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JUN 11 2001

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850**WARNING LETTER****VIA FEDERAL EXPRESS****VIA FACSIMILE**Mr. Simon Tian  
President  
Telstar Innovations Inc.  
4734 Topeka Avenue  
Oakford, Pennsylvania 19053Re: TDP BioSpectrum Lamps and  
Infrotonic Qigong Machine

Dear Mr. Tian:

The Food and Drug Administration (FDA) has reviewed information on your websites at <http://www.findhealer.com>, <http://www.myholistic.com>, and <http://www.chinamed.org>, for the TDP BioSpectrum Lamps and Infrotonic Qigong Machine, and various other products. These products are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). These websites appear to contain identical information.

Telstar Innovations Inc. imports products from Asia, as stated on your "Mall" page at <http://www.findhealer.com/mall/index.php3>. Telstar Innovations also holds two premarket notifications (510(k)s), as follows:

1. K933584 for the Sacred Crane TDP, an infrared lamp intended for the temporary relief of muscular pains and to improve superficial circulation where applied, and
2. K964182 for the Qi-Gong Massager, a therapeutic vibrator intended for the relief of minor aches and pains, increased local circulation, and muscle relaxation.

Premarket notifications (510(k)s) cleared for other firms' TDP and Qi-Gong devices have the same basic intended uses described above.

During FDA's review of both of your 510(k)s, inappropriate medical claims for the devices were discussed with you, and you made labeling changes to eliminate the various claims that were not cleared for the devices, which included describing the massager as "Infratonic."

Your website is promoting the Qi-Gong and TDP devices for medical claims that exceed those cleared for the devices, and which include claims that were discussed with you during the 510(k) reviews. The Qi-Gong is called the Infratonic Qigong Machine (QGM). The website at <http://www.findhealer.com/mall/telstar/htd.php3> has claims that include, but are not limited to, that the machines "simulate the very low frequency sound waves emitted by Qi Gong masters which have demonstrated remarkable healing abilities for thousand of years. Clinical Studies have shown that the infrasonic waves that emanate from the QGM have a very similar effect as the healing power of the Qi Gong healers..." ".....the alpha wave infrasonic vibration it emmits (sic) help deep relaxation, sleep and body-mind harmony." The link to the Infratonic Qigong Machine V5.0 with Chaos at <http://www.findhealer.com/mall/telstar/Q001.php3> describes the device as "QiGong Master Outgoing Energy Simulator—also called Qigong machine, infratonic QGM FDA approved." There is a subsequent "Special Introduction to Qigong" that claims that the qigong machine your firm sells simulates the qi

energy of light qigong masters, simulates outgoing energy of Qigong masters, and is able to penetrate the deeper layer of the muscles in human body. Further claims state that the machine is devoted to regulating the Qi (or Chi) flow in meridians and collaterals, promoting the circulation of Qi and blood, easing pain, dispersing stagnation, improving organic functions, and accelerating the vascular circulation and the metabolism, so that a patient can achieve the aim of preventing and treating diseases and strengthening the body constitution. There is a clinical case study section at <http://www.findhealer.com/mall/telstar/articles/qgmclinic.php3> that discusses the use of the QGM Infrasonic massager to treat cataracts, digestion, chest pain, heart palpitations, surgical scars, impotence, cancer pain, and macular degeneration.

