Dear Commissioner Hamburg:

Consumers Union, the policy and advocacy division of Consumer Reports®, is writing to the Food and Drug Administration (FDA) about changes we would like to see regarding sunscreen safety for consumers. In the July issue of Consumer Reports®, we report our findings of our tests of 20 sunscreens (a copy of the article is attached to this letter).

Our findings lead us to several concerns about whether consumers are truly receiving the protection they believe they are getting when they apply sunscreen. We are therefore asking the FDA to strengthen its sunscreen safety regulations in three ways.

First, we urge the FDA to move quickly to review sunscreen ingredients that may offer better sun protection, including those that have been widely used in Europe and other countries for years. We understand that the agency has approved ecamsule, and that the agency is reviewing other applications. We urge the FDA to move as quickly as possible on its consideration of the safety and effectiveness of other sunscreen ingredients, so that consumers may have access to the best sun protection available.

Second, we urge the FDA to provide consumers with information on how to safely use sprays, and on whether all active ingredients are appropriate for use in sprays or certain types of sprays. We understand that the FDA requested additional information about the effectiveness and safety of sunscreen sprays in 2011. However, there are concerns that people are not applying enough of the product to benefit. We have also noted just this year that some types of spray sunscreens on the market now contain titanium dioxide and zinc oxide. We are concerned about the health risks of unintentionally inhaling sunscreen, especially the minerals in them, since titanium dioxide is considered to be a Class 2B carcinogen when inhaled. We urge the agency to consider whether these or other spray delivery systems may lead to an inhalation risk of these minerals.
Finally, we ask that the agency provide consumers with additional information about high-SPF products. Our testing has found that extremely high-SPF products do not meet their claims. We are submitting this data to the agency for your consideration as you review the high-SPF claims. We appreciate that the FDA in 2011 proposed limiting the maximum SPF to 50+, as there is a lack of evidence that products with higher SPF values offer additional protection. We urge the FDA to finalize this proposal as soon as possible. Consumers continue to perceive high-SPF sunscreens as more effective than lower ones, and if such perception is unwarranted, they should have the information to make educated purchases.

We thank you for your consideration.

Sincerely,

Urvashi Rangan, Ph.D.  
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Ami V. Gadhia  
Senior Policy Counsel