



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

April 21, 1999

WARNING LETTER
CIN-WL-99-138

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Anthony D. Presutto, President
Leader Co., Inc.
931 North Main Street, Suite 101
North Canton, OH 44720

Dear Mr. Presutto:

This letter is in reference to your product Aloe Vera Gel promoted with disease claims that include "irritable bowel syndrome ... antibacterial ... anti-pruritic, arthritis ... athlete's foot, boils ... chicken pox ... cold sores ... colitis ... ear infection, eczema, fever blisters, fungicidal, gastritis ... hemorrhoids ... psoriasis, skin rashes ... tonsillitis, ulcers, vaginitis, virucidal."

Based on the claims made for this product and its intended uses, this product is a drug, and a "new drug" [section 201 of the Act]. It may not be legally marketed in the United States without an approved new drug application [section 505(a) of the Act]. The product is also misbranded because the labeling fails to bear adequate directions for use and is false and misleading because the labeling suggests that the product is safe and effective for its intended uses when this has not been established [section 502 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.

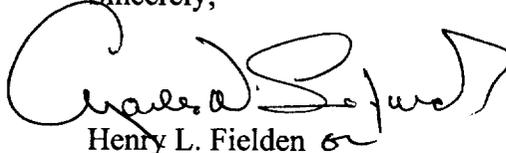
We request that you take prompt action to correct these violations. Failure to correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction 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 occur. If corrective action cannot be completed within 15 working days, state the reason for the delay within which the corrections will be implemented.

Your should reply to Leonard J. Farr, Compliance Officer, US Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry L. Fielden". The signature is fluid and cursive, with a large initial "H" and a long, sweeping tail that extends to the right.

Henry L. Fielden
District Director
Cincinnati District Office