Continued from previous page

service at Memorial Sloan Kettering Cancer Center in New York. Using both an in vivo and an in vitro test to assess UVA protection "will hopefully address concerns raised about each test," added Dr. Halpern.

He expressed hope that responses during the comment period won't slow down the process of implementing the regulations. He added that capping the SPF at 50+ is an improvement, but was concerned that this might be a disincentive for the manufacturing of ultrahigh SPF sunscreens.

Under the proposed regulation, manufacturers of over-the-counter sunscreen products would be required to test their products for UVA protection using a specific test to measure the product's ability to reduce the amount of UVA light that passes through it and a test that measures the product's ability to prevent tanning. The UVA rating would be based on the lowest of the two test results. If a manufacturer does not perform the tests, or the tests find no UVA protection, then the label will have to state "no UVA protection."

UVB protection will continue to be based on the SPF rating, but the FDA has proposed changes to the SPF testing methods to make the results more accurate and reproducible.

Under the regulation, companies would also be able to combine avobenzone with either zinc oxide or ensulizole, which Dr. Holman said would increase the number of sunscreen products available. The agency would consider revising the upper SPF limit allowed in the packages if data become available that support accurate testing of sunscreens with an SPF greater than 50.

During the comment period, the FDA is requesting comments and more information about the safety of sunscreen ingredients that use nanotechnology, because of the potential risk of nanoparticle ingredients penetrating consumers' skin, and on novel sunscreen formulations, such as foams, sprays, and towelettes. The proposal does not apply to insect repellant products combined with sunscreens, but it does apply to cosmetic products that contain sunscreen and SPF claims.

The FDA is accepting written comment on the proposal for 90 days following the announcement, until Nov. 26. ■

More information, including how to make a written comment, is available online at www.fda.gov/cder/drug/infopage/sunscreen/default.htm.

Combination Gel Improves Acne in Phase III Study

CHICAGO — An aqueous gel formula that combines 0.025% tretinoin and 1.2% clindamycin phosphate significantly reduces both inflammatory and noninflammatory acne lesions, Dr. James Leyden said in a poster presented at the annual meeting of the Society for Pediatric Dermatology.

The combination gel, marketed as Ziana, has been approved by the Food and Drug Administration for once-daily topical treatment of acne vulgaris in children aged 12 years and older.

In a phase III study, 1,710 patients aged 12-18 years were randomized into four groups to receive the combination gel, a tretinoin-only gel, a clindamycin phosphate–only gel, or a placebo gel. The baseline acne conditions ranged from mild to severe; patients were required to have 20-100 noninflammatory lesions, 20-50 inflammatory lesions, and two nodules to enroll in the study.

Overall, the patients in the combination gel group showed significantly greater reductions in the number of inflammatory lesions, noninflammatory lesions, and total lesion counts after 12 weeks of daily treatment, compared with the other groups, wrote Dr. Leyden of Broomall, Pa. He has received financial support from several drug manufacturers, including Medicis Pharmaceutical Corp., which manufactures Ziana and sponsored the study.

The average reductions for inflammatory and noninflammatory lesions, respectively, were 46% and 35% for the combination group; 35% and 26% for the tretinoin group; 36% and 23% for the clindamycin phosphate group; and 16% and 9% for the placebo group. The average reduction in total lesion count was 39% for the combination group, 30% for the tretinoin group, 29% for the clindamycin phosphate group, and 12% for the placebo group.

In addition, tolerability data from a subset of 45 patients were presented in a separate poster at the meeting. The findings showed that the clindamycin phosphate/tretinoin combination gel was as well tolerated as 0.1% adapalene gel and significantly better tolerated than 0.1% tretinoin microsphere gel based on clinical evaluation of redness and scaling and patient reports of burning, stinging, and itching, Dr. Leyden reported.

—Heidi Splete