



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUEST

Chao Zhang, President
Blue Light Inc.
111 S. Cayuga St.
Ithaca, New York 14850

December 18, 2000

File No: NYK 2001-31

Dear Mr. Zhang:

We inspected your firm, located at 111 South Cayuga Street, Ithaca, NY on May 15, 22, and 26, 2000 and found that you have serious violations of sections 402, 403, 502, and 505 of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the food and dietary supplement labeling regulations on the Internet through links in FDA's home page at www.fda.gov.

The name of the product, "Mi Niao Xi Shi Fang Kidney Stone Formula M032" in and of itself carries a disease claim with the implication of use for treating kidney stones.

Based on the labeled claim for this product and its intended use, the product is a drug [section 201(g) of the Act]. It is also a new drug [section 201(p) of the Act] and may not be legally marketed in the United States without an approved New Drug Application [section 505(a) of the Act].

The drug is also misbranded [section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the product is safe and effective for its intended uses when, in fact, this has not been established [section 502(a) of the Act].

The products ChemoAid, FibroCare, Healthy Heart, Zhi Qiao (Chao), Zhi Shi (Chao), Zhi Shi Dao Zhi Wan, Zhi Shi Dao Zhi Wan (capsules), Ma Huang (Sheng), Ma Huang (Zhi), Ma Huang (Gen), Ban Xia Zhi Ke Fang, Ban Xia Zhi Ke Fang (capsules), Ding Chuan Tang, Ding Chuan Tang (capsules), Hua Gai San, Hua Gai San (capsules), Ma Xing Shi Gan Tang, Ma Xing Shi Gan Tang (capsules), Shi Shen Tang, Shi Shen Tang (capsules), Tuo Min Fang, Tuo Min Fang (capsules), Zhi Xiao Ling, Zhi Xiao Ling (capsules), Fang Ji Huang Qi Tang, Fang Ji Huang Qi Tang (capsules), Tian Ji Huang, Tian Hua Fen, Gua Lou Pi, Gua Lou Ren, Quan Gua Lou, Gua Lou Xie Bai Bai Jiu Tang, Gua Lou Xie Bai Bai Jiu Tang (capsules), Xiao Xian Xiong Tang, Ci

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Shi (Ling), Ci Shi (Duan), Er Long Zuo Ci Wan, Er Long Zuo Ci Wan (capsules), Da Fu Pi, Wu Pi Yin, Wu Pi Yin (capsules), Sheng Bai Wan do not include the mandatory statement of identity required for dietary supplements. The use of the statement “as a dietary supplement” in the instructions for use is not a suitable alternative to the statutory requirement that a dietary supplement be “labeled as a dietary supplement.” [21 CFR 101.3(g) and sections 403(i)(1) and 403(s)(2)(B) of the Act].

The products are also misbranded because the labels fail to bear nutrition labeling and they are not exempt from this requirement (“Supplement Facts” panel) [21 CFR 101.36 and section 403(q)(5)(F) of the Act].

The products ChemoAid, FibroCare, Healthy Heart, Zhi Shi Dao Zhi Wan (capsules), Ban Xia Zhi Ke Fang (capsules), Ding Chuan Tang (capsules), Hua Gai San (capsules), Ma Xing Shi Gan Tang (capsules), Shi Shen Tang (capsules), Tuo Min Fang (capsules), Zhi Xiao Ling (capsules), Fang Ji Huang Qi Tang (capsules), Gua Lou Xie Bai Bai Jiu Tang (capsules), Er Long Zuo Ci Wan (capsules), Wu Pi Yin (capsules) contain ingredients that are not declared on the label. Each of these products is contained in a capsule, but the capsule ingredients are not declared on the label. [21 CFR 101.4 and section 403(i)(2) of the Act].

The products ChemoAid, FibroCare, Healthy Heart, Zhi Qiao (Chao), Zhi Shi (Chao), Zhi Shi Dao Zhi Wan, Zhi Shi Dao Zhi Wan (capsules), Ma Huang (Sheng), Ma Huang (Zhi), Ma Huang (Gen), Ban Xia Zhi Ke Fang, Ban Xia Zhi Ke Fang (capsules), Ding Chuan Tang, Ding Chuan Tang (capsules), Hua Gai San, Hua Gai San (capsules), Ma Xing Shi Gan Tang, Ma Xing Shi Gan Tang (capsules), Shi Shen Tang, Shi Shen Tang (capsules), Tuo Min Fang, Tuo Min Fang (capsules), Zhi Xiao Ling, Zhi Xiao Ling (capsules), Fang Ji Huang Qi Tang, Fang Ji Huang Qi Tang (capsules), Tian Ji Huang, Tian Hua Fen, Gua Lou Pi, Gua Lou Ren, Quan Gua Lou, Gua Lou Xie Bai Bai Jiu Tang, Gua Lou Xie Bai Bai Jiu Tang (capsules), Xiao Xian Xiong Tang, Ci Shi (Ling), Ci Shi (Duan), Er Long Zuo Ci Wan, Er Long Zuo Ci Wan (capsules), Da Fu Pi, Wu Pi Yin, Wu Pi Yin (capsules), Sheng Bai Wan are misbranded because they contain botanical or herbal dietary ingredients or extracts of an herb or botanical and the labels do not identify the part of the plant from which the dietary ingredients are derived [21 CFR 101.4(h) and section 403(s)(2)(C) of the Act].

