



CBER-04-014

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

WARNING LETTER

AUG 31 2004

FEDEX

www.bellezaintegral.com c/o
Belleza Integral C.A.
El Camoruco
Piso 12 Of 8
Av Bolivar N
Valencia, Venezuela 2001

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your website at Internet address: <http://www.bellezaintegral.com> and has determined that several of the products on your website 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/or biological products, as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 USC 262(i)].

Several of your Biocell Ultravital products, including H-Ultracell, Cellorgane Complexe, Thymoenzym, Mekenz H7, and H-Citoplacell, are considered drugs and/or biological products because the therapeutic claims, as shown on your web site, establish their intended use as drugs.

- H-Ultracell -- Your website states that H-Ultracell is an "Anti-Ageing [sic] Vaccine" composed of ingredients including "extracts of embrionary tissues of lamb foetus [sic]" and "human placenta." In addition, the website indicates that the product includes "syringes with placental liquid of human origin." Your website also states, "During the last 5 years, it has been proven that H-Ultracell . . . [i]mproves cardiac performance and renal function, as well as the functions of liver, spleen, and other organs . . . ; Reduces arterial tension, raises good cholesterol (HDL) and reduces bad cholesterol (LDL); . . . Prevents osteoporosis . . . and accelerates the recuperation from wounds . . ." Your website also states, "No adverse reactions have been observed in any case in the recommended doses" and "We recommend you to be 'vaccinated' every year . . ."
- Cellorgane -- Your website states that Cellorgane is composed of "biological components" including "organs and enzymes." Moreover, "Cellorgane acts as a coadyuvant [sic] in specific treatments, and it's afficiecy [sic] has been proof [sic]

in the next cases: Arteriosclerosis, . . . Arthritis, . . . Immune system disorders, Hepatic deficiency, Rickets.” Your website also states that Cellorgane has “[n]o side effects” and that “[t]olerance, antigenicity, and toxicity tests have determined that this product is totally harmless in doses twice as large as those recommended here” and is “Non-interactive with other medicines.”

- Thymoenzym -- Your website states that Thymoenzym is composed of ingredients including “thymic extract which originates from young calves” and that it is an “effective activator of the immunological system . . . specially indicated to prevent and cure bacterial and viral diseases.” The website also indicates that “Thymoenzyme is successfully used in: Hepatitis, Neuropathies, Rheumatoid arthritis, Breast cancer, Kaposi’s Sarcoma (AIDS), Cancer of the Prostate, Lung cancer, Cancer of the Uterus, Hodgkin’s Disease.”
- Mekenz H7 -- Your website states that Mekenz H7 is composed of ingredients including “cellular extracts of mesenchymatose tissue.” Moreover, the product is indicated for treating “[a]rthritis,” “metabolic diseases,” “neuromuscular diseases,” and “[h]ypertension” among other things.
- H-Citoplacell -- Your website states that H-Citoplacell is composed of ingredients including “Human placenta” and “thymus extract.” Your website lists “Hypertension,” “Degenerative diseases,” “Arteriosclerosis,” and “Osteoporosis” as “some of the ailments, deficiencies and chronic affections that substantially improve with the continuous use of H-Citoplacell.”

Regarding H-Ultracell, which your website indicates is composed of ingredients including “fresh foetus [sic] tissue of unborn lamb,” and Thymoenzym, which your website indicates is composed of ingredients including “thymic extract which originates from young calves,” 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 9 CFR 95.4, specifically prohibit the importation of ruminant products used in many of the commercial medias, extracts, reagents, and anti sera, for in vivo or in vitro use. Additionally, the FDA has issued letters (dated May 3, 1991, December 17, 1993, May 9, 1996, and April 19, 2000) and a guidance document (September 1997) requesting that manufacturers not use materials derived from ruminants that have resided in or originated from countries where BSE has been diagnosed in the manufacture of FDA-regulated products intended for administration to humans.

It appears that Biocell Ultravital products, including H-Ultracell, Cellorgane Complexe, Thymoenzym, Mekenz H7, and H-Citoplacell, are offered for sale to U.S. citizens because the order page of your website provides for payment and shipment to U.S. addresses. Furthermore, the order page displays order numbers and a direct link to a U.S. Postal Service website allowing individuals to track and confirm delivery of products shipped into the U.S.

Please be advised that in order to introduce or deliver for introduction a biologic into interstate commerce, a valid biologics license (BLA) or new drug application (NDA) must be in effect. (21 U.S.C. 355(a); 42 U.S.C. 262(a)). A BLA or NDA is issued only after a showing of safety and effectiveness (for an NDA) or safety, purity and potency (for a BLA) for the product's intended use. While in the development stage, drug and biological products may be distributed for clinical use in humans only if the sponsor has on file an accepted investigational new drug application (21 U.S.C. 355(i); 21 CFR Part 312). Your product is not the subject of an approved BLA or NDA or an IND. Therefore, your shipments of product represent violations of the Act and/or the PHS Act and may result in the Agency seeking such relief as provided by law. (21 U.S.C. 331).

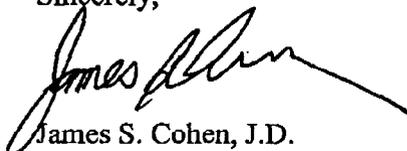
To avoid violating the Act and the PHS Act, you should immediately cease distributing in the United States the products described above until you receive an IND, BLA, or NDA from the FDA.

This letter is not intended to serve as an all-inclusive review of your website and/or the products marketed by Belleza Integral C.A. It is your responsibility to ensure that all products marketed on your website are in compliance with the Act and the PHS Act and their implementing regulations. You should take prompt action to correct the violations noted above. Failure to correct these violations promptly may result in regulatory action such as seizure 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 James S. Cohen, J.D., Acting Director, Office of Compliance and Biologics Quality, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852-1448.

If you have any questions regarding this letter, please contact Ms. Anna Flynn at (301) 827-6201.

Sincerely,



James S. Cohen, J.D.
Acting Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosures:

Internet website pages from <http://www.bellezaintegral.com>