DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
St. Louis Branch
12 Sunnen Drive, Suite 122
St. Louis, MO 63143-3800
(314) 645-1167
(314) 645-2969 (FAX)

December 16, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert L. Montgomery
President and CEO
Reliv International, Inc.
136 Chesterfield Industrial Blvd.
Chesterfield, MO 63005

Dear Sir:

This letter is in reference to your firm's marketing and distribution of the product, "Arthaffect." Promotional material (labeling) for this product makes therapeutic claims that causes the products to be a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Examples of the claims include the following:

- "A breakthrough in the fight against degenerative joint conditions";
- "Published clinical studies [include references to] osteoarthritis . . . osteo- and chondropathies . . . ";
- "Whether your joints ache from age or an active lifestyle, Reliv Arthaffect does more than treat the symptoms of degenerative joint conditions - it focuses on the source of the problems";
- "Traditional joint products simply treat the symptoms of degenerative joint conditions. In contrast, Reliv Arthaffect focuses on the source of these problems . . . ";
- "It contains patented Arthred, a protein proven to help fight degenerative joint conditions";
- " . . . active people who refuse to slow down because of the pain of degenerative joint conditions"; and
- "Fights degenerative joint conditions"; and
- "Tired of joint pain."

The product is a "new drug" because there is no evidence that it is generally recognized as safe and effective for its intended use [Section 201(p) of the Act]. Therefore, it may not be legally marketed in this country without an approved new Drug Application [Section 505(a) of the Act].

It is also misbranded because its labeling fails to bear adequate directions for use for the condition for which they offer it [Section 502(f)(1) of the Act]. Its labeling is false and misleading as it suggests that the product be safe and effective for its intended use when, in fact, this has not been established [Section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which you will carry out the corrections.

Send your reply to the attention of Andrew H. Paeng, Compliance Officer, 12 Sunnen Drive, Suite 122, St. Louis, MO 63143-3800

Sincerely,

W. Mike Rogers
Director, Kansas City District