DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

July 27, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2001-029

Carl Hastings, Ph.D.
Executive Vice President
Reliv International, Inc.
136 Chesterfield Industrial Blvd.
P.O. Box 405
Chesterfield, MO 63005-0405

Dear Dr. Hastings:

An inspection of your firm located at the above address on March 19-20, 2001 revealed that you manufacture various dietary supplements. Our review of your products' labels reveals that certain products are misbranded and in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling, as follows:

1. The products, "Classic", "SoySentials", "FibRestore", "Soy Sense" and "Arthaffect", are misbranded within the meaning of Section 403(q)(5)(F) of the Act in that these labels fail to bear the correct nutrition labeling format ("Supplement Facts" panel), which is required under 21 CFR 101.36, and are not exempt from this requirement.

2. The products, "Classic", "SoySentials", "FibRestore", "Soy Sense" and "Arthaffect", are misbranded within the meaning of Sections 403(i)(1) and 403(s)(2)(B) of the Act in that the label fails to identify the products using the term dietary supplement [21 CFR 101.3(g)], or other alternative descriptive term authorized by regulation.

Most of the above violations concern certain new labeling requirements, and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the dietary supplements to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes and regulations enforced by the U.S. Food and Drug Administration (FDA).

You should know that 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 supplements.

It is necessary for you to take action on these matters now. Please let this office know in writing within fifteen (15) working days from the date you received 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 correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District