Consumer Protection Coalition
853 North Highway 89
Suite 69
Chino Valley, AZ 86323

Submitted 7/11/2013

July 11, 2013

VIA U.S. CERTIFIED MAIL
Charles Harwood, Acting Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-470
Washington, D.C. 20580

Re: TA-Sciences® Telomerase Activation (TA-65®)

Director Harwood:

I am the head of a public interest group called the Consumer Protection Coalition. The Consumer Protection Coalition is a group of concerned citizens who seek to draw government attention to instances of fraud and deception in the market that cause injury to consumers. I write seeking formal investigation of TA-Sciences' advertising practices concerning its dietary supplement, TA-65®.[1] TA-Sciences markets its dietary supplement as a "clinically proven" therapy for significant age-related conditions in elderly patients. It claims that by lengthening telomeres within a person's cells, TA-65 rejuvenates the individual, extends life, and results in major health benefits.[2] The problem is that publicly available scientific literature does not support the strong marketing claims appearing in TA Science's labeling and promotional content. Experts have stated that TA-65 is modern day snake oil, promising major health benefits, at a substantial cost, with little credible evidence to support bold establishment claims. At the staggering cost of up to $2,200 for a three month supply, American consumers face substantial harm if TA-Sciences proceeds to market without sound scientific evidence. According to experts, preliminary data suggests that TA-65 could also increase cell proliferation which could create heightened cancer risks. I explain these points in greater detail below. In sum, as a purchaser of dietary supplement products, I request that FTC intervene to ensure that the dietary supplement market remains safe, reliable, and free of false or misleading content.

[1] Telomerase Activation Sciences, Inc. ("TA Sciences") is located at 420 Lexington Ave., Suite 2900, New York, NY 10170; its phone number is 212-588-8805; and it has a website at www.tasciences.com.

[2] A "telomere" is essentially the end portion of a chromosome. Telomeres become progressively shorter each time a cell divides. *See* TA-Sciences, "TA-65 Science," *at* http://www.tasciences.com/introduction-to-telomere-science/.

I. Background:

Since at least 2007, Telomerase Activation Sciences, Inc. ("TA-Sciences") has sold a "nutraceutical" ingredient as a dietary supplement, evading the rigors of FDA's drug approval process, and in violation of the Federal Trade Commission Act. The product, TA-65®, is a purified extract of *Astralagus membranaceous*, a flowering plant commonly used in traditional Chinese medicine. Based on a "proprietary process to refine and purify TA-65," TA-Sciences promises cellular rejuvenation through "telomerase activation." In short, TA-Sciences claims that (1) the length of one's telomeres directly influence health and vitality, and (2) that TA-Sciences' product will increase the length of telomeres, such that consumers will experience a renewed, rejuvenated physical condition.

Specifically, TA-Sciences promises "lengthened telomeres, restoration of weak immune systems, bone density improvements and other important bio market improvements" in consumers who are "[o]ver 70 years of age, or [a]re of any age and have measured their telomeres and found them to be short, or [h]ave reason to believe that strengthening their immune system would have particular benefit."[3] TA-Sciences provides a "TA-65 Dosing Guideline" to help consumers determine the proper amount for certain physiological benefits.[4] TA-Sciences claims repeatedly that its product is "proven" or "clinically proven" to "lengthen short telomeres, restore the immune system, and improve other important biomarkers."

Consumers pay a steep price for a "dietary supplement" of such promise. TA-Sciences advertises a lower maintenance dose at $600 for a three month supply. It sells higher, more efficacious doses at $2,200 for a three month supply.[5]

As explained in greater detail below, the publicly available scientific evidence does not support TA-Sciences' bold claims. Published studies have shown that telomere length does not increase at all. TA-Sciences supports its "clinically proven" establishment claims with animal and in vitro studies—studies that fall short of the qualitative level TA-Sciences represented to consumers. Other studies have common deficiencies, including small sample sizes without control groups. Ultimately, TA-Sciences likely has little credible evidence that its ingestible product actually lengthens telomeres, or stems the effects of human age-related conditions.

