Peter Elsner**

*Friedrich Schiller University, Jena, Germany*

**Howard I. Maibach**

*University of California, San Francisco, California*



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## **About the Series**

The Cosmetic Science and Technology series was conceived to permit discussion of a broad range of current knowledge and theories of cosmetic science and technology. The series is composed of both books written by a single author and edited volumes with a number of contributors. Authorities from industry, academia, and the government participate in writing these books.

The aim of the series is to cover the many facets of cosmetic science and technology. Topics are drawn from a wide spectrum of disciplines ranging from chemistry, physics, biochemistry, and analytical and consumer evaluations to safety, efficacy, toxicity, and regulatory questions. Organic, inorganic, physical and polymer chemistry, emulsion and lipid technology, microbiology, dermatology, and toxicology all play important roles in cosmetic science.

There is little commonality in the scientific methods, processes, and formulations required for the wide variety of cosmetics and toiletries in the market. Products range from preparations for hair, oral, and skin care to lipsticks, nail polishes and extenders, deodorants, body powders and aerosols, to quasi-pharmaceutical over-the-counter products such as antiperspirants, dandruff shampoos, antimicrobial soaps, and acne and sun screen products.

Cosmetics and toiletries represent a highly diversified field involving many subsections of

science and “art.” Even in these days of high technology, art and intuition continue to play an important part in the development of formulations, their evaluation, selection of raw materials, and, perhaps most importantly, the successful marketing of new products. The application of more sophisticated scientific methodologies that gained steam in the 1980s has increased in such areas as claim substantiation, safety testing, product testing, and chemical analysis and has led to a better understanding of the properties of skin and hair. Molecular modeling techniques are beginning to be applied to data obtained in skin sensory studies.

Emphasis in the Cosmetic Science and Technology series is placed on reporting the current status of cosmetic technology and science and changing regulatory climates and presenting historical reviews. The series has now grown to 26 books dealing with the constantly changing technologies and trends in the cosmetic industry, including globalization. Several of the volumes have been translated into Japanese and Chinese. Contributions range from highly sophisticated and scientific treatises to primers and presentations of practical applications. Authors are encouraged to present their own concepts as well as established theories. Contributors have been asked not to shy away from fields that are in a state of transition, nor to hesitate to present detailed discussions of their own work. Altogether, we intend to develop in this series a collection of critical surveys and ideas covering diverse phases of the cosmetic industry.

The 13 chapters in *Multifunctional Cosmetics* cover multifunctional products for hair, nail, oral, and skin care, as well as products with enhanced sunscreen and antimicrobial properties. Several chapters deal with the development of claim support data, the role of packaging, and consumer research on the perception of multifunctional cosmetic products. The authors keep in mind that

in the case of cosmetics, it is not only the physical effects that can be measured on the skin or hair, but also the sensory effects that have to be taken into account. Cosmetics can have a psychological and social impact that cannot be underestimated.

I want to thank all the contributors for participating in this project and particularly the editors, Perry Romanowski and Randy Schueller, for conceiving, organizing, and coordinating this book. It is the second book that they have contributed to this series and we appreciate their efforts. Special thanks are due to Sandra Beberman and Erin Nihill of the editorial and production staff at Marcel Dekker, Inc. Finally, I would like to thank my wife, Eva, without whose constant support and editorial help I would not have undertaken this project.

Eric Jungermann, Ph.D.

# COSMETIC SCIENCE AND TECHNOLOGY

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***ADDITIONAL VOLUMES IN PREPARATION***

## Preface

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The term “cosmeceuticals,” coined by Albert Kligman 20 years ago, has rightfully provoked thought and discussion among scientists, industry, and regulating authorities. Basically, the controversy revolves around the question of whether there are any substances applied to the skin that do *not* modify its structure and function. Since scientific evidence shows that even purportedly “inert” substances such as water may profoundly change the structure and function of the skin, this does not seem helpful in distinguishing cosmetics from drugs. Indeed, there is a legal problem with the definition of cosmetics in the United States, but not in other major countries such as Europe and Japan.

In Europe, the Council Directive 76/768/EEC of 27 July 1976, as amended by six Directives, defines cosmetic products in Article 1:

A cosmetic product means any substance or preparation intended for placing into contact with the various parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them, in order to keep them in good condition, change their appearance or correct body odours.

Thus, a cosmetic is defined by its mode of application and by the intention with which it is used. While cosmetics are used on normal or nearly normal skin, drugs are defined as preparations to be used for the treatment of diseased skin. Obviously, there remains a gray zone between what is considered “normal” as opposed to “diseased” skin. This may vary depending on the individual, the society, and over time. In this situation, Article 2 of the Council Directive is helpful.

A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use.

