Cosmeceuticals
Drugs vs. Cosmetics

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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

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 ketaconazole-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% α 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.

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