Carol Greider is one of several scientists who won a Nobel for discovering telomerase.[6] When asked to comment on TA-Sciences' scientific support in 2011 Greider stated that she had not "seen yet that they actually change telomere length, which is the clear real indicator."[7] Even supporters of TA-65 have conceded that the dietary supplement contains significantly lowered concentrations of the purported anti-aging ingredient.[8]

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[3] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/; *see generally* http://www.tasciences.com/ (last visited June 25, 2013).
[4] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/.
[5] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/.
[6] *See* Thea Singer, "New Anti-Aging Pill Under Fire," The Daily Beast (Apr. 11, 2011), *available at* http://www.thedailybeast.com/articles/2011/04/11/anti-aging-pill-new-study-on-ta-65-sparks-controversy.html (last visited June 25, 2013).
[7] *Id.* (noting that, according to Greider, oral ingestion of the product in pill form is unlikely to be efficacious).
[8] *See id.*

II. TA-Sciences' Product Claims Are Not Supported by Competent and Reliable Scientific Evidence

TA-Sciences offers TA-65 and its "Patton Protocol" for an exorbitant sum of up to $2,200 (3 month supply). For that money, TA-Sciences claims that its product is clinically proven lengthen an individual's telomeres, thus extending the life cycle and rejuvenating the consumer. The problem is that TA-Sciences has no scientific evidence that its product actually lengthens telomeres, and certainly not the level of scientific evidence required to support a "clinically proven" establishment claim.

Advertisements that claim a certain type or level of support are "establishment claims." *See Thompson Medical Co., Inv. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986). For instance, a claim that a product's effectiveness is supported by clinical proof is an establishment claim. *See Removatron Intern. Corp. v. FTC*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989). In short, if "an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." *See In the Matter of Pom Wonderful LLC*, 9344, 2012 WL 2340406, at *196 (F.T.C. May 17, 2012). TA-Sciences likely cannot meet that burden.

The publicly available evidence consists of animal and in vitro studies, and other human studies of questionable methodological quality. In a 2011 study of laboratory mice, the authors observed that the "average telomere length was not significantly increased in the 1- or 2-year-old TA-65-treated groups compared to untreated controls." *See* de Jesus, *supra*, at 7 (contradicting TA-Sciences' express claim that its product has "been proven to lengthen short telomeres").[9] In 2013, researchers observed statistically significant increases in telomerase activity in TA-65 treated cultures. *See* Molgora, et al., *supra*, at 59. However, that study applied TA-65 directly to laboratory cell cultures. The study had a drastically small sample size with only six donors, and the results measured only telomerase activity, rather than telomere length over longer durations. *Id.* at 59-65. Given that information, the authors themselves explained that "[f]urther studies should include a larger sample size, which could help confirm or change our observations." *Id.* at 65 (describing the study as "preliminary"). The FTC does not consider in vitro or animal studies as support for dietary supplement structure/function claims or health claims.[10]

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[9] Note, also, that the 2011 study of laboratory mice involved supplementation with a final TA-65 "concentration of 25 mg kg^{-1} body weight/day," which is substantially higher than TA-Sciences offers for sale. One capsule of TA-65 includes approximately 8mg of the purified Astragalus Root Extract. Even when taken at the "high" dose of four (4) capsules per day, the resulting supplementation of 32mg daily is less than two percent of the amount tested in the 2011 de Jesus study (assuming an average weight of male adults is about 80 kg). Therefore, even assuming the mouse study produced statistically significant results, the justification for an extrapolation to humans from such a high dosing amount in mice is not explained in the literature.

[10] Another study in 2011, performed by investigators associated with TA-Sciences, tested only 13 subjects in an uncontrolled protocol. *See* Calvin B. Harley, et al., "A Natural Product Telomerase Activator As Part Of a Health Maintenance Program" Rejuvenation Res. 2011 February; 14(1): 45–56 (noting that "[t]wo independent measures of median or mean telomere length ... showed no consistent change with time on Patton Protocol-1"). The authors explained that "[d]ata from [the] study were collected primarily as a hypothesis-generating exercise because subjects were not participating in a controlled prospective study, and statistical analyses were not formally defined *a priori*." *Id.* at 49.

