DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
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P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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May 5, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECIEPT REQUESTED

Mr. David Hinton
President
Similasan Corporation
108 North Ridge Street
Breckenridge, Colorado 80424

Ref#: DEN-03-14

Dear Mr. Hinton:

This letter is written in reference to the marketing of the drug product, Similasan Healthy Relief HOMEOPATHIC Ear Drops, by your firm. Product labeling, including the immediate container label, the retail product box, and the package insert each indicate that this product is for treating earache. Further, your Internet website, www.healthyrelief.com, also indicates that this product is intended for treating earache.

Because Similasan Healthy Relief HOMEOPATHIC Ear Drops is intended to provide temporary relief from symptoms of earache, it is an article intended for use in the mitigation of disease in man. Therefore, it is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Further, because earache is usually caused by some underlying disease process that requires diagnosis and treatment by a physician, and accordingly should not be self-treated, this product is a drug that is not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Accordingly, the marketing of this drug is a violation of the Act as follows:

The drug is misbranded within the meaning of Section 503(b)(1) of the Act in that it is not dispensed pursuant to the prescription of a practitioner licensed by law to administer

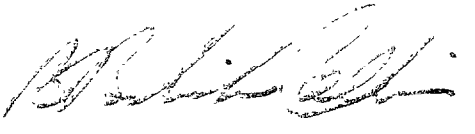
such drug. The drug is further misbranded within the meaning of Section 503(b)(4) of the Act in that the product label fails to bear the statement, "Rx only".
The drug is also misbranded within the meaning of 502(f)(1) of the Act in that its labeling fails to bear adequate directions for use as this term is defined in Title 21, Code of Federal Regulations Part 201.5. The condition for which it is offered is not amenable to self-diagnosis and treatment by the individuals who are not medical practitioners; therefore, adequate directions for use cannot be written under which a layman can use this drug safely and for the purpose for which it is intended.

This letter is not intended to address all of your firm's violative practices, products, labeling, or Internet websites, nor is it intended to be a complete review of the labeling of the product, Similasan Healthy Relief HOMEOPATHIC Ear Drops. It is your responsibility as the marketer of drug products to assure that they are in conformance with all requirements of the Act and its implementing regulations including those that apply to prescription drugs.

Please advise us in writing within fifteen (15) working days after the receipt of this letter of the specific actions you have taken to correct the violations. Failure to achieve prompt correction may result in enforcement action being initiated by the FDA without further notice. These include seizure of illegal products and/or injunctive actions against the manufacturer or distributor of illegal products.

Your written reply should be directed to Compliance Officer Dr. William B. Martin at the address at the letterhead.

Sincerely yours,



B. Belinda Collins
Denver District Director