Therefore, consumer safety is of utmost importance in cosmetics, while it is a relative issue in drugs, where a balanced benefit–risk assessment has to be made de-

pending on the severity of the disease. This is reflected by a recent decision of the Scientific Committee on Cosmetics and Non-Food Products (SCCNFP) of the European Commission regarding the use of the antifungal ketoconazole in cosmetics. Following a thorough review of the safety profile of the substance, the SCCNFP decided that there were no safety concerns in using up to 2% ketoconazole in cosmetic products. Obviously, this only refers to the cosmetic use of ketoconazole-containing products (e.g., as antidandruff preparations); when used to treat fungal skin disease, they would be considered drugs from a regulatory point of view.

The Council of Europe is an intergovernmental institution that fosters cooperation between European countries. Members are not only the European Union member states, but also nearly all other countries on the European Continent. Its Public Health Committee/Committee of Experts on Cosmetic Products states in a recent document (Comparative Study on Borderline Products and Borderline Situations, RD 4-1/32/1999) that a cosmetic product has to fulfill the four criteria of *function* (Art. 1 as above); *presentation* (i.e., the claims made for the product); *mode of application* (i.e., externally or on the mucous membranes of the oral cavity); and *composition* (i.e., not containing a prohibited substance or too much of a regulated substance). The Committee has analyzed these criteria for a number of cosmetic designations and substances and found that remarkable differences exist in the regulatory approach between countries. For example, in Switzerland, products containing up to 10%  $\alpha$  hydroxyacids are considered cosmetics, whereas concentrations above 10% lead to the classification of pharmaceutical. In Austria, the concentration limit is 30%, while there is no limit in Belgium, Finland, Germany, the Netherlands, and the U.K. (RD 4-1/32/1999). Since different classification of the same products hinders free movement of goods and has a negative effect on the establishment and functioning of a common market, the Committee rightfully proposes to start a harmonization process regarding these borderline products, and states

Such a harmonisation process may come to the benefit of all parties involved—including the consumer.

We hope that this book will contribute to a sincere discussion of the status of “cosmeceuticals,” products that are intended for cosmetic use but contain active substances. Since people worldwide are getting older, becoming more aware of their skin health and appearance, and more committed to use safe and effective products to achieve this goal, this debate is a timely one.

Finally, we would like to take the opportunity to thank the contributors to this book, all experts in their fields, who devoted time and effort to their chapters. We are also indebted to Sandra Beberman and Elyce Misher of Marcel Dekker, Publishers, who were more than helpful in the editorial process.

*Peter Elsner*  
*Howard I. Maibach*

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## *Contributors*

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**Saqib J. Bashir, B.Sc. (Hons), M.B., Ch.B.** Department of Dermatology, University of California, San Francisco, California

**Ai-Lean Chew, M.B., Ch.B.** Department of Dermatology, University of California, San Francisco, California

**Antonei Benjamin Csóka** University of California, San Francisco, California

**William J. Cunningham, M.D.** Cu-Tech, Inc., Mountain Lakes, New Jersey

**Frank Dreher, Ph.D.** Department of Dermatology, University of California, San Francisco, California

**Tamotsu Ebihara, M.D.** Department of Dermatology, Saiseikai Central Hospital, Tokyo, Japan

**Peter Elsner, M.D.** Department of Dermatology, Friedrich Schiller University, Jena, Germany

**Jan Faergemann, M.D., Ph.D.** Department of Dermatology, Sahlgrenska University Hospital, Gothenberg, Sweden

**Trinh Hermanns-Lê, M.D.** Department of Dermatopathology, University of Liège, Liège, Belgium

**Philip G. Hewitt, Ph.D.** Institute of Toxicology, Merck kGaA, Darmstadt, Germany

**Peter Barton Hutt** Covington & Burling, Washington, D.C.

**Tsuneo Jinnai** Sansho Pharmaceutical Company, Fukuoka, Japan

**Alain Khaiat, Ph.D.** Johnson & Johnson Asia Pacific, Singapore

**Albert M. Kligman, M.D., Ph.D.** Department of Dermatology, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania

**Marie Lodén, M.Sc. Pharm., Dr. Med. Sci.** Department of Dermatological Research and Development, ACO Hud AB, Stockholm, Sweden

**Howard I. Maibach, M.D.** Department of Dermatology, University of California, San Francisco, California

**Bozena B. Michniak, Ph.D.** Department of Basic Pharmaceutical Sciences, College of Pharmacy, University of South Carolina, Columbia, South Carolina

