



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
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Irvine, California 92612-2506
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 25, 2011

W/L 44-11

Adam Vincent Gilmer, President and Co-Founder
Ethos Environmental, Inc. (d.b.a. Regeneca International, Inc.)
One Technology Drive
Suite C515
Irvine, CA 92618

Dear Mr. Gilmer:

This letter concerns your firm's marketing and distribution of the product "Regenerect." Laboratory analyses conducted by the U.S. Food and Drug Administration (FDA) concluded that multiple lots of Regenerect contain sulfoildenafilafil, which is a phosphodiesterase type-5 (PDE-5) inhibitor and an analogue of sildenafil.[\[1\]](#) Sildenafil is the active pharmaceutical ingredient in Viagra, an FDA-approved drug for the treatment of erectile dysfunction (ED). As described below, your marketing and distribution of Regenerect violate the Federal Food, Drug, and Cosmetic Act (the Act).

Regenerect is labeled as a dietary supplement. However, Regenerect's labeling statements make clear that Regenerect is a drug, as defined by section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)], because Regenerect is intended to prevent, treat, or cure disease conditions and/or affect the structure or function of the body. Labeling statements documenting the intended use of Regenerect, include, but are not limited to, the following:

- "[A]n alternative to chemical erectile stimulants including products like Viagra*, Cialis*, Levitra* and other pharmaceutical drugs in the category."
- "Regenerect is an erectile stimulant that increases the size and duration of erections."
- "Natural Male Erectile Stimulant"

- “Drug-free blend of natural, herbal ingredients that enhance and support sexual response.”
- “Better Than Viagra”

Under section 201(g)(1) of the Act (last sentence), the structure/functions claims permitted for dietary supplements must be made in accordance with section 403(r)(6) of the Act [21 U.S.C. §343(r)(6)]. However, the structure/function claims made for Regenerect do not conform to section 403(r)(6). Therefore, Regenerect is subject to regulation as a drug. Section 403(r)(6) authorizes claims that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body or that characterize the way in which a nutrient or dietary ingredient maintains the structure or function of the body. The male enhancement structure/function claims made for Regenerect do not describe the effects of a nutrients or dietary ingredients in the product. Rather, the structure/function claims are clearly made for the product as it relates to its sulfoildenafil content. Sulfoildenafil is not a nutrient or a dietary ingredient, as defined in section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)], but is a synthetic active pharmaceutical ingredient. For all of these reasons, Regenerect is a drug within the meaning of section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)].

Moreover, Regenerect is a new drug, as defined by section 201(p) of the Act [21 U.S.C. § 321(p)], because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your marketing and distribution of Regenerect without such an approved application violates these provisions of the Act.

Furthermore, Regenerect is a “prescription drug” as defined at section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], because, in light of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, Regenerect is not safe for use except under the supervision of a practitioner licensed by law to administer it. Regenerect contains sulfoildenafil, a PDE-5 inhibitor. Indeed, all PDE-5 inhibitors which have been approved for marketing by FDA are limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drugs. Regenerect, however, is labeled and sold as a non-prescription product.

According to section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layman can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs can only be used safely at the direction and under the supervision of a licensed practitioner. Therefore, it is impossible to write “adequate directions for use” for prescription drugs. As such, the labeling of Regenerect fails to bear adequate directions for its intended use. Regenerect is not exempt from the requirement that its labeling bear adequate directions for use under 21 C.F.R. §§ 201.100(c)(2) and 201.115 because no FDA-approved application is in effect for Regenerect. For these reasons, Regenerect is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)].

Additionally, under section 502(a) of the Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the Act [21 U.S.C. § 321(n)], provides that, in determining whether an article's labeling or advertising "is misleading, there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . ." The labeling of Regenerect does not declare that it contains the PDE-5 inhibitor, sulfoildenafilafil. The undeclared PDE-5 inhibitor in Regenerect may pose serious health risks because consumers with underlying medical issues may take the product without knowing that it can cause serious harm or interact in dangerous ways with other drugs they may be taking. For example, consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin) and can lower blood pressure to dangerous levels. Further, consumers who have been advised against taking PDE-5 inhibitors because of comorbidities or the potential drug interactions may seek products like Regenerect because it is marketed as not containing the active ingredients in approved ED drugs. The failure to disclose the presence of sulfoildenafilafil renders your product's labeling false and misleading. Regenerect is, therefore, misbranded under Section 502(a) of the Act [21 U.S.C. § 352(a)].

The undeclared PDE-5 inhibitor contained in Regenerect also causes it to be misbranded under section 502(f)(2) of the Act [21 U.S.C. § 352(f)(2)], because the labeling lacks adequate warnings for the protection of users. As previously noted, there is potential for adverse events associated with the use of Regenerect, particularly since someone who takes it would be unaware of the presence of the PDE-5 inhibitor, sulfoildenafilafil. For example, patients who take nitrates and consume Regenerect may be at risk of life-threatening hypotension. Consequently, your product, Regenerect, is misbranded under sections 502(f)(2) of the Act [21 U.S.C. § 352(f)(2)].

The introduction or delivery for introduction into interstate commerce of this misbranded product violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your product. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence as well as the occurrence of other violations. It is your responsibility to ensure that your firm, and any drug or dietary supplement product manufactured or distributed by you or your firm, comply with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure, injunction, and/or prosecution as the Act authorizes under sections 302 and 304 of the Act [21 U.S.C. §§ 332 and 334]. In addition, there is criminal liability for all violations of the prohibited acts described in section 301 of the Act [21 U.S.C. §331]. Other federal agencies may take this Warning Letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates or approval of pending new drug applications listing your facility as a *manufacturer* until the above violations are corrected.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. You can find guidance and information for the regulated industry regarding regulations for drug products through links at FDA's website at <http://www.fda.gov/oc/industry>.

Your response should be sent to:

Blake Bevill
Director, Compliance Branch
Food and Drug Administration
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612

Sincerely,
/S
Alonza E. Cruse
District Director

Cc:
Ester S. Mark, M.D.
23521 Paseo De Valencia
Laguna Hills, CA 92653

Medical Board of California
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

California Department of Public Health
Food and Drug Branch
1500 Capitol Avenue, MS-7602
Sacramento, CA 95899-7413

[1] In April 28, 2011, your firm conducted a voluntary recall of specific lots of "Regenerect™" after FDA found that the product contained sulfoildenafil.