

AUG - 5 1996

Ms. Camila de Wit  
Marketing Director  
Boston BioScience  
40 Spring Street, P.O. Box 465  
Watertown, Massachusetts 02272-0465

Dear Ms. de Wit:

This is in response to your letter of July 16, 1996 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 on the labels or in the labeling of your product CellfHelp:

Repairs skin cell damaged by everyday exposure to sunlight.

CellfHelp promotes the skin's DNA repair system and prevents the spread of DNA damaged skin cells.

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 diseases. Yet, the statement that you are making for this product suggest that it is intended for these purposes, in that it claims to repair skin cells damaged by everyday exposure to sunlight and promote the skin's DNA repair system and prevent the spread of DNA damaged skin cells. These claims on the label or in the labeling of this product evidence that it is intended to prevent the formation and spread of abnormal cells and to repair, that is, to treat damaged cells. Thus, the product is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Furthermore, it is unclear whether your product, CellfHelp, is a product to be ingested or is a topical preparation to be applied to the skin. Section 201(ff)(2)(A)(i) of the act states that the term "dietary supplement" means a product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form. Thus, if CellfHelp is a topical product that is applied to the skin, it does not meet the definition of a dietary supplement and would not be subject to regulation under the food provisions of the act.

975-0163

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Please contact us if we may be of further assistance.

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, New England Office, Office of Compliance, HFR-NE200

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