Moreover, when a claim urges consumers to substitute a product for conventional medical care or treatment, the advertiser should bear a heightened standard to substantiate claims. *See In re POM Wonderful*, 2012 WL 2340406, at *205 (citing *In re Daniel Chapter One*, 2009 FTC LEXIS 157, at *284, *282 (Initial Decision) (finding that where representations in some instances suggested that individuals forgo traditional cancer treatments in favor of purchasing and consuming the challenged products and evidence showed that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health, the consequences of a false claim required a higher level of substantiation). In promoting TA-65 to elderly patients for the repair or treatment of serious health conditions, TA-Sciences may steer consumers away from proven, efficacious medical treatments.

TA-Sciences promotes its TA-65 molecule as a drug, targeting sensitive populations with the promise of "magic" results in treatment of potentially serious age-related conditions. For instance, on its website TA-Sciences offers its "nutraceutical" product with various "dosing guidelines."[11] For the most sensitive population, including those over 70 years of age, TA-Sciences claims a concentrated dose will reverse substantial health problems. This higher dose is appropriate, claims TA-Sciences, for those who "[h]ave reason to believe that strengthening their immune system would have particular benefit."[12] In those individuals, taking TA-65 would lead to a "restoration of weak immune systems, bone density improvements, and other important bio market improvements which usually decline with age."[13] TA-Sciences links directly to a science library that lists "telomere science" by disease.[14]

Consumers read those claims in context with telomerase activation studies that focused on therapeutic activity. For example, in a 2013 study sponsored in part by RevGenetics (a distributor of TA-Sciences TA-65 product), the researchers reported that TA-65 stimulation would be "particularly critical during acute viral infection, since rapid early vigorous proliferation is essential for effective immune control over the infection." *See* Molgora, B.; Bateman, R.; Sweeney, G.; Finger, D.; Dimler, T.; Effros, R.B.; Valenzuela, H.F. Functional Assessment of Pharmacological Telomerase Activators in Human T Cells. *Cells* 2013, 2, 57-66 (examining "*pharmacological* telomerase activators" and stating that "our data suggest that TA-65 may be useful in treating both HIV disease and other clinical situations requiring enhanced T cell telomerase activity).

TA-65 is sold primarily for its pharmacological effect, to wit, the activation of telomerase through cell stimulation. The very fact that TA-65 sells for more than $700/month is indicative of its drug purpose. What dietary supplement is offered at such exorbitant costs? Indeed, the heavy price suggests that TA-Sciences preys upon those sensitive populations who are most in need of a miracle, or "magic pill." Falsely advertised medicinal products expose consumers to significant harm. Those false advertising campaigns create a risk that consumers will substitute for conventional medical therapy.

TA-Sciences' advertising is even more troublesome because the product may present health risks that are not accurately conveyed to consumers. Experts have observed that TA-65's

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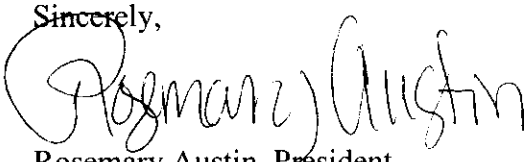
[11] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/.
[12] *Id.*
[13] *Id.*
[14] *See* http://www.licensee.tasciences.com/ (under the navigation menu, "TA Sciences").

telomerase activation mechanism contributes to cell proliferation and, thus, may create a risk of cancer. *See* Singer, *supra* at note 4. TA-Sciences acknowledges the "theoretical risk" that "unwanted cell proliferation" could create increased cancer risk, but the company "believe[s] the potential beneficial effects of activating telomerase and maintaining healthy tissue function outweigh [that] theoretical risk."[15] At least one TA-65 study in laboratory mice revealed an increase in liver cancer, although those findings were found not to reach statistical significance. *See* de Jesus, Bruno Bernardes, et al. "The telomerase activator TA-65 elongates short telomeres and increases health span of adult/old mice without increasing cancer incidence." *Aging cell* 10.4 (2011): 604-621. Given the "theoretical risks" in a high-potency, drug-like moiety, the FTC should require a high level of substantiation showing that the product perform as advertised and , so, the benefits do substantially outweigh the risks. That information should come from toxicological and other safety data, including, for instance: genetox batteries; maximum tolerated dose; NOAEL data; repeat-dose tolerability studies in humans; generational rodent reproductive studies; and/or teratology data. That information, and FTC's response to same, should be disclosed publicly to assure the consuming public.