The product “Healthy Heart” is misbranded because the label bears a health claim (i.e., healthy heart) which has not been authorized by FDA regulation [section 403(r)(1)(A) of the Act].

The products Bin Lang, Mu Xiang Bing Lang Wan, Ji Ming San, and Bin Lang Si Xiao Wan are adulterated because they contain betel nut or ingredients derived from betel nuts. Betel nut contains arecoline, an alkaloid that has been demonstrated to cause cancer in animals [sections 402(a)(1), 402(f)(1)(A), and 402(f)(1)(D) of the Act].

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The products Sheng Bai Wan and ChemoAid are adulterated because they contain human placenta. Human placenta is not a dietary ingredient under section 201(ff)(1) of the Act. It is not a vitamin, a mineral, an herb or botanical, or an amino acid [section 201(ff)(1)(A-E) of the Act]. It is not a “dietary substance for use by man to supplement the diet by increasing the total dietary intake” [section 201(ff)(1)(E) of the Act]. While the term “dietary substance” is not defined in either the Act itself or the statute’s legislative history, the term must be interpreted in accordance with its common, usual meaning. The term “dietary” means “of or relating to diet” and the term “diet” means “an organism’s usual food and drink,” and the term “substance” generically refers to “that which has mass, occupies space, and can be perceived.” “Dietary substance,” therefore, under a common-sense understanding of the term, means simply substances customarily used as human food or drink. Human tissue is not a dietary ingredient under this definition. Nor is it a concentrate, metabolite, constituent, extract, or combination of any ingredient above [section 201(ff)(1)(F) of the Act]. Human tissue also is not a food under section 201(f) of the Act in that it is not “an article used for food or drink for man.” Given that human tissue is not “food” or a dietary ingredient, and that it may transmit human disease, a dietary supplement that contains it is adulterated. [sections 402(a)(1), 402(f)(1)(A), and 402(a)(3) of the Act].

The product Zi He Che is adulterated because it contains human placenta. Although labeled a dietary supplement, it is not a dietary supplement because it contains no dietary ingredients defined in section 201(ff)(1) of the Act. Therefore, it is a food that is adulterated because it consists in whole or in part of an article that is unfit for use as food [sections 402(a)(1) and 402(a)(3) of the Act].

The products Guan Mu Tong and Fen Fang Ji are adulterated because they contain *Aristolochia* spp. *Aristolochia* spp. contain aristolochic acids that are powerful nephrotoxic and carcinogenic agents that cause the dietary supplement to be unsafe [sections 402(a)(1), 402(f)(1)(A), and 402(f)(1)(D) of the Act].

The products Fu Zi (Zhi), Chuan Wu (Zhi), Cao Wu (Zhi), Si Ni Tang, Si Ni Tang (capsules), Fu Zi Li Zhong Tang, Fu Zi Li Zhong Tang (capsules), Ma Huang Xi Xin Fu Zi Tang, and Ma Huang Xi Xin Fu Zi Tang (capsules) are adulterated because they contain *Aconite* spp. *Aconite* spp. contain cardiac glycosides that can cause serious adverse events such as abnormal heart rate and rhythm, and could lead to heart attack. The presence of cardiac glycosides in *aconite* spp. cause dietary supplements that contain this ingredient to be unsafe [sections 402(a)(1), 402(f)(1)(A), and 402(f)(1)(D) of the Act].

A recent check indicates these products are still being offered for sale by your firm.

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We also object to the claim made in paragraph one of the introductory page that these products "are formally imported and inspected by the FDA," which is false and misleading in that it implies Agency endorsement of these products.

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of the labels of your products to assure that they comply with the Act and regulations.

You should know these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your dietary supplement products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your corrections.

Your reply should be sent to Richard T. Trainor, Compliance Officer, U.S. Food and Drug Administration, 300 Hamilton Ave., White Plains, New York 10601. If you have any questions concerning the violations noted, then please contact Mr. Trainor at 914-682-6166 x26.

Sincerely,

A handwritten signature in black ink, appearing to read "E. W. Thomas", with a long horizontal flourish extending to the right.

Edward W. Thomas
Acting District Director