



12/30/96 RSB d1681b

December 20, 1996

Food and Drug Administration
Kansas City District Office
11830 West 80th Street
PO Box 15905
Lenexa, Kansas 66255-5905

Telephone: (913) 752-2100

WARNING LETTER

Jeffrey Topper, Owner
Saturn-Chem
2206 West Highway 76
Branson Mall #9
Branson, Missouri 65616

Ref.# KAN-97-06

Dear Mr. Topper:

This is in reference to _____ which is distributed by your firm. The product contains _____ as the active ingredient and the immediate container label offers the product for relief of conditions such as sinus, sinus headaches, cold and head congestion, asthma, bronchitis, laryngitis, emphysema, and chest congestion. A promotional brochure bears additional claims for the relief of cold sores, bacterial infection of the feet, carpal tunnel syndrome, and gout. These make _____ a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act).

The product is subject to final regulations which cover topical OTC cough and cold preparations contained in Title 21 Code of Federal Regulations (21 CFR 341 - copy enclosed for your reference). _____ is not generally recognized as safe and effective (GRAS/E) for any of the indications permitted under the final rules covering the cough and cold preparations. Further, eucalyptus oil offered for relief of cold sores and fever blisters is not acceptable as a topical analgesic preparation [21 CFR 310.545(a)(10)(v)], and there is no evidence to show that eucalyptus oil is acceptable for bacterial infection of the feet, carpal tunnel syndrome, or gout. Therefore, we consider _____ a new drug within the meaning of Section 201(p) of the Act which may not be legally marketed in this country unless it has an approved New Drug Application (NDA).

_____ is also misbranded within the meaning of Section 501(f)(1) of the Act in that its labeling fails to bear adequate directions for the labeled uses.

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that the drug products you distribute

DISTRIBUTION:

Orig. & Encl.: Addressee
bcc: LF; FF(No CFN); HFA-224; HFD-310; HFI-35/DIB(via FOI);
HFC-210; SP/RP; IBRF

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are in compliance with the Act and regulations promulgated under the Act. Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be made. Your reply should be directed to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure: 21 CFR 341