



Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

NOV 5, 2012

WARNING LETTER

VIA UNITED PARCEL SERVICE

Mike Haarlander
Chief Executive Officer
The Avalon Effect, Inc.
2000 Mallory Lane
Suite 130-604
Franklin, Tennessee 37067

Re: Quantum Series Personal Wellness Pack
Refer to CPT1200143 when replying to this letter.

Dear Mr. Haarlander:

The Food and Drug Administration (FDA) has learned that your firm is marketing the Quantum Series Personal Wellness Pack in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The product is a device within the meaning of section 201(h) of the Act, 21 U.S.C. § 321(h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body. The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country for which approval is not required.

The Office of Compliance, in FDA's Center for Devices and Radiological Health, recently reviewed your firm's website, www.theavaloneffect.com, and various linked websites. This review identified a number of claims for the Quantum Series Personal Wellness Pack that cause this product to meet the Act's definition of a device. For example, your firm's web page at www.theavaloneffect.com/benefits.asp includes the following statements:

- "I hurt my hip and in 15 minutes that pain was gone with no bruising after having used the Avalon Effect. Love this machine!"
- "I have been using the Avalon light therapy on my clients and have had nothing but positive feedback from everyone. They experience everything from a more relaxed state of mind, to migraine headaches going away, to muscle relaxation, to more joint flexibility."
- "For more than a decade I'd been waking up with chronic muscular tension and pain in my jaw, neck, shoulder, and hip. Freed from chronic pain, I have copious energy, a sense of joy and I no longer feel prematurely old at 51."

In addition, FDA's review of your firm's Tumblr site at www.theavaloneffect.tumblr.com (last visited on October 30, 2012) and your firm's Facebook site at www.facebook.com/theavaloneffect, which are linked directly from your website's main page at www.theavaloneffect.com, found the following "device" claims for the Quantum Series Personal Wellness Pack:

- "Fungal meningitis"
- "MRSA"
- "Concussions"
- "Lupus"
- "Lyme disease"

- "Aneurysms"
- "Skin cancer"
- "Atherosclerosis"
- "Allergies"
- "Alzheimer's disease"
- "Leg ulcers"

The above-listed disease claims that appear on your firm's Tumblr site include a hyperlink to an audio recording of a call hosted by Tinka Smith, Avalon Founder, in which she discusses the use of the Quantum Series Personal Wellness Pack for the symptoms of the listed diseases.

FDA also found "device" claims on your firm's other websites and on the Avalon Effect's web pages on third party websites, all of which are linked directly from your website at www.theavaloneffect.com:

- www.theavalonsummit.com (for example, at www.theavalonsummit.com/?page_id=9, last visited on October 30, 2012)
- www.quantumlighteffect.com (for example, at www.quantumlighteffect.com/explanation-of-light-system-with-wes-burwell, last visited on October 30, 2012)
- mobile.twitter.com/TheAvalonEffect (last visited on October 30, 2012)
- www.facebook.com/theavaloneffect (last visited on October 30, 2012)
- www.youtube.com/user/TheAvalonEffect (for example, at www.youtube.com/watch?v=mAAJPedf1Ww&list=UUUDV-RshWoAD62pbU-Ir8bg&index=22&feature=plcp, <http://www.youtube.com/watch?v=Rh8FTHSnnce&feature=plcp>, last visited October 30, 2012).

Furthermore, FDA notes that the Quantum Series Personal Wellness Pack is marketed with claims for the product to affect the structure or function of the body; these claims likewise cause the product to meet the Act's definition of a device. Examples of these claims are found on the following websites, all of which are linked from your website at www.theavaloneffect.com:

- "Explanation of Light System with Wes Burwell" (www.youtube.com/watch?v=t5cxkctlano&list=UUUDV-RshWoAD62pbU-Ir8bg&index=1&feature=plcp, last visited on October 31, 2012)
- "Understanding the frequencies of Avalon" (https://www.fuzemeeting.com/replay_meeting/99d6ea4d/2297913, last visited on October 31, 2012)

A review of our records reveals that your firm has not obtained marketing approval or clearance before your firm began offering your product for sale, which is a violation of the law. Specifically, the Quantum Series Personal Wellness Pack is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency [21 CFR 807.81(b)]. The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

FDA previously sent correspondence to your firm on August 15, 2012. Your firm's legal counsel provided a written response on September 21, 2012, stating, "Avalon does not intend for any of its products to be used in the treatment, cure, mitigation, prevention or diagnosis of any disease. It does not intend to make, nor does it believe it has made, any of the claims identified in the letter referred to above." However, FDA's review of your firm's website and various linked websites identified specific claims regarding the Quantum Series Personal Wellness Pack's use in the treatment, cure, mitigation, or prevention of diseases.

Your firm must stop marketing the Quantum Series Personal Wellness Pack with the claims noted above or similar claims that cause the product to meet the Act's definition of a device. Failure to promptly correct the violations addressed in this letter may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are

advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you received this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Please direct your response to:

Thomas A. Slater
Chief, Field Operations Branch
Food and Drug Administration
White Oak Building 66
Room 2622
10903 New Hampshire Ave.
Silver Spring, Maryland 20993

We remind you that only written communications are considered official.

Finally, you should know that this letter is not intended to be an all-inclusive list of your firm's violations. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. Your firm should investigate and determine the causes of the violations and take prompt actions to correct the violations and bring your firm's products into compliance.

Sincerely,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and Radiological Health