To the extent TA-Sciences claims that its products lengthen telomeres on its commercial website, the product labeling and advertising is false or misleading. As explained above, the limited publicly available scientific information reveals that TA-65 does not actually increase telomere length. Accordingly, the FTC should demand competent and reliable scientific evidence showing that TA-65 performs as claimed, before American consumers invest substantial money hoping to reverse signs of aging, or stave off significant degenerative conditions.

Thank you in advance for your consideration of this matter. I trust that the FTC will take necessary action to ensure a safe, reliable consumer market free of false and misleading promotional content.

Sincerely,



Rosemary Austin, President
Consumer Protection Coalition
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Attachments: (4)

[15] http://www.tasciences.com/faq/.

Consumer Protection Coalition
853 North Highway 89
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Submitted 7/11/2013

July 11, 2013

VIA U.S. CERTIFIED MAIL
Barbara O. Schneeman, Ph.D., Director
Office of Nutrition, Labeling, and Dietary Supplements
Food and Drug Administration
CPK-1 Bldg. Room 4C096
5100 Paint Branch Parkway
College Park, MD 20740

Re: TA-Sciences® Telomerase Activation (TA-65®)

Dr. Schneeman:

I am the head of a public interest group called the Consumer Protection Coalition. The Consumer Protection Coalition is a group of concerned citizens who seek to draw government attention to instances of fraud and deception in the market that cause injury to consumers. I write seeking formal investigation of TA-Sciences' advertising practices concerning its dietary supplement, TA-65®.[1] TA-65 contains a new dietary ingredient without a history of safe, lawful use in the United States. TA-65 is, therefore, adulterated as a matter of law. *See* 21 U.S.C. § 350b. Notwithstanding, the product is marketed and sold for its drug-like properties, rendering the product an unapproved new drug under the FDCA. *See* 21 U.S.C. § 321(g)(1), (ff); 21 U.S.C. § 355(a). Finally, the publicly available scientific record does not support the strong marketing claims appearing in TA Science's labeling and promotional content. With a staggering cost of up to $2,200 for a three month supply, American consumers face substantial harm if TA-Sciences proceeds without sound scientific evidence. According to experts, preliminary data suggests that TA-65 could increase cell proliferation which could create heightened cancer risks. I explain these points in greater detail below. In sum, as a purchaser of dietary supplement products, I request that the FDA and FTC intervene to ensure that the dietary supplement market remains safe, reliable, and free of adulterated or misbranded product.

I. Background:

Since at least 2007, Telomerase Activation Sciences, Inc. ("TA-Sciences") has sold a "nutraceutical" ingredient as a dietary supplement, evading the rigors of FDA's drug approval process. The product, TA-65®, is a purified extract of *Astralagus membranaceous*, a flowering plant commonly used in traditional Chinese medicine. Based on a "proprietary process to refine

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and purify TA-65," TA-Sciences promises cellular rejuvenation through "telomerase activation." In short, TA-Sciences claims that (1) the length of one's telomeres directly influence health and vitality, and (2) that TA-Sciences' product will increase the length of telomeres, such that consumers will experience a renewed, rejuvenated physical condition.

Specifically, TA-Sciences promises "lengthened telomeres, restoration of weak immune systems, bone density improvements and other important bio marker improvements" in consumers who are "[o]ver 70 years of age, or [a]re of any age and have measured their telomeres and found them to be short, or [h]ave reason to believe that strengthening their immune system would have particular benefit."[2] TA-Sciences provides a "TA-65 Dosing Guideline" to help consumers determine the proper amount for certain physiological benefits.[3] TA-Sciences claims repeatedly that its product is "proven" or "clinically proven" to "lengthen short telomeres, restore the immune system, and improve other important biomarkers."

Consumers pay a steep price for a "dietary supplement" of such promise. TA-Sciences advertises a lower maintenance dose at $600 for a three month supply. It sells higher, more efficacious doses at $2,200 for a three month supply.[4]

As explained in greater detail below, the publicly available scientific evidence does not support TA-Sciences' bold claims. Published studies have shown that telomere length does not increase at all. TA-Sciences supports its "clinically proven" establishment claims with animal and in vitro studies—studies that fall short of the qualitative level TA-Sciences represented to consumers. Other studies have common deficiencies, including small sample sizes without control groups. Ultimately, TA-Sciences likely has little credible evidence that its ingestible product actually lengthens telomeres, or stems the effects of human age-related conditions.