It states on your website that TDP stands for bio-spectrum in Chinese, at the link to “History of the Bio-Spectrum Inventions” at <http://www.findhealer.com/mall/telstar/articles/bio-spectrum.php3>. Information on the TDP Lamp at the website heading <http://www.findhealer.com/mall/telstar/fir2.php3> states “There is family of bio-spectrum such as the TDP lamp, which is probably more important than acupuncture in the medical field...” and “These therapeutic devices are universal, because their therapeutic function is universal (sic)...some doctors set up special clinic only to use these machines treating a variety of chronic ailments (from pain, arthritis, bone injury to prostatitis, brochitis (sic), we just can not name all)...” The website also discusses a “third generation” TDP lamp called the WS (Wide Spectrum) lamp, and the “second generation” TDP lamp, called the MF (Mineral Far Infrared), both of which are variations on the TDP lamp. The “Treatment Range of MF Machines –Second Generation TDP Lamp” discussed at <http://www.findhealer.com/mall/telstar/I006.php3> notes treatments for medical conditions involving the endocrine, respiratory, digestive, and circulatory systems. Additional claims are made for the MF Lamp for therapy, health maintenance, healthcare, and recovery relating to various medical conditions. There is a link to “Bio-Spectrum Lamp Clinical Studies” at <http://www.findhealer.com/mall/telstar/articles/clinic.php3> and a link to “Application Guide for Bio-Spectrum (TD/MF) Lamps” at <http://www.findhealer.com/mall/telstar/articles/guide.php3>, which discuss off-label uses for these devices.

In addition to the TDP and Qi-Gong devices, several other products are promoted on the website, including the Chi machines, the Ultimate massager, micro cluster water machines, magnetic plaster, a blood pressure regulator, a hypertension bracelet, and the MEAD and MSED computer systems. Medical claims that have not been cleared or approved by the FDA are made for these products. The blood pressure regulator and hypertension bracelet claim to relieve or lower hypertension and hypotension. The blood pressure regulator claims to electronically stimulate ear acupuncture points to balance the meridian system, then reduce blood pressure. Additional claims are made for the blood pressure monitor and hypertension bracelet where the reader is told “...the small device is ideal for sufferers of first-degree and second-degree hypertension and may be used in place of hypertension drugs or reduce the dosage of hypertension drugs,” and “...it may reduce or eliminate traditional medication used in the reduction of high blood pressure...” Blood pressure devices are cleared by FDA to measure blood pressure only.

Examples of claims made for some of the other products mentioned include, but are not limited to: the MEAD/MSED use the body’s electric conductivity to measure resistance based on acupuncture meridian points to test for nutritional deficiencies, allergies, weak organ systems and then the computer can tell you what supplements, herbs, or drugs will do the best for a particular patient; the magnetic plaster can be used in the pain location or acupoint locations for ache, asthma, and mammary disease, and users indicate they have successfully used it for various other conditions such as arthritis, tennis elbow, tendovaginitis, etc.; and the ultimate massager uses “magnetic acupuncture and mechanical acupuncture to activate the important acupoints around the up face and homogenize the blood, Qi, to improve the adjusting functions of the facial muscles and eye nerves and reach the purpose of relax brain, facial massager, all kind of eye-concerning ailments.”

Website sections covering Clinical Studies, Testimonials, and FAQs also promote off-label medical claims for the products on the website.

Your website contains information, terms and technologies pertaining to holistic research from the Orient, that are being used in the practice of medicine, homeopathy, acupuncture, and other complementary disciplines. The devices you promote have not received FDA clearance for use in alternative or complementary healthcare or for any other purposes beyond their cleared indications for use. Additionally, any device using electrical measurements between or along acupuncture points for the analysis of health or treatment has not been cleared for marketing, and are considered Class III investigational devices. The claims you have made for those devices having 510(k)s significantly modify the intended use(s) as defined under 21 CFR 801.4. Other products are promoted with medical claims that have not been reviewed or cleared via a premarket notification or PMA.

The TDP Lamp and Qi-Gong machine are adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have an approved application for premarket (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The TDP Lamp and Qi-Gong are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with the products you are promoting. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place, and actions to prevent similar violations in the future. Please indicate what steps you plan to take as far as the information and training that is being provided by your firm to practitioners, clinics, and users of the device. 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 completed.

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

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A copy of this letter is being sent to FDA's Philadelphia District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Philadelphia District Office (HFR-CE100), US Customhouse, 2<sup>nd</sup> & Chestnut Streets, Room 900, Philadelphia, Pennsylvania 19106.

Sincerely yours,

  


Larry Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health