



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

616

PHILADELPHIA DISTRICT

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

97-PHI-32

July 9, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jeffrey F. Lehman, President
Shank's Extracts, Inc.
350 Richardson Drive
Lancaster, PA 17603

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>7/10/97</u>
Reviewed by: <u>Jim Miller</u>	

Dear Mr. Lehman:

This letter is in reference to the drug products Rawleigh Internal Anti-Pain Oil, Rawleigh External Anti-Pain Oil, Rawleigh Liniment, Rawleigh Internal Liniment, Shank's Antiseptic Salve, Rawleigh Ready Relief Inhalant, and Rawleigh Antiseptic Solution which are manufactured and distributed by your firm. This letter also makes reference to the inspection conducted by Food and Drug Administration (FDA) Investigator Steven E. Kane on December 5-8 and 12, 1995 and to the inspection conducted by FDA investigator John R. Miller in March 1993.

These 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 general regulations covering OTC drugs found in Title 21 Code of Federal Regulations (CFR) Section 330, specific OTC drug product monograph(s), or tentative final OTC drug product monograph(s). If this is not the case, the product is a new drug as described in Section 201 (p) of the Act, which may not be legally marketed in the United States unless it has an approved new drug application (NDA), found in Section 505(b) of the Act.

Rawleigh INTERNAL ANTI-PAIN OIL

This product is labeled to contain alcohol 69%, oil of cloves, methyl salicylate, oils of syn, mustard, peppermint, and cajeput as the active ingredients. This product, is indicated for either oral ingestion or for topical application to relieve stomach pain and gas, and is subject to the final rule for Antiflatulent Products for OTC Human

bcc: HFA-224, HFC-210, HFC-120, HFD-310 (B. Williams),
WARN Ltr File, HFRMA-100, HFRMA-150, HFRMA-150 (S. Kane), EF,
HFI-35, CFN: 2515166, Distributed by

Use found under 21 CFR Section 332 (copy attached), which became effective on September 2, 1993. The product fails to meet the requirements of this final rule in that the ingredients are not permitted for the indications listed.

Rawleigh EXTERNAL ANTI-PAIN OIL

This product is labeled to contain oil of cloves 2.1%, oil of mustard 0.5%, oil of peppermint 0.37%, and oil of cajeput 0.3%, and is indicated for the relief of muscular aches and pains.

Rawleigh LINIMENT

This product is labeled to contain capsicum oleoresin 0.237%, camphor 0.45%, and is indicated for relief of rheumatic pains and sprains.

The two above cited drugs are subject to the tentative final monograph (TFM) for External Analgesic Drug Products for OTC Human Use (copy attached) which was published in the Federal Register on February 8, 1983. These products do not meet the proposed formulation and labeling requirements.

Rawleigh INTERNAL LINIMENT

This product is labeled to contain alcohol 48%, oleoresin capsicum, oils of hemlock and spearmint as active ingredients. It is indicated to help relieve cold discomforts and stomach pains. It is subject to final rule of Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use found 21 CFR Section 341 (copy attached). The product fails to meet the requirements of the final rule in that the ingredients are not permitted for the indications listed.

SHANK'S ANTISEPTIC SALVE

This product is labeled to contain white petrolatum, camphor, bee's wax, creosote, methyl salicylate, sassafras oil, eucalyptus oil, and is indicated for quick relief for minor cuts, burns, acne, piles, and insect bites. This product, based on its acne claim, is subject to the final rule for Topical Acne Drug Products for OTC Human Use which became effective on August 16, 1992, found in 21 CFR Section 333 (copy attached). This product, based on its piles claim, is also subject to the final rule for Anorectal Drug Products for OTC Human Use found in 21 CFR Section 346 (copy

attached) which became effective on August 3, 1991. The product fails to meet the requirements of the final rules in that the ingredients are not permitted for the indications listed.

Rawleigh READY RELIEF INHALANT

This product is labeled to contain alcohol 53%, oil of lavender, menthol, camphor, oil of dwarf pine needles, oil of juniper berries, oil of eucalyptus, and musc ambrette solution as active ingredients. Because this product is indicated to provide nasal relief, it is subject to final rule of Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use found in 21 CFR Section 341. This product fails to meet the requirements of the final rules in that the ingredients are not permitted for the indications listed.

Rawleigh ANTISEPTIC SOLUTION

This product is labeled to contain alcohol 25%, benzoic acid, and formalin as active ingredients. This product is indicated for use as a mouth wash and gargle, or for topical use to kill germs on cuts, scratches, burns, and insect bites. Based on its intended use as topical antibacterial, it is subject to the TFM for Topical Antimicrobial Drug Products for OTC Human Use (copy attached) which was published in the Federal Register on July 22, 1991. This product fails to meet the proposed formulation and labeling requirements of this TFM.

We do not have any information that the products cited above which are indicated for conditions not subject to final rule were marketed in the United States prior to December 4, 1975. Therefore, these products fail to meet the conditions for marketing ingredients recommended for OTC use under the OTC drug review found in 21 CFR Section 330.13.

Based on their failure to meet the stated requirements, these products are "new drugs" as described in Section 201 (p) of the Act, and they may not be legally marketed in the United States since they are not approved as stated in Section 505(b) of the Act. These products are also misbranded under Section 502(f)(1) of the Act, because their labeling fails to bear adequate directions for use.

All of these products are further misbranded under Section 502(o) of the Act, because they have not been drug listed with the Food

Warning Letter: Shank's Extracts, Inc.

and Drug Administration as required under Section 510(j) of the Act.

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 requirements of the Act and its implementing regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

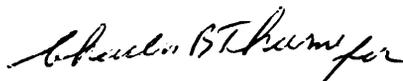
We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

At the close of the December 1995 inspection of your firm's drug manufacturing operation, you received an FDA-483, List of Inspectional Observations (copy attached), which listed a number of deviations from regulations promulgated under the Federal Food, Drug and Cosmetic Act, specifically, the current good manufacturing practice regulations (CGMP) as prescribed in Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. Be aware that your firm's corrective actions with respect to each item listed in the FDA-483 will be evaluated during the next Food and Drug Administration inspection of your firm.

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

Your reply should be sent to the James C. Illuminati, Compliance Officer, at the above-referenced address.

Sincerely,



Diana J. Kolaitis
District Director
Philadelphia District