

SEP 24 1996

Mr. Richard J. Litner
Nutrinfo
40 Spring Street
P.O. Box 1097
Watertown, Massachusetts 02272-1097

Dear Mr. Litner:

This is in response to your letter to the Food and Drug Administration (FDA) dated August 15, 1996, on behalf of your client Boston BioScience, Inc., requesting that FDA clarify our position concerning the claims made for the product *Cellf Help*TM. Your letter is in response to a letter from FDA dated August 5, 1996.

Your letter implied that the following statements will continue to be made for *Cellf Help*TM:

Repairs skin cell damaged by everyday exposure to sunlight.

*Cellf Help*TM promotes the skin's DNA repair system and prevents the spread of DNA damaged skin cells

As stated in our previous letter, statements that claim to repair "skin cell damaged by everyday exposure to sunlight" and to promote "the DNA repair system and prevent the spread of DNA damaged skin cells" are not statements permitted under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). These statements evidence that this product is intended to prevent the formation and spread of abnormal cells and to repair, that is, to treat, damaged cells. Use of these claims on the label or in the labeling of this product may subject it to regulation under the drug provisions of the act.

We stated in our August 5, 1996 letter that it was unclear whether your product, *Cellf Help*TM, was a product to be ingested or is a topical preparation to be applied to the skin. We acknowledge that *Cellf Help*TM is a product for oral ingestion in capsule form and is not a topical preparation to be applied to the skin.

975-0163

LET 26

Page 2 - Mr. Richard J. Litner

Please contact us if we may be of further assistance.

Sincerely yours,

**James T. Tanner
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, New England District Office, Office of Compliance, HFR-NE200

**FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200**