DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 25 1996

Barry Sugarman
President
Liquipharm® Inc.
10716 McCune Avenue
Los Angeles, California 90034

Dear Mr. Sugarman:

This is in response to your letter of May 21, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements for Cellrenu-C
(Vitamin C Topical Lotion and Cream):

1. Aqueous Therapy, Anti-Wrinkle Cycle Formula

2. Cellrenu-C adds and replenishes Vitamin C to your skin. Vitamin C in your skin aids the cycle that your body naturally takes to gradually improve your skin tone and elasticity, by increasing collagen production and by controlling the inflammatory response associated with ultraviolet light exposure. This is extremely important because repeated sun exposure results in damage to collagen, elastin, proeoglycan, cell membranes and nuclear constituents. In time, these changes may result in wrinkles and skin cancer.

3. Vitamin C has some amazing benefits when it comes to our skin. Topical Vitamin C can deliver more than 20 times the amount of Vitamin C found in Normal skin.

This product does not meet the definition of a dietary supplement in 201(ff)(2)(A)(i) of the act, which states that the term "dietary supplement" means a product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form. Furthermore, it appears that this product is intended for drug use within the meaning of section 201(g)(1) of the act in that it is intended to affect the structure or function of the body of man (i.e., prevent wrinkles, improve skin elasticity by increasing collagen production) and to prevent disease (i.e., control the inflammatory response associated with ultraviolet light exposure which prevents changes that result in skin cancer).

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of disease. The term "therapy" is defined in Stedman's Medical

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Dictionary, 24th Edition, 1982, as "treatment of disease by various methods." The statement, "Aqueous Therapy, Anti-Wrinkle Cycle Formula," which you are making for your product, clearly implies that this product is in fact intended for treating a disease in that it claims to be a therapy. Therefore, this claim does not qualify as a claim permitted under section 403(r)(6) of the act. Use of this claim on the label or in the labeling of your product is likely to make it subject to regulation under the drug provisions of the act.

Finally, the brand name "Cellrenu-C™," apparently derived from the term "cell renewal," implies that this product is intended for use by persons to affect the structure or function of the body of man, and that "Cellrenu-C™" is intended for other than food use within the meaning of section 201(g)(1)(C) of the act. Any representation that a product is intended for medical or therapeutic use may cause the product to be considered a drug. According to section 201(g) of the act, a drug is defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals. A manufacturer who wishes to make claims under section 201(g)(1) of the act must contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, Division of Drug Labeling Compliance, Rm. 166 MPN, HFD-310, 7520 Standish Place, Rockville, Maryland 20855, and the product must be proven to be both safe and effective for its intended use.

We hope this information is helpful.

Sincerely yours,

James Tanner, Ph.D.
Acting Director, Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200