



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CBER-03-013

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20862-1448

September 26, 2003

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Gisella Thomas
Chief Executive Officer
Target Your Health, Inc.
P.O. Box 177
Wildomar, California 92595

Dear Ms. Thomas:

The Food and Drug Administration (FDA) has reviewed your website at Internet address: <http://www.targetyourhealth.org> and has determined that your Live Cell Growth Factors are being promoted for conditions that cause the products to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)] and biological products, as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 USC 262].

The Live Cell Growth Factors are considered drugs because the therapeutic claims, as shown on your web site, establish their intended use as drugs.* In describing the Live Cell Growth Factors, your website states that "live cells from sheep or cattle embryos have the potential to adapt and *heal organs or body tissue in need of repair*" (emphasis added). Your website also states that "Live Cell Growth Factor is fully safe"

Your website contains numerous personal testimonials that constitute therapeutic claims. These testimonials include, but are not limited to, the following:

1. [REDACTED] a child whose symptoms included: "Autism, no eye contact, no speech, woke up every night between 2-3 o'clock." "The next day after taking the first Total Brain, he began to speak and sing; he also doesn't wake up during the night."

* It appears that your firm markets several products under the description "Live Growth Factors," including the following: "Embryoblaste," "Artery," "Cartilage," "Whole Brain," "Muscle," "Eye," "Pancreas," "Skin," "Lung," "Spleen," "Kidney," "Heart," "Whole Embryo," "Liver," "Pituitary Gland," "Hypothalamus," "Intestine," "Spinal Cord," "Bone Marrow," "Adrenal Gland," "Testis," "Thymus," "Vessel," and "Vein." See <http://www.targetyourhealth.org/growthfactor2.htm>. This Warning Letter applies to the marketing of each of these products.

2. [REDACTED] exhibited "history of prostate cancer." After taking a "3 vial rotation for 6 month [sic] for a total of 12 vials of Thymus-Embryoblaste-Prostate-Testis-Total Brain nutritional supplements; after 6 month [sic], decrease to 2 vials a week for a total treatment time of 2 years," the "tumor regressed 80% as the treatment continues."

Additional examples of the claims observed on your website include, but are not limited to, the following: "[T]he embryoblaste (mesenchymatous tissue) is traditionally used in case of . . . degeneration of connective tissue. . . ."; "[T]he embryo cartilage is traditionally used in degenerative rheumatism"; "[W]hole embryo brain is traditionally used in cases of premature senescence."; "[T]he embryo skin is traditionally used as a supplement for a regular treatment in certain skin disorders such as psoriasis, vitiligo, desquamation, and eczema."; "[T]he embryo hypothalamus is traditionally used . . . in the regulation of endocrine disorders."; and "[S]pinal cord is traditionally used in degenerative neurological disorders and as a post-traumatic remedy."

Your website also states, "The Live Cells are removed from animals in approved slaughterhouses that have passed all health controls. The veterinary controls certify that the animals are healthy, suitable for human consumption and free of any spongiform encephalitis." However, please be advised that on December 12, 1997, the United States Department of Agriculture (USDA) established restrictions on the importation of certain ruminant products, including meat and meat products from ruminants, due to Bovine Spongiform Encephalopathy (BSE). The regulations found in Title 9 of the Code of Federal Regulations, section 95.4, published August 14, 2001, specifically prohibit the importation of ruminant products used in many of the commercial medias, extracts, reagents, antisera, etc., for in vivo or in vitro use. Additionally, the FDA has issued letters (dated May 3, 1991, December 17, 1993, April 19, 2000, and May 9, 1996) and a guidance document (September 1997) requesting that materials derived from ruminants which have resided in or originated from countries where BSE has been diagnosed not be used in the manufacture of FDA-regulated products intended for administration to humans. In those letters and in that guidance, the FDA further strongly recommended that manufacturers take steps to assure that materials derived from all species of ruminant animals born, raised or slaughtered in countries where BSE is known to exist, or countries where the USDA has been unable to assure FDA that BSE does not exist, are not used in the manufacture of FDA-regulated products intended for administration to humans.

It appears that the Live Cell Growth Factors are offered for sale to U.S. citizens because the "Personal Orders" page of the website provides for payment and shipment to U.S. addresses. These products appear to be available to anyone who orders the products from your website, notwithstanding the website's statement, "Take Live Cell Growth Factors as prescribed by your health professional."

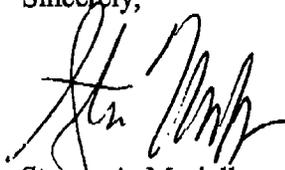
Please be advised that in order to introduce or deliver for introduction a biologic into interstate commerce, a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, biologic products may be distributed for clinical use in humans only if the

sponsor has on file an accepted investigational new drug application as specified by the regulations (21 U.S.C. 355(i); 21 CFR Part 312). Based on a review of our files, your product is not the subject of an approved biologics license application (BLA) or an investigational new drug application (IND). Therefore, your shipments of product for which a valid license or IND is not in effect represent violations of the Act and the PHS Act and may result in the Agency seeking such relief as provided by law. (21 U.S.C. 331).

This letter is not intended to be an all-inclusive review of your website and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Acts and their implementing regulations. You should take prompt action to correct the violations noted above. Failure to promptly correct these violations may result in regulatory action such as seizure and/or injunction without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. 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. Your response should be sent to the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852-1448, Attention Mr. Steven Masiello, Director, Office of Compliance and Biologics Quality.

Sincerely,



Steven A. Masiello
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

cc: Roland Lauzen ND
Technical Consultant and Life Cell Growth Factor Expert
Target Your Health, Inc.
P.O. Box 177
Wildomar, California 92595