



Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, Fl 32751

**HAND-DELIVERED**

**WARNING LETTER**

**FLA-03-15**

January 10, 2003

Marcelo Luna, CEO and Administrator  
Life Extension Center, Inc.  
4836 S.W. 8<sup>th</sup> Street  
Miami, Florida 33114-2142

Dear Mr. Luna:

During an inspection of your firm on February 21-25, 2002, FDA Investigator Dianiris Ayala found that your firm imports and distributes a product, which is labeled and promoted for conditions causing it to be considered a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The product is considered to be a drug because it contains a recognized drug ingredient, Ibuprofen, and because of the claims declared in the product labeling and in the promotional brochure entitled "Life Extension Foundation, The Directory of Life Extension Technologies 2001", and on the Life Extension Foundation Product website, as follows:

**Dolgel 100mg** – Used as directed, provides fast and effective relief from rheumatic pain, and muscular aches, backache, lumbago fibrositis and swelling from strains, sprains and sports injuries.

Because such labeling includes statements which represent and suggest that this article is intended for use in the cure, mitigation, treatment, or prevention of disease conditions, this product is a drug within Section 201(g) of the Act. Further, we are unaware of substantial scientific evidence, which documents that this drug is generally recognized as safe and effective for the above referenced conditions. Accordingly, marketing this drug is a violation of the Act as follows:

This drug may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Act, since it is a new drug within the meaning of Section 201(p) of the Act and no approval of a new drug application filed pursuant to Section 505(b) of the Act is effective for such drug.

The drug is also misbranded within the meaning of Section 502(a) in that its labeling is false and misleading because it suggests that there is substantial scientific evidence to establish that the drug is safe and effective for its intended uses when in fact such evidence does not exist.

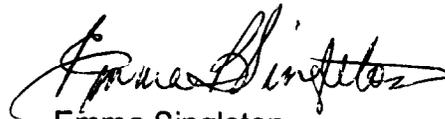
The drug is further misbranded pursuant to Section 502(f)(1) in that its labeling fails to bear adequate directions for the uses for which it is offered and it is not exempt from this requirement under 21 CFR 201.115 since it is a new drug within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is in effect for this drug.

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters so that they may take this information into account when considering the award of contracts. Additionally, no pending applications will be approved until the violations have been corrected.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products. Please notify this office in writing within 15 working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. 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 implemented.

Your reply should be sent to the Food and Drug Administration, Florida District, 555 Winderley Place, Suite 200, Maitland, Florida 32751, attn: Timothy J. Couzins, Compliance Officer, telephone number (407) 475-4728.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma Singleton". The signature is fluid and cursive, with a prominent initial "E" and a long, sweeping underline.

Emma Singleton  
Director, Florida District