



d1987b

Certified/Return Receipt Requested

August 5, 1998

Food and Drug Administration  
Kansas City District Office  
11630 West 80th Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

**WARNING LETTER**

Charles Hankins, Chief Executive  
Officer  
Herbal Pop Enterprises, Inc.  
918 West 8th  
Coffeyville, KS 67337

Ref.# KAN-98-023

Dear Mr. Hankins:

This is in reference to "herbalpops" cough drop on a stick™ which is manufactured by your firm. The product contains eucalyptus oil and anise as the active ingredients and is offered for, among other things, the temporary relief of occasional minor coughs and minor irritations due to airborne allergies.

Based on the claims listed above, "herbalpops" cough drop on a stick™ is a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act)]. The product is subject to final regulations covering OTC cough and cold preparations codified at Title 21 Code of Federal Regulations (21 CFR) Part 341 (copy enclosed for your reference). Under these regulations eucalyptus oil and anise are not generally recognized as safe and effective for the conditions noted above. Therefore, we consider "herbalpops" a "new drug" (Section 201(p) of the Act) which may not be legally marketed in this country unless it is subject to an approved New Drug Application (NDA) (Section 505 of the Act).

The "herbalpops" cough drop on a stick™ is misbranded [Section 501(f)(1) and (f)(2) of the Act] in that its labeling fails to bear adequate directions for use and required warnings as specified in the regulations [21 CFR 341.74(c) and (d)].

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 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.

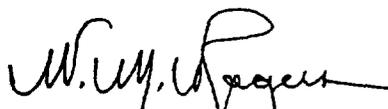
Page 2

August 4, 1998

Herbal Pops Enterprises, Inc.

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,

A handwritten signature in black ink, appearing to read "W. Michael Rogers". The signature is fluid and cursive, with a long horizontal stroke at the end.

W. Michael Rogers  
District Director  
Kansas City District

Enclosure: 21 CFR 341