Final Sunscreen Regulations Expected This Fall

BY ELIZABETH MECHCATIE

The long-awaited regulation on sunscreen labeling is expected to be issued by the Food and Drug Administration this fall, more than 2 years after the agency proposed the regulation to address issues concerning testing and labeling requirements for ultraviolet A protection.

Rita Chappelle, a spokesperson for the FDA, said in an interview that the agency anticipates a final ruling by September but is not providing any more specific information about what elements of the proposed rule would be included in the final rule.

The proposed rule, announced in the summer of 2007, includes a rating system that would use 1-4 stars on sunscreen product labels to indicate the degree of ultraviolet A (UVA) protection the product provides and a prominent warning regarding skin cancer and other risks of sun exposure in the "Drug Facts" box. The proposed rule also caps the maximum sun protection factor (SPF) claim allowed at SPF 50+ and includes guidance on how to measure UVA protection.

Ms. Chappelle also said that changes are being made to the proposed rule based on comments that the FDA received in response to the proposal—even those that came in after the 90-day comment period was closed in November 2007. The FDA received more than 3,000 comments in response to the proposal, which included a large amount of scientific data on topics such as UVA, UVB, and nanotechnology. The FDA had requested more information about the safety of sunscreen products that use nanotechnology because of the potential risk of nanoparticle ingredients penetrating the skin.

In an interview, Dr. Henry Lim, chairman of dermatology, at the Henry Ford Health System, Detroit, said that he did not know what the final rule would include, but that he and other dermatologists are looking forward to the release of the new regulations, which will be beneficial to consumers, particularly with the added information about UVA.

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DR. LIM

At a meeting that industry and American Academy of Dermatology representatives had with the FDA in December, Dr. Lim, chair of the Academy's council on science and research said that agency officials had questions about labeling issues, and asked industry representatives for information about the tests for UVA protection. ■

Rosacea Research Grants Awarded

The National Rosacea Society awarded the following four research grants to advance the knowledge of rosacea:

► Dr. Robert W. Walters and Dr. Robert J. Lefkowitz of Duke University in Durham, N.C., received $25,000 to investigate the role of beta-arrestin in cutaneous flushing.

► Dr. Curdin Conrad of the University of Texas M.D. Anderson Cancer Center in Houston, and Dr. Alexander Navarini of the University Hospital Zurich, received $21,450 to investigate the role of plasmacytoid dendritic cell and interferon alpha in rosacea.

► Dr. Richard Gallo of the University of California, San Diego, and Dr. Kenshi Yamasaki of the Veterans Medical Research Foundation in San Diego, received $25,000 to continue their research into how cathelicidins might contribute to the development of papulopustular rosacea.

► Dr. Joseph Rothnagel and Dr. Manuela Trabi of the University of Queensland, Australia, received $18,000 to investigate the role of tissue kallikreins in the development of rosacea.

Researchers interested in applying for grants can visit www.rosacea.org. ■