DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

d16375

December 13, 1996

97-DAL-WL-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Ms. Gwo-Rung Holloway, President
Advanced Composite Technologies, Inc.
10821 Gulfdale
San Antonio, Texas 78216

Dear Ms. Holloway:

This letter is in reference to the marketing of Libest Spur Effect pads by your firm. Labeling with your product states or suggests that Libest Spur Effect pads are useful in treating or relieving pain from trauma, such as contusions, sprains, strains, tennis elbow, lumbar intervertebral disk prolapse, rheumatoid arthritis and other conditions.

We are concerned about the following claims and statements which are made for the products.

The product insert states that the product provides "FAST, POWERFUL RELIEF FROM THE PAIN FROM SPUR OR TRUMA" (SIC).

* "The soft tissue pain is mostly caused by chemical stimulation derived from non-bacterial inflammation following truma or spur. LIBEST gives fast and powerful relief from pain from truma, such as contusion, sprains and strains as well as spur."

* "It was proved to be safe and no stimulation to skin according to toxicological study carried out by Zhejiang Medical University Toxicology department. It has been tried by hundreds of patients 90% cured and exerted no any adverse effect (SIC)."

* "As soon as the strap is applied the medicine penetrates the skin and reaches subcutaneous tissue, opens up the skeletal channels, activates blood circulation and removes stasis, relieves inflammation and pain, softens rigidity and reduces swelling, and finally alleviates the pain derived constantly from the focus of hyperosteogeny."

The labels make the following claims:

Libest Spur Effect Pads No. 1 is recommended for:
* Hyperosteogeny (Spur)
* Vertebra and Arthralgia
* Omarthritis, Tennis Elbow
* Soft Tissue Injury, etc.

Libest Spur Effect No. 3 is recommended for:
* Hyperosteogeny (Cervical, thoracic, and lumbar vertebrae)
* Omarthritis
* Pain (after union)

Libest Spur Effect No. 4 is recommended for:
* Prolapse of lumbar intervertebral disc
* Hyperosteogeony (lumbar vertebrae, coccygeal vertebrae)
* Aseptic inflammation (Hip bone, Thigh)

Libest Spur Effect No. 5 is recommended for:
* Hyperosteogeny (knee joint)
* Rheumatoid arthritis
* Soft Tissue injury (Extensive)
* Aseptic inflammation (Extensive)

We are not aware of any information which shows that your products, or any similar OTC drug, have been marketed in the United States on or before December 4, 1975, nor any scientific evidence to establish that these products are generally recognized as safe and effective.

Based on the intended uses, Libest Spur Effect pads are drugs according to the definition given by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). These products are new drugs according to Section 201(p) of the Act and may not be introduced into interstate commerce (Section 505(a) of the Act) since no application for the product has been approved according to the requirements of Section 505(b). These products are also misbranded because the labeling fails to bear adequate directions for use for the conditions for which they are offered (Section 502(f)(1) of the Act).

Additionally, these drugs are misbranded within the meaning of Section 502(a) of the Act because their labeling is false and misleading. It suggests that there is substantial scientific evidence to establish that the drugs are safe and effective for their intended uses. In fact, such substantial evidence does not exist.

Further, these drugs are misbranded according to the requirement of Section 502(o) of the Act since they were processed, repackaged or relabeled in an establishment not registered under section 510 of the Act.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all drug products which you distribute have met with the requirements of the Act and its implementing regulations.

We request that you reply within fifteen (15) working days of your receipt of this letter, stating the specific action(s) you have taken to correct the stated violations. Failure to promptly correct these deviations may result in enforcement action without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against a manufacturer or distributor of illegal products.

Your reply should be sent to the attention of Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

Joseph R. Baca
District Director

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