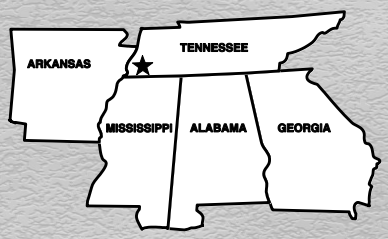
SCC
SOCIETY OF COSMETIC CHEMISTS

THE SOUTHEAST CHAPTER



Volume XXIX, Number 2 April 2016

Southeast Chapter Speaker Dinner Meeting

Wednesday, April 27, 2016

Speaker: Andy Bainbridge

Presentation: "The World According to Patent Examiners"

Location: Owen Brennan's Restaurant
6150 Poplar Ave.
Memphis, TN

5:30 pm to 6:00 pm - Social Hour / Registration
6:00 pm to 7:30 pm - Dinner
7:30 pm Speaker

$45 SCC Chapter member
$55 non-SCC member

RSVP by noon, April 25th to Cubie Lamb
(662) 890-2306 or e-mail: clamb@jstrickland.net

Inside this Issue…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Save the Date
The Carolina Chapter of the
Society of Cosmetic Chemists
Presents
Naturally
Kiawah
Symposium
April 20-22, 2016
Kiawah Island Golf Resort
Kiawah Island, South Carolina

Message from the Southeast Chair

We started off 2016 with a great speaker-dinner presentation in Chattanooga. The presentation given by Mark Chandler on "Formulating for Efficacy" was insightful and entertaining. The March meeting was held at the Public House Chattanooga where the food was excellent, and the venue beautiful. Special thanks to Colonial Chemical for sponsoring the cocktail hour. Also special thanks to Dennis Abbeduto and Christine Anderson's efforts in co-ordinating the meeting in Chattanooga.

For the April chapter meeting, we will be having a special treat. Andy Bainbridge of the US patent examiners office will be traveling to Memphis to discuss his perspective on patents and all things related to them. His presentation is titled "The World According To Patent Examiners". For all of you who have worked on patents and wondered about the process this will be your opportunity to hear about the other side of the patent process. I understand Andy can be quite entertaining, so please come to the meeting and enjoy the evening with us.

Every year the Southeast Chapter typically hosts five chapter meetings: three speaker-dinner presentations, our Suppliers Social Event in June, and Officers Installation. This year instead of having the September presentation meeting, the chapter will host a CEP course at the Bayer Consumer site in Memphis. Stay tuned for further details on the topic.

The Southeast Suppliers Social Event has tentatively been set for Wednesday, June 15th at Stax Museum in Memphis. It is always a great time, and we always appreciate the support provided by our sponsors.

Looking forward to seeing you at our scientific dinner meeting on April 27th in Memphis. Please RSVP to Cubie Lamb, Chapter Secretary, clamb@jstrickland.net.

Sincerely,
Stephen Baldwin
SCC Southeast Chapter Chair

Is It a Cosmetic, a Drug, or Both?

(reprinted from the FDA website)

Whether a product is a cosmetic or a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. Firms sometimes violate the law by marketing a cosmetic with a drug claim or by marketing a drug as if it were a cosmetic, without adhering to requirements for drugs.

How does the law define a cosmetic?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)]. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product.

How does the law define a drug?

The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

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How can a product be both a cosmetic and a drug?

Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

What about "cosmeceuticals"?

The FD&C Act does not recognize any such category as "cosmeceuticals." A product can be a drug, a cosmetic, or a combination of both, but the term "cosmeceutical" has no meaning under the law.

How is a product's intended use established?

Intended use may be established in a number of ways. The following are some examples:

- Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, increase or decrease the production of melanin (pigment) in the skin, or regenerate cells.
- Consumer perception, which may be established through the product's reputation. This means asking why the consumer is buying it and what the consumer expects it to do.
- Ingredients that cause a product to be considered a drug because they have a well-known (to the public and industry) therapeutic use. An example is fluoride in toothpaste.

This principle also holds true for "essential oils." For example, a fragrance marketed for promoting attractiveness is a cosmetic. But a fragrance marketed with certain "aromatherapy" claims, such as assertions that the scent will help the consumer sleep or quit smoking, meets the definition of a drug because of its intended use. Similarly, a massage oil that is simply intended to lubricate the skin and impart fragrance is a cosmetic, but if the product is intended for a therapeutic use, such as relieving muscle pain, it's a drug.

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How approval requirements are different?

Under the FD&C Act, cosmetic products and ingredients, with the exception of color additives, do not require FDA approval before they go on the market. Drugs, however, must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. These monographs specify conditions whereby OTC drug ingredients are generally recognized as safe and effective, and not misbranded. Certain OTC drugs may remain on the market without an NDA approval until a monograph for its class of drugs is finalized as a regulation. However, once FDA has made a final determination on the status of an OTC drug c ategory, such products must either be the subject of an approved **NDA** [FD&C Act, sec. 505(a) and (b)], or comply with the appropriate **monograph** for an OTC drug. (**A note on the term "new drug":** Despite the word "new," a "new drug" may have been in use for many years. If a product is intended for use as a drug, it must comply with the require-ments outlined above.)

What do these terms mean?

- An **NDA** is the vehicle through which drug sponsors formally propose that FDA approve a pharmaceutical for sale and marketing in the United States. FDA only approves an NDA after determining, for example, that the data is adequate to show the drug's safety and effectiveness for its proposed use and that its benefits outweigh the risks. The NDA system is also used for new ingredients and for new indications entering the OTC marketplace for the first time. For example, the newer OTC products (previously available only by prescription) are first approved through the NDA system, and their "switch" to OTC status is then approved, also through the NDA system.
- FDA has published **monographs**, or rules, for a number of OTC drug categories. These monographs, which are published in the Federal Register, state requirements for categories of nonprescription drugs, such as what ingredients may be used and for what intended use. Among the many nonprescription drug categories covered by OTC monographs are
- acne medications
- treatments for dandruff, seborrheic dermatitis, and psoriasis
- sunscreens

NEXTGEN TO BRIDGE THE GAP ACROSS PROFESSIONAL LEVELS

Last year the society introduced a critical initiative, SCC NextGen, that will offer the necessary skills and training needed for career advancement. NextGen was designed to help young professionals *(with less than 5 years of industry experience)* and students further their education, so that they may attain successful and rewarding careers. NextGen will provide registrants with the confidence to enter the workforce knowing that their education and training are aligned with workforce needs and that they have the support of fellow colleagues.

The society plans to accomplish this mission by...

1. Presenting critical Education tracks at meetings and events (eg. Critical Thinking & Innovation, Basic Cosmetic Science, Introduction to Polymer Science and Its Applications).
2. Networking at national meetings and events.
3. Coordinating small group projects where Mentees and Mentors engage in a technical area of shared interest. The goal for the Mentee is to present a paper or organize a workshop in the second year of program.
4. Collaborating with universities to supplement the education of their students. All colleges/universities participating in the NextGen program are eligible to provide students with their first year of membership for free.

Please contact the SCC National office at scc@scconline.org or call (212) 668-1500 for more information on how you or your university can get involved. All are welcome and encouraged to join!

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29TH CONGRESS
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8 KEYNOTES

74 PODIUM PRESENTATIONS

350 POSTER PRESENTATIONS

2-DAY EXHIBITION

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