



June 1, 2000

Charles Ganley, MD
FDA CEDR
Division of OTC Drug Products
Attn: Document Control Room
5600 Fishers Lane, HFD - 560
Rockville, MD 20857

Dear Dr. Ganley:

This letter is in reference to Docket No. 78N-0038.

Thank you for your March 8, 2000 response to the American Cancer Society about our concern that sunscreen labels should provide information about frequency of reapplication to retain effectiveness. We appreciate your response which we have reviewed and discussed, in particular your closing statement: "The agency will reconsider the reapplication and/or water resistance statements in the OTC sunscreen drug product monograph pending the submission and evaluation of data necessary to substantiate additions to or modifications of these statements."

This statement seems to indicate that additional documentation is needed in two main areas:

1) how people use sunscreen and 2) the rate at which sunscreen degrades over time. To understand how people use sunscreen we would commission a survey to research public perception about how much protection they get from sunscreen and how they actually use sunscreen. Additionally, the American Cancer Society would plan a scientific conference to define the research questions relative to deterioration of sunscreen protection over time. These questions would be the basis of an RFP for further research.

Prior to the American Cancer Society conducting any research on this issue, we would like to ascertain from you that these data would be germane to the points made by FDA in its March 8 response to American Cancer Society, and depending on the specific results obtained, potentially sufficient to lead the FDA to reconsider the reapplication statement in the OTC sunscreen monograph.

Sincerely,


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