



OCT 9 1996

WARNING LETTER

VIA FEDERAL EXPRESS

Dear [REDACTED]

The Food and Drug Administration (FDA) has reviewed your current catalog, which includes on page 3 a pictorial representation of, and a quote from, the July-August 1995 issue of FDA's publication, FDA Consumer. You have quoted the following statement, "[REDACTED], has received clearance to market its [REDACTED] clothing for sun protection and is allowed to claim an SPF of 30 for its products." Your clothing is considered a medical device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the act). Your catalogue is defined as labeling under section 201(m) of the act.

As we informed you in our letter dated November 13, 1995, FDA's regulations prohibit you from making representations that create an impression that FDA has granted official approval of your product. The regulations at 21 CFR 807.97 provide that submission of premarket notification in accordance with the regulations and a determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II (i.e., 510(k) marketing clearance) does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

In your January 4, 1996, response to our November, 1995 letter, you said that your reference in your then current brochure to FDA's June 1993 Talk Paper clearly referred to your clothing as being cleared, not approved, and that the statement was not misleading and did not misbrand your products. As stated above, 21 CFR 807.97 prohibits representation that give the impression that a product has official FDA approval, including 510(k) marketing clearance. Your statements give the impression that your product has official FDA approval - whether you use the word "approval" or the word "clearance" is irrelevant. You also stated in your letter that you

considered it anomalous that FDA would consider it acceptable for the Agency to release a Talk Paper but not for the company to quote it. The FDA's distribution of a Talk Paper or the FDA Consumer is part of the Agency's communication with the public and is not intended to promote a particular drug, device or other regulated product. However, your pictorial representations of the Talk Paper and the FDA Consumer and statements from those publications that create any impression of FDA approval or clearance are prohibited by section 807.97.

Use of the agency's publications or the fact or representation that you have received 510(k) clearance misbrands your [REDACTED] clothing under section 502(a) of the act because the labeling is misleading.

Your brochure also says that your product was the "first line of sun protective clothing to meet published medical guidelines." FDA is unaware of any published medical guidelines for sun protective clothing and therefore without appropriate substantiation this statement may further misbrand your products.

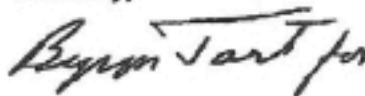
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address misleading information currently in the marketplace and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Deborah Wolf, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Seattle District office. Please send a copy of your response to the District Director, Seattle District Office (HFR-PA340), 22201 23rd Drive S.E., P.O. Box 3012, Bothell, WA 98041-3012.

Sincerely,



Lillian Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health