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VIA FEDERAL EXPRESSFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751WARNING LETTER

FLA-02-54

June 29, 2002

Darin Grey
GHMedical.com
1250 E. Hallandale Beach Blvd.
Penthouse A and
442 Sunset Drive
Hallandale, FL 33009

Dear Mr. Grey:

This letter concerns **Saizen 5 mg., 15 IU. [somatropin (rDNA origin) for injection]** also known as recombinant human growth hormone (HGH) which is currently marketed by your firm as shown on your Internet site www.ghmedical.com. According to information on this site, **Saizen** is being promoted as part of an anti-aging treatment regimen. Ordering instructions for the drug are provided on the site.

The intended anti-aging treatment use for **Saizen** is conveyed through claims on your Internet site. These include statements such as "...Saizen ... Looking and feeling younger... Saizen may also be used for hormone rejuvenation therapy... Benefits gradually occur over a six to twelve month period... Benefits of HGH... include... 15% average decrease in fat... 8% average increase in muscle and lean body structure... improved skin texture... decrease skin wrinkles... greater bone density... increased time for healing... increased immunity and resistance to infection... increased libido... increase in both energy and strength... improvement of sleep pattern... increase of cardiac output and kidney function... HGH is known to many as the one and only hormone replacement with the capabilities of reversing the biological age..."

Saizen is a "drug" as defined by 21 U.S.C. 321(g). **Saizen** has a new drug application (N019-764) approved by FDA. **Saizen** is approved for one indication only, namely for the long-term treatment of children with growth failure due to inadequate secretion of endogenous growth hormone. The conditions recommended or suggested for the **Saizen** sold through your web site such as hormone rejuvenation therapy and reversing the biological age, among others, render it a "new drug" as defined by 21 U.S.C. 321(p). Under 21 U.S.C. 355(a), a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. The continued distribution of this product without an approved NDA violates 21 U.S.C. 355.

In addition, your **Saizen** is misbranded under 21 U.S.C. 352(f)(1) because its labeling fails to bear adequate directions for the uses for which it is being offered and it is not exempt from this requirement under 21 CFR section 201.115 since it is an unapproved new drug.

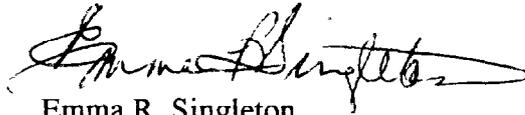
Finally, distribution of your HGH product violates 21 U.S.C. 333(f). **Saizen** is being promoted and distributed on your web site for an unapproved use. There are no recombinant HGH products that are approved by the Food and Drug Administration (FDA) for anti-aging treatment. 21 U.S.C. 333(e) states that "... whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under 21 U.S.C. 355 and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, United States Code, or both."

This letter is not intended to be an all-inclusive review of your Internet sites, and the products your firm may market. The violations of the Act described above are not intended to be an all-inclusive list of the deficiencies of you and your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with Federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure, injunction, and/or prosecution.

We request that you reply in writing within fifteen (15) days of your receipt of this letter stating the action your firm will take to discontinue marketing of this drug product. Your response should be directed to Martin E. Katz, Compliance Officer, at the U.S. Food and Drug Administration, Florida District, 555 Winderley Place, Suite 200, Maitland, FL 32751, telephone number 407-475-4729.

Sincerely yours,



Emma R. Singleton
Director
Florida District Office

cc:

