Cosmetic irritants: Howard I. Maibach, MD, of the University of California, talked about our continuing need for safer products in all cell-renewal classifications. He wondered whether AHAs and retinoic acid (RA) work in the same way. he also questioned whether there is a specific receptor for these products and if they are irritants.

Maibach found that a 21-day cumulative irritancy test did not predict consumer problems. AHAs alter the SC, which can be measured by TEWL. Using a 24-hr. application in a Hill Top polypropylene chamber with 99% pure sodium lauryl sulfate (SLS) as a reference, he found a greater response of the SLS, 24 hrs before RA application. He measured this by the amount of redness, as both gave scaling. SLS before R4 enhanced different TEWL.

Maibach then applied 12% glycolic acid (GA) at pH 7 and 0.1% at pH 7.3 to six subjects for 60 min. per day, which was subsequently washed off. He repeated this for 5 days for 2 weeks. Maibach found that erythema was greater using GA than using RA, while scaling was more with RA than GA. SC turn overtime was better with GA than with RA. He also found that a little ethanol accelerates this, but water doesn't. Lactic acid (LA) at pH 2.3 and 4 caused burning, itching and stinging. However, both GA and LA can be used with anti-irritants to achieve a level of no response with people more than 70 years old as opposed to individuals aged 1847. Maibach concluded that the effect of GA and RA on skin is not irritation.

Overlapping regulation: Jim Akerson, president of Akerson Associates, led a panel discussion on regulatory pitfalls. Gerald McEwen Jr, PhD, JD, vice president of science for Cosmetic, Toiletry and Fragrance Association (CTFA), spoke first, He started off by saying that the term, "cosmeceutical" has a drug implication and wondered if such use would prompt someone to conclude that the cosmetics industry wants to be regulated in the same way as the drug industry. The key to a cosmetic becoming regulated as a drug is by its intended effects; labeling and advertising determines this intent.

Akerson then compared the legal differences between drug and cosmetic regulation. He noted that Title 21 of the U.S. Code of Federal Regulations has 1,000 pages for drugs and only 30 for cosmetics. Similarly, the FDA Act of 1938 contains 90 pages for drugs and l-1/2 pages for cosmetics.

Cosmetics have to meet only two requirements to be marketed: They must be safe, and they should be expected to sell. Drugs, on the other hand, require full reports of safety and efficacy, to be submitted to and approved by the FDA. The FDA must also approve the components used by the manufacturer, They cannot be changed without an amended NDA that needs samples, labels and patents. The cosmetic industry clearly does not want to go down this road.