Carol Greider is one of several scientists who won a Nobel for discovering telomerase.[5] When asked to comment on TA-Sciences' scientific support in 2011 Greider stated that she had not "seen yet that they actually change telomere length, which is the clear real indicator."[6] Even supporters of TA-65 have conceded that the dietary supplement contains significantly lowered concentrations of the purported anti-aging ingredient.[7]

II. The TA-65 Proprietary, Potent Extraction of Astralagus Botanical Root Is a New Dietary Ingredient Under 21 U.S.C. § 350b

TA-Sciences claims that TA-65 is the product of a proprietary extraction and purification process that yields an end product unlike any other product available to United States

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[2] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/; *see generally* http://www.tasciences.com/ (last visited June 25, 2013).
[3] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/.
[4] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/.
[5] *See* Thea Singer, "New Anti-Aging Pill Under Fire," The Daily Beast (Apr. 11, 2011), *available at* http://www.thedailybeast.com/articles/2011/04/11/anti-aging-pill-new-study-on-ta-65-sparks-controversy.html (last visited June 25, 2013).
[6] *Id.* (noting that, according to Greider, oral ingestion of the product in pill form is unlikely to be efficacious).
[7] *See id.*

consumers.[8] TA-Sciences claims to be, therefore, the "first company to isolate TA-65 from the plant."[9] If TA-Sciences advertises truthfully, its final molecular compound is chemically distinct from dietary ingredients sourced from *Astralagus membranaceous*.

Any dietary supplement that contains a "new dietary ingredient" (NDI) is adulterated under 21 U.S.C. § 350b unless it (1) contains "only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered"; or (2) there is a history of safe use shown through a 75-day NDI notification submitted to the FDA. *See* 21 U.S.C. §350b(a)(1), (2). FDA has explained that certain common manufacturing methods do not result in "chemical alteration," such as minor loss of volatile components, dehydration, lyophilization, and milling. By contrast, certain advanced manufacturing methods would produce a chemically distinct product. For instance, chemical alteration may result from "[a] process which makes or breaks chemical bonds such as hydrolysis or esterification, unless the bonds created by the process are reversed when the ingredient is dissolved in water..." *See* FDA Draft Guidance, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" (July 2011), at IV.B.4. The "removal of some components of a tincture or solution" or "[c]hanging the manufacturing method for an ingredient" may also change the chemical composition of a product, necessitating a 75-day NDI filing.

TA-Sciences' proprietary manufacturing process likely alters the chemical composition of the traditional dietary ingredient (*Astralagus membranaceous*) by rendering the end product a more potent, distinct molecule that is not naturally available in any substantial dose. By TA-Sciences' own admission, the product they sell is not at all similar or comparable to other products marketed in the United States. Because TA-65 is a unique, proprietary, and highly potent version of a component part of Astralagus root, the product should have proceeded through the NDI process to ensure safety.

The potential risks inherent to the TA-65 product likely affect any "history of use" analysis required by 21 U.S.C. § 350b(a)(2). Therefore, even if TA-Sciences submitted a 75-day notification, the FDA should now determine substantively whether TA-Sciences supplied ample data. Experts have observed that TA-65's telomerase activation mechanism contributes to cell proliferation and, thus, may create a risk of cancer. *See* Singer, *supra* at note 4. TA-Sciences acknowledges the "theoretical risk" that "unwanted cell proliferation" could create increased cancer risk, but the company "believe[s] the potential beneficial effects of activating telomerase and maintaining healthy tissue function outweigh [that] theoretical risk."[10] At least one TA-65 study in laboratory mice revealed an increase in liver cancer, although those findings were found not to reach statistical significance. *See* de Jesus, Bruno Bernardes, et al. "The telomerase activator TA-65 elongates short telomeres and increases health span of adult/old mice without increasing cancer incidence." *Aging cell* 10.4 (2011): 604-621. Given the "theoretical risks" in a high-potency, drug-like moiety, the FDA should require toxicological and other safety data commonly submitted in NDI submissions: genetox batteries; maximum tolerated dose; NOAEL data; repeat-dose tolerability studies in humans; generational rodent reproductive studies; and/or

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[8] *See generally*, http://www.tasciences.com/faq/. In other sections of its website, TA-Sciences explains that it "tested four commonly available medicinal plant extracts and none of them contained any measurable amounts of TA-65..."