**Kazuhiro Mio** University of California, San Francisco, California

**Hideo Nakayama, M.D.** Nakayama Dermatology Clinic, Tokyo, Japan

**Birgit A. Neudecker** University of California, San Francisco, California

**Kenkichi Ōba, M.D., Ph.D.** Lion Corporation, Tokyo, Japan

**Lester Packer, Ph.D.** Department of Molecular Cell Biology, University of California, Berkeley, California

**Gérald E. Piérard, M.D., Ph.D.** Department of Dermatopathology, University of Liège, Liège, Belgium

**Claudine Piérard-Franchimont, M.D., Ph.D.** Department of Dermatopathology, University of Liège, Liège, Belgium

**Noriko Satoh, M.D.** Department of Dermatology, Yanagihara Hospital, Tokyo, Japan

**Mitchell L. Schlossman** Kobo Products, Inc., South Plainfield, New Jersey

**Robert Stern** University of California, San Francisco, California

**Jens J. Thiele, M.D.** Heinrich-Heine-University, Düsseldorf, Germany

**Ronald J. Trancik, Ph.D.** Pharmacia & Upjohn, Consumer Healthcare, Peapack, New Jersey

**Bert Jan Vermeer** Department of Dermatology, Leiden University Medical Center, Leiden, The Netherlands

**Philip W. Wertz, Ph.D.** Dows Institute, University of Iowa, Iowa City, Iowa

**Walter Wigger-Alberti, M.D.** Department of Dermatology, University of Jena, Jena, Germany

**Hongbo Zhai, M.D.** Department of Dermatology, University of California, San Francisco, California



# *Cosmeceuticals: Do We Need a New Category?*

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**Albert M. Kligman**

*University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania*

I introduced the term cosmeceuticals almost 20 years ago at a meeting of the Society of Cosmetic Chemists. I thought this neologism was both timely and useful, since it would reconcile archaic legal statutes with modern science.

I anticipated immediate endorsement of a concept whose time had come. Instead, the response was immediate disapproval and denouncement. My colleagues in the industry branded me a troublemaker, unfaithful to those who had supported my research. Since then, the cosmeceutical concept has generated a huge amount of controversy. Along the way, the term has acquired political, economic, and legal connotations that have further obscured the intended purpose of the idea.

Whether one is pro or con, the term cosmeceutical has permanently entered the vocabulary of skin care science. For some, the term has been transformed into a marketing tool, touting the benefits of skin care products. Others see it as a provocation for unwanted, costly, regulatory actions. The most benign view is that the category is superfluous and has no *raison d'être*. Cosmeceuticals seem to have a certain semantic resonance, as witnessed by similar sounding neologisms; for example, neutraceuticals (foods with health benefits) and neoceuticals (over-the-counter drugs with cosmetic effects).

In any case, the term is here to stay and has provoked lively debates that, in the end, may strengthen our understanding of the science of cosmetics. I think it will be informative to review the history of this curious case.

I present the unfolding story from the viewpoint of an investigative dermatologist who appreciates the tremendous technical strides made by the cosmetic industry in recent times.

Interest in cosmeceuticals has rushed forward at an impressive pace. Seminars entitled “Cosmeceuticals” are being staged annually. These forums are well attended by groups having widely different backgrounds and interests (regulators, basic scientists, physicians, manufacturers, publishers, merchandisers, lawyers, toxicologists, pharmacologists, and industry watchers). Papers and books have been written covering every aspect of the subject, and these provide a rich source of information (1).

Cosmeceuticals are a hot topic on an international scale. The literature has expanded rapidly, presenting a great variety of views dictated by special interests. A number of forces have converged to power this surge of interest. It would seem that some merchandisers have realized the potential for increasing the sale of products that go well beyond the traditional view of cosmetics as merely decorative or camouflaging. Skin care products can now be viewed as active they do something useful and beneficial. They contain “bioactives” which, though not medicinal, are endowed with functional and measurable attributes. Alternative terms for cosmeceuticals have sprung up (performance cosmetics, functional cosmetics, dermoceuticals, active cosmetics). All these imply value added desirable attributes, the touchstone for success in a wildly competitive marketplace.

This is a marketer’s playground, which makes it possible to incorporate in skin care products an unlimited number of active substances from natural sources (plants, the sea, the earth). The list of beckoning substances, including those synthesized by chemists, is staggering, including vitamins, antioxidants, anti-inflammatories, mood-influencing fragrances (aromatherapy), and even such exotica as placenta, amniotic fluid serum, and hormones ad infinitum. The choices range from the preposterous to the persuasive, and cover the spectrum from the irrational to the rational.

The natural and green movements also provide a background for understanding the robust interest in cosmeceuticals. For many uninformed consumers, natural is good and synthetic is bad; green protects the environment and prevents cruelty to animals. The phrases, “not tested on animals” and “cruelty-free” have become a marketing ploy that is often hypocritical and false. Marketers understand these lofty impulses of consumers and are quite willing to cater to the widespread prejudices of a chemophobic population. However, cosmeceuticals are here to stay because they serve the multiple needs of manufacturers and consumers.

