

Wm. C. Waggoner, Ph. D., F.A.A.C.T.
Executive Director
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324 Belleville Avenue
Bloomfield, NJ 07003

JUN 22 1985

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Dear Dr. Waggoner:

This is in response to your letter dated January 10, 1985 requesting the agency's position on the use of whirlpool baths with water agitation for testing of waterproof and water-resistant claims for sunscreens. Your letter was referred to my office for reply.

As you may know, OTC sunscreen drug products were reviewed by the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Products. The advance notice of proposed rulemaking which contains the Panel's conclusions and recommendations to the FDA on sunscreen drug products was published in the FEDERAL REGISTER on August 25, 1978 (copy enclosed). The report was prepared independently of the FDA, and the agency has not yet fully evaluated the report, which does not necessarily reflect the agency's position on any particular matter contained in it. The Panel did not discuss the use of whirlpool baths in the testing of waterproof and water-resistant claims for sunscreens. The Panel discussed the testing of waterproof and water-resistant claims for sunscreens on page 39263 of its report.

The purpose of publishing the Panel's report was to stimulate discussion and to obtain public comment from all interested sources before FDA reaches any decision on the Panel's recommendations. In response to publication of the Panel's report, FDA received 72 comments from drug manufacturers, consumers, and experts in the field of sunscreen testing. FDA is currently evaluating the Panel's report and the comments received, and will issue a tentative final monograph in the FEDERAL REGISTER at a future date. The FDA may accept, reject, or modify the Panel's recommendations based on its own review and on the comments received. The administrative record for the Panel's sunscreen report is closed, but interested persons will be able to submit comments on the tentative final monograph before the FDA issues a final monograph.

I regret that I cannot be more helpful to you at this time. Thank you for your interest.

Sincerely yours,

Saul Bader, Ph. D.
Chief, Eye, Ear, Nose, Throat, and
Oral Cavity Drug Monographs Branch
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