[9] *See* http://www.tasciences.com/ta-65/.

[10] http://www.tasciences.com/faq/.

teratology data. That information, or FDA's response to same, should be disclosed publicly to assure the consuming public.

To the extent TA-Sciences failed to submit ample data, or the proper 75-day notification, the product is adulterated as a matter of law. *See* 21 U.S.C. § 350b. The product appears to be an isolated, synthetic version of a compound found in extracts of Astragalus membranaceus root at trace levels. The FDA has determined that synthetic botanical products are not "dietary ingredients." Moreover, if TA-Sciences has failed to supply the requisite NDI submission, and the product is therefore not "lawfully" marketed, the product is likely not a dietary supplement under 21 U.S.C. § 321(ff)(3)(B)(ii) because the article has already been investigated as a drug.[11]

III. TA-65 Is an Unapproved Drug

TA-Sciences promotes its TA-65 molecule as a drug, targeting sensitive populations with the promise of "magic" results in treatment of potentially serious age-related conditions. For instance, on its website TA-Sciences offers its "nutraceutical" product with various "dosing guidelines."[12] For the most sensitive population, including those over 70 years of age, TA-Sciences claims a concentrated dose will reverse substantial health problems. This higher dose is appropriate, claims TA-Sciences, for those who "[h]ave reason to believe that strengthening their immune system would have particular benefit."[13] In those individuals, taking TA-65 would lead to a "restoration of weak immune systems, bone density improvements, and other important bio marker improvements which usually decline with age."[14] TA-Sciences links directly to a science library that lists "telomere science" under disease headings.[15]

Consumers read those claims in context with telomerase activation studies that focused on therapeutic activity. For example, in a 2013 study sponsored in part by RevGenetics (a distributor of TA-Sciences TA-65 product), the researchers reported that TA-65 stimulation would be "particularly critical during acute viral infection, since rapid early vigorous proliferation is essential for effective immune control over the infection." *See* Molgora, B.; Bateman, R.; Sweeney, G.; Finger, D.; Dimler, T.; Effros, R.B.; Valenzuela, H.F. Functional Assessment of Pharmacological Telomerase Activators in Human T Cells. *Cells* 2013, 2, 57-66 (examining "*pharmacological* telomerase activators" and stating that "our data suggest that TA-

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[11] *See* Molgora, B.; Bateman, R.; Sweeney, G.; Finger, D.; Dimler, T.; Effros, R.B.; Valenzuela, H.F. Functional Assessment of Pharmacological Telomerase Activators in Human T Cells. *Cells* 2013, 2, 57-66 (explaining that the identical TAT2 and TA-65 molecule has been investigated as a treatment for HIV, and that "[t]he ability to regulate telomerase activity is viewed as very therapeutically important in the fields of aging and cancer"). In 2009, the FDA held that pyridoximine-containing products could not be sold as dietary supplements because the form of Vitamin B6 (naturally present in many foods) had been first investigated as a drug before it was sold lawfully as a dietary supplement. *See* FDA Docket No. FDA-2005-P-0259 (Jan. 12, 2009).

[12] *See* http://www.tasciences.com/ta-65/ta-65-dosing-guideline/.

[13] *Id.*

[14] *Id.*

[15] *See* http://www.licensee.tasciences.com/ (under the navigation menu, "TA Sciences"). That "Telomere Science Library," available directly through TA-Sciences' website, links telomeres with disease conditions, including: Alzheimer's, anemia, atherosclerosis, cancer, dementia, HIV, and osteoporosis. *See* http://www.telomerescience.com/.

65 may be useful in treating both HIV disease and other clinical situations requiring enhanced T cell telomerase activity).

