



Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PUNGED

July 8, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98-40

John A. Miller
President
Alwyn Company, Inc.
East Highway 60
Lake Crystal, MN 56055

Dear Mr. Miller:

During a recent inspection at your facility located at Lake Crystal, MN, Investigator Marie A. Fadden determined that you manufacture, repack and distribute the above referenced products.

The labeling for "Lupicare™," including promotional material, bears claims such as "...reduce bacteria that potentially can cause disease..." and "...soothe the pain and discomfort of skin lesions, rashes and irritations attributed to systemic lupus erythematosus (SLE) and discoid lupus erythemytosus (DLE)." Additionally, your firm promotes this product on the Internet and in newspaper advertisements as effective in treating psoriasis with claims such as "...soothing and reducing psoriasis skin inflammations." Based on these claims the product is a drug [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)].

It is also subject to the Final Rule covering OTC dandruff, seborrheic dermatitis, and psoriasis drug products [Title 21, Code of Federal Regulations, Part 358, Subpart H (21 CFR 358 Subpart H)]. The product fails to meet the requirements

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of this Final Rule since the active ingredient declared on the label, chloroxylenol, is not acceptable for the treatment of psoriasis. Further, the labeling does not comply with the Final Rule with respect to the required statement of identity, indications, warnings and directions for use [21 CFR 358.750(a), (b), (c) and (d)].

In addition to the declared active ingredient, chloroxylenol, the label bears claims that extracts of arnica, St. John's Wort, chamomile, and witch hazel--apparently inactive ingredients--have the ability to reduce skin inflammation and soothe the discomfort due to the inflammatory process. We are unaware of any evidence that this combination of ingredients is generally recognized as safe and effective for the indications noted above. Further, such claims for inactive ingredients are not permitted.

According to its product label, "Myconil™ Personal Feminine Hygiene Wash" contains miconazole nitrate 2% and is intended to be used as an antifungal cleanser. Based on the antifungal claims, the product is a drug [Section 201(g) of the Act] subject to the Final Rule for Topical Antifungal Drug Products (21 CFR 333 Subpart C). The product fails to meet the requirements of this Final Rule in that the statement of identity, indications, warnings, and directions for use do not comply with the regulation [21 CFR Part 333.250 (a), (b), (c), and (d)].

In addition, accompanying labeling for "Myconil™ Personal Feminine Hygiene Wash" bears claims that the product is useful in reducing urinary tract infections, preventing venereal diseases, preventing bacterial vaginosis, and vaginal yeast infections.

Based on the above, "Lupicare™" and "Myconil™ Personal Feminine Hygiene Wash" are both new drugs [Section 201(p) of the Act] which may not be legally marketed [Section 505(a) of the Act] since they do not have approved New Drug Applications (NDA) [Section 505(b)]. These products are also misbranded [Section 502(f)(1) and 502(f)(2) of the Act] for failure to bear adequate directions for use and required warnings.

In addition, our investigator documented significant violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals (21 CFR 210

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and 211):

- Failure to verify the identity of each component of a drug product [21 CFR 211.84(d)(1)]. For example, you fail to perform identity and purity testing on each lot of raw materials (active ingredients) received.
- Failure to establish the reliability of the supplier's analysis through appropriate validation of the supplier's test results at appropriate intervals [21 CFR 211.84(d)(2)]. For example, you do not validate the Certificates of Analysis received from your suppliers at least annually. In lieu of validating the COA, you need to test each component for conformity with written specifications for purity, strength and quality. You are doing no such testing.
- Failure to have a written testing program designed to assess the stability characteristics of drug products, and failure to test an adequate number of batches to determine an appropriate expiration date [21 CFR 211.166]. For example, you do not perform any stability testing to support the two year expiration date on your products.
- Failure to have written procedