



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

CERTIFIED LETTER  
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-68

August 20, 1998

Dr. Kotha S. Sekharam  
Chief Executive Officer  
Innovative Health Products  
6950 Bryan Dairy Road  
Largo, Florida 34647

Dear Dr. Sekharam:

During an inspection of Energy Factors, Largo, Florida facility conducted on October 20-24, 28, 29, November 10-14, 17, 20, 21, and December 9, 1997, FDA Investigator Karen Hirshfield determined that the firm manufactured and marketed products that were labeled and promoted for various conditions and diseases. We understand that you recently purchased Energy Factors, Inc., but the same products are still being manufactured, labeled and promoted without change. Therefore, these products are being promoted for conditions and diseases, as discussed below, which cause them to be drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

1. Eye Protection: Macular Degeneration Prevention.
2. Sun Protection: A Whole New Idea in U.V. Protection. Presupplementation with Beta Carotene...combined with topical sunscreens is more effective than sunscreens alone.
3. Physician's Slim and Trim Herbal Phen and TrimFast Herbal Phen-Fen: These product names suggest they are alternatives to the prescription drugs, Phentermine and Fenfluramine, which are products intended to treat obesity. Labeling your products as alternatives to Phentermine and/or Fenfluramine represents that your products are intended to treat obesity.
4. ARTHRITIS RELIEF CREAM: Contains Capsaicin for the relief of pain of arthritis, bursitis, rheumatism, muscle aches.

5. **ARTHRITIS RELIEF Natural White Willow CAPSULES:** For the temporary relief of minor aches and pains associated with simple backache, arthritis, strains, bruises, and sprains...each capsule contains 500 mg. White Willow.
6. **ARTHRITIS RELIEF Natural Boswellin CAPSULES:** To reduce inflammation caused by arthritis, rheumatism, bursitis, and other conditions...each capsule contains 250 mg. Boswellin which contains 150 mg. Boswellic Acid (Triterpenoids).
7. **ARTHRITIS RELIEF Soothing Bath Salts WITH DEAD SEA SALTS AND RAINFOREST HERBS:** For the temporary relief of minor aches and pains associated with simple backache, arthritis, strains, bruises and sprains...Contains Salt from the Dead Sea plus extracts of angelica, barberry, chaparral, turmeric, burdock, white willow, black haw, yucca, and black cohosh.
8. **HERPE KURE:** Based on its name, this product is intended to treat/cure herpes infections. It is for topical application and contains the ingredients potassium iodide, demineralized water, licorice powder, domiphen bromide, L-lysine, and alcohol.
9. **Meno-Care:** Contains natural progesterone and claims to be a safe alternative for hormonal equilibrium.

With the exception of Arthritis Relief Cream, we are unaware of any evidence which establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, with the exception of Arthritis Relief Cream, these products are new drugs as described in Section 201(p) of the Act which may not be marketed since no new drug application required by Section 505 of the Act has been approved for these drugs.

These drugs are misbranded under Section 502(a) of the Act because their labeling is false and misleading since they suggest that there is evidence that these drugs are safe and effective for their intended use, when, in fact, this has not been established. The drugs are further misbranded under Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for use.

The inspection revealed that these drugs, including the Arthritis Relief Cream, are adulterated as described in section 501(a)(2)(B) of the Act, in that they are OTC drugs and the methods used in, or the facilities or controls used for, their manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs. Deviations from Title 21, Code of Federal Regulations (21 CFR), Part 211 are as follows: failure to have

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specifications for raw materials or components; failure to perform any inspection or testing on these items; failure to perform or have any record of finished product testing prior to release; failure to establish a stability program; deviations are made to formulations without documentation, review, or notification to customers for products manufactured under contract; failure to have adequate environmental controls or equipment cleaning procedures designed to prevent contamination or cross-contamination between manufactured products; master and batch production records are incomplete, inadequate and, in some cases, non-existent; and label controls are lacking to prevent labeling errors.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is now your responsibility to ensure adherence to each requirement of the Act and regulations for all products manufactured and distributed.

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

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Florida District Office, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, attention: Martin E. Katz, Compliance Officer.

Sincerely,



Douglas D. Tolen  
Director, Florida District

Enclosures