DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

March 2, 2010

Kenneth A. Cook
President
Environmental Working Group
1436 U St. N.W., Suite 100
Washington, D.C. 20009

Dear Mr. Cook:

Thank you for the letter of July 15 to Commissioner Hamburg regarding sunscreen safety standards, which has been referred to our office for reply. In this country, most sunscreen products are currently marketed under an over-the-counter (OTC) drug monograph entitled "Sunscreen Drug Products for Over-the-Counter Human Use (21 CFR part 352).

We have consistently responded to the dynamic nature of research and development in OTC sunscreen drug products in the different sunscreen monograph rulemakings. A listing of the many rules, as well as other FDA actions, can be accessed at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm.

We published a final rule for sunscreens in 1999. The 1999 final rule dealt specifically with sunscreen products providing protection against the type of ultraviolet (UV) radiation that is primarily responsible for sunburn – UVB radiation. At that time, we had not yet developed regulations to address the testing and labeling of sunscreen products that would protect against UVA radiation, which contributes to a variety of forms of skin damage including skin cancer and premature skin aging. Because the 1999 rule did not include regulations for sunscreens providing protection against UVA radiation, in 2001, we delayed implementation of the rule. Even though the final rule implementation has been delayed, the regulations established in the final rule are listed in the Code of Federal Regulations (CFR) governing food and drugs at part 352 (http://www.access.gpo.gov/nara/cfr/waisidx_09/21cfr352_09.html). Although we are aware of some exceptions, we believe that many sunscreen manufacturers have implemented the labeling and testing standards included in 21 CFR 352.

Following a thorough review of public comments received in response to the 1999 final rule and reviews and analyses of other data and information related to protection against UVA radiation, we published a sunscreen proposed rule in 2007. This proposed rule would amend the final OTC sunscreen monograph to include regulations governing the testing and labeling of sunscreen drug products providing protection against both UVB and UVA radiation. In response to our request for public comment on the proposed rule, we received nearly 3,000 submissions from the public. We would like to note that we typically do not receive more than 100 submissions on a proposed rule. Many of the submissions included technical data and references to the scientific literature. All of this data and information has to be fully evaluated in the preparation of a new final rule.

Although we understand your concern regarding the protracted nature of this process, we trust that you will appreciate the need for us to continue to fully investigate and evaluate new research and development for sunscreen products, permit adequate opportunity for public comment, and weigh all research and development fairly and with full input from FDA subject area experts as well as industry stakeholders and the American public. Thank you again for contacting us about this important public safety issue.

Sincerely,

Jeff D. O'Neill
Policy Analyst
Office of the Executive Secretariat, FDA