



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

1326 b

297 Plus Park Boulevard
Nashville, TN 37217

June 17, 1998

CERTIFIED-RETURN RECEIPT REQUESTED

Mildred Long, President
J. Strickland & Company
P. O. Box 840
Memphis, TN 38101

WARNING LETTER 98-NSV-15

Ref: "Black and White Ointment®" 2-1/4 oz.
"Black and White Ointment®" 5/8 oz.

Dear Ms. Long:

This letter concerns the above listed products which are manufactured by your firm. The two "Black and White Ointment®" products are labeled for "the temporary relief of itching, burning, and stinging caused by acne pimples or eczema."

The above products are drugs as described in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are intended to treat, cure, or prevent disease. Since these products are offered for sale over-the-counter (OTC), they are required to comply with the general regulations covering OTC drugs found in Title 21 Code of Federal Regulations (CFR) Section 330, and specific final or tentative final OTC drug product monographs. If this is not the case, the products are new drugs as described in section 201(p) of the Act, which may not be legally marketed in the United States unless they have an approved new drug application (NDA), found in Section 505(b) of the Act.

Based on their formulation and labeling the above products are external analgesic drug products, and are thus subject to the tentative final monograph (TFM) for External Analgesic Drug Products published in the Federal Register on February 8, 1983. The two "Black and White Ointment®" products are indicated for the treatment of disease conditions not considered under the OTC drug review for external analgesic drugs containing resorcinol or any other active ingredient. Further, we do not have any information that your products, or any substantially equivalent product have been marketed in the United States prior to December 4, 1975. Since these products are not subject to the OTC drug review, they are "new drugs" (as described in Section 201(p) of

Mildred Long, President - Page 2

the Act) and may not be legally marketed in the United States since they are not approved (Section 505(b) of the Act). These drugs are also misbranded [Section 502(f)(1)], because their labeling fails to bear adequate directions for use.

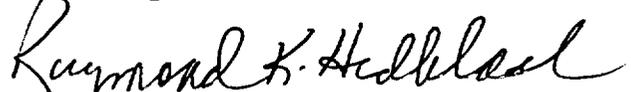
The above list of violations is not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to ensure that the drug products you distribute meet all the requirements of the Act and its implementing regulations. Federal agencies are advised of issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific actions you will take to correct these violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrections cannot be completed within fifteen (15) working days, please state the reason for the delay and the time within which corrections will be completed.

Your reply should be addressed to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,



Raymond K. Hedblad
Director, Nashville District

RKH/k1