## THE 1938 FOOD, DRUG, AND COSMETIC ACT: THE BEGINNING OF TROUBLE

In 1938, the U.S. Congress enacted a statute that officially defined cosmetics and drugs in detailed terms, setting up formal criteria for classifying a product as either a drug or a cosmetic. No intermediate category exists, although it was appreciated that a topical could be both a cosmetic and a drug at the same time. This remains the law to this very day.

The 1938 act came into being as a corrective reaction against the ludicrous number of elixirs and patent medicines—some dangerous—which promised cures for all human ailments. It defined a cosmetic, in pertinent part, as an “article intended for beautifying and promoting attractiveness.” In contrast, a drug was defined as a substance for use in the diagnosis, cure, treatment, or prevention of disease, *intended to affect the structure and function of the body*. This last clause legally determines whether a formulation is a drug or a cosmetic. It is this narrow phrase that prompted me to coin the term cosmeceutical.

It is important to note that it is not the ingredients in a product, but the claims in labeling or advertising, that determine whether the substance will be classified as a cosmetic or a drug. Congress also declared that the “intended” use would determine a product’s classification. Thus, if the intended use relates to the diagnosis and treatment of a disease, the substance is a drug; if its intended use is described in advertisements as promoting attractiveness, the substance is a cosmetic. Thus, in reality, you are what you claim you are.

## ENTER COSMECEUTICALS

When the 1938 law was written, the science of cosmetology was primitive and crude, steeped in folklore and unsupported claims. The 1938 definition of a drug is now completely archaic and, in fact, an oxymoron. With the great advances in our understanding of skin physiology, it is impossible to think of a single substance that cannot, under some circumstances, alter the structure and function of skin. The most compelling example is water, the milieu in which all vital processes occur which is considered innocuous. However, when a water-moistened cotton pad is sealed to human skin for 2 days, proinflammatory substances such as interleukins are released from the dead stratum corneum. These incite a series of cytotoxic changes in the viable epidermis below (2). In another few days, an inflammatory reaction is provoked in the dermis. This is the basis for the adverse clinical events associated with prolonged exposure to water, for example, in bartenders, housewives, canners, etc. Thus water can be beneficial in emulsions that hydrate xerotic skin or harmful under intensive exposure.

Another traditional substance considered inert is petrolatum. However, various studies show that petrolatum promotes healing of wounds and prevents ultraviolet-induced tumors, even though it is not a sunscreen (3). These are clearly medicinal effects that affect the structure and function of skin, yet no rational person would want petrolatum to be reclassified as a drug. From these and many other examples, it is apparent that nearly all cosmetic articles would have to be reclassified as drugs, if a strict interpretation of the “structure and function” proviso of the 1938 act were used.

Most skin care products lie somewhere in between drugs and cosmetics. They comprise a continuous spectrum of substances intermediate between the two polar categories defined by Congress. Some traditional cosmetics are more druglike in their beneficial effects and some drugs impact principally on appearance. It is this intermediate, broad-spectrum range of substances that consists of both drugs and cosmetics which justifies the fusion term *cosmeceuticals*. This is simply a biological concept that recognizes the new realities of skin care products.

This acceptance of biological reality does not mean that we need new laws that officially define in statutory terms the category of *cosmeceuticals*. The FDA has always had the authority to determine from advertising claims and labeling whether a product promoted as a cosmetic has crossed the line and requires reclassification as a drug.

*Cosmeceutical* is a pragmatic term that enables us to state without pretense the benefits of a product. It is not an invitation to pass new laws.

A strict, legal interpretation of the 1938 law would necessitate the conversion of “active” cosmetics to drugs. This would be a disaster of the highest magnitude that would immediately stifle innovation and creativity. Drug development is slow and costly, and requires proof of efficacy and safety. Cosmetics, on the other hand, do not require premarketing clearance and can be rapidly commercialized provided that the claims are not grossly misleading.

Over the years, and to its credit, the FDA has been flexible and permissive in the way in which it has viewed claims, some of which are unequivocally exaggerated. The trouble comes when some cosmetic manufacturers make frank drug claims for their products. In this case, the FDA sends out warning letters that require relabeling of the products without necessarily changing any of the ingredients. Competitors who are prudent and conscientious may be at a disadvantage if they make less aggressive claims, an issue highlighted by the “antiaging” claims made for certain  $\alpha$ -hydroxy acids.

*Cosmeceuticals* enable cosmetic scientists to communicate with each other regarding the standards that must be met to justify performance claims, without resorting to hype.