

47T-35
4/2/97
Bjks

M784N



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

APR - 1 1997

VIA FEDERAL EXPRESS

Mr. Kevin DeVito
President
Harrier, Incorporated
2200 Pacific Coast Highway, Suite 301
Hermosa Beach, California 90254

Re: Bioptron Infrared Lamp,
K922900, K965255

Dear Mr. DeVito:

The Food and Drug Administration (FDA) has reviewed promotional materials for the Bioptron Infrared Lamp. The Bioptron Lamp is distributed by Harrier, Incorporated (Harrier), manufactured by [redacted] and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Bioptron Lamp has been cleared under section 510(k) of the Act and is intended to relieve minor pain by means of heat therapy.

Our review of a promotional piece titled, Bioptron® A Revolutionary Skin Care Device, distributed by Harrier, promotes the device for intended uses in the medical specialty fields of dermatology, rheumatology/orthopaedics, and wound healing which have not been cleared by the agency. The following are representative examples taken from your promotional literature and are not meant to be all-inclusive:

Dermatology Claims

- All skin disorders that are caused by infections or allergens, such as acne vulgaris, herpes genitalis recurrens, herpes simplex orig., herpes zoster, ulcus cruris, irritative facial dermatitis;

Rheumatology/Orthopaedic Claims

- treatment of soft tissue injuries such as those frequently encountered in sports medicine;

- muscle strain/contusion, stretching of a ligament, tendinitis (sic), tenosynovitis, bursitis;
- soft tissue hematoma;
- painful muscle spasms i.e., myofibrosis, fibrositis, muscular rheumatism, myofascial syndrome, synovitis of the knee joints following meniscectomy, humeral epicondylitis, psoriatic arthritis);
- vertebral spondilopathy, post-operative articular and spinal surgery;

Wound Healing

- claims of accelerated wound healing and rapid granulation of poorly perfused tissue such as diabetic gangrene;
- treatment of bed sores, venous leg ulcers, post thrombic ulcers, persistent fistulae, burns, preparation and after-care of skin grafts, promotion of wound healing for primary surgical wounds, to improve scar formation, and to reduce keloid formation.

Additionally, we have reviewed the home page at the Internet address: <http://publinet.it/GBVC/sponsor/bioptron/>. This web site includes similar indications for use that were identified above and which have not been cleared as part of your 510(k) submission.

Promotional claims for a given device, or class of devices, are strictly limited to those indications that were specifically allowed for and identified in the labeling submitted as part of the premarket notification made pursuant to section 510(k). Based on the 510(k) submission, the device was found to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. The regulations promulgated under 21 CFR 801.4 provide that the term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the devices. That intent may be shown by labeling claims or promotional materials. Making claims regarding dermatological, rheumatological, orthopaedic, or skin/wound conditions for your device constitutes a major change or modification in the intended use of the device. Pursuant to section 510(k), and as explained under 21 CFR 807.81(a)(3)(ii), such changes require the submission of a new premarket notification.

Promotion of the Bioptron Infrared Lamp for the medical fields of dermatology, rheumatology, orthopaedics, and/or wound healing

claims has misbranded your device under section 502(o) of the Act in that appropriate premarket notification required by section 510(k) of the Act was not submitted.

The Bioptron Infrared Lamp marketed with claims for dermatology, rheumatology, orthopaedics, and/or skin or wound conditions is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigational device exemption under section 520(g).

We have also reviewed several journal reprint articles which you distributed to a physician in Rochester, New York. These references also describe use of the Bioptron Lamp for intended uses which have not been cleared. Manufacturers and/or distributors may not distribute peer-reviewed journal reprints that discuss off-label uses of a device. However, unsolicited requests for journal reprints which include discussions of off-label uses of a device may be filled.

Finally, we note that in your February 11, 1997 response to the Rochester physician, you mention FDA's registration of the device in conjunction with some of the off-label uses. The agency does not object to manufacturers or distributors providing information regarding the marketing status, 510(k) number, or registration information pertaining to a device in response to written inquiries. However, in this particular context, Harrier has misbranded the Bioptron device by referencing FDA's registration in its promotional material. The agency's regulations under 21 CFR 807.39 provide that registration of a device establishment and assignment of a registration number do not denote agency approval of the establishment or its products, and that any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Bioptron Infrared Lamp. 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.

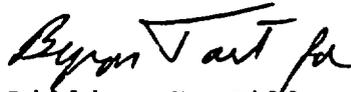
Page 4 - Mr. Kevin DeVito

You should take prompt action to correct these violations. Failure to promptly correct these deviations 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 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. 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 Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Los Angeles District Office (HFR-PA200), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health