TA-65 is sold primarily for its pharmacological effect, to wit, the activation of telomerase through cell stimulation. That offering is beyond the letter and spirit of the DSHEA, which defines "dietary supplements" as products "intended to supplement the diet..." *See* 21 U.S.C. § 321(ff)(1). TA-65 is not intended to supplement the diet with a nutrient or article consumed in the food supply. Rather, TA-65 is a highly potent, isolated molecule intended to function as an anti-aging drug product.

IV. TA-Sciences' Product Claims Are Not Supported by Reliable Scientific Evidence

TA-Sciences offers TA-65 and its "Patton Protocol" for an exorbitant sum of up to $2,200 (3 month supply). For that money, TA-Sciences claims that its product is clinically proven lengthen an individual's telomeres, thus extending the life cycle and rejuvenating the consumer. The problem is that TA-Sciences has no scientific evidence that its product actually lengthens telomeres, and certainly not the level of scientific evidence required to support a "clinically proven" establishment claim.

The publicly available evidence consists of animal and in vitro studies, and other human studies of questionable methodological quality. In a 2011 study of laboratory mice, the authors observed that the "average telomere length was not significantly increased in the 1- or 2-year-old TA-65-treated groups compared to untreated controls." *See* de Jesus, *supra*, at 7 (contradicting TA-Sciences' express claim that its product has "been proven to lengthen short telomeres").[16] In 2013, researchers observed statistically significant increases in telomerase activity in TA-65 treated cultures. *See* Molgora, et al., *supra*, at 59. However, that study applied TA-65 directly to laboratory cell cultures. The study had a drastically small sample size with only six donors, and the results measured only telomerase activity, rather than telomere length over longer durations. *Id.* at 59-65. Given that information, the authors themselves explained that "[f]urther studies should include a larger sample size, which could help confirm or change our observations." *Id.* at 65 (describing the study as "preliminary"). The FDA does not consider in vitro or animal studies as support for dietary supplement structure/function claims or health claims.[17]

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[16] Note, also, that the 2011 study of laboratory mice involved supplementation with a final TA-65 "concentration of 25 mg kg^{-1} body weight/day," which is substantially higher than TA-Sciences offers for sale. One capsule of TA-65 includes approximately 8mg of the purified Astragalus Root Extract. Even when taken at the "high" dose of four (4) capsules per day, the resulting supplementation of 32mg daily is less than two percent of the amount tested in the 2011 de Jesus study (assuming an average weight of male adults is about 80 kg). Therefore, even assuming the mouse study produced statistically significant results, the justification for an extrapolation to humans from such a high dosing amount in mice is not explained in the literature.

[17] Another study in 2011, performed by investigators associated with TA-Sciences, tested only 13 subjects in an uncontrolled protocol. *See* Calvin B. Harley, et al., "A Natural Product Telomerase Activator As Part Of a Health Maintenance Program" Rejuvenation Res. 2011 February; 14(1): 45–56 (noting that "[t]wo independent measures of median or mean telomere length ... showed no consistent change with time on Patton Protocol-1"). The authors explained that "[d]ata from [the] study were collected primarily as a hypothesis-generating exercise because subjects were not participating in a controlled prospective study, and statistical analyses were not formally defined *a priori*." *Id.* at 49.

The federal FDCA (21 U.S.C. 343(a), (r)) requires that dietary supplement labels and labeling be truthful. A dietary supplement is "misbranded" if "its labeling is false or misleading in any particular." *See* 21 U.S.C. § 343(a). To the extent TA-Sciences claims that its products lengthen telomeres on its commercial website, the product labeling and advertising is false or misleading. As explained above, the limited publicly available scientific information reveals that TA-65 does not actually increase telomere length. Accordingly, the FDA and FTC should demand competent and reliable scientific evidence showing that TA-65 performs as claimed, before American consumers invest substantial money hoping to reverse signs of aging, or stave off significant degenerative conditions.

Thank you in advance for your consideration of this matter. I trust that FDA and its sister agencies will take necessary action to ensure a safe and reliable consumer market.

Sincerely,

Rosemary Austin

Rosemary Austin, President
Consumer Protection Coalition
853 North Highway 89
Suite 69
Chino Valley, AZ 86323

Attachments: (4)

CC: Roberta F. Wagner, Deputy Director
Office of Regulatory Affairs
Food and Drug Administration
CPK-1 Bldg. Room 3B066
5100 Paint Branch Parkway
College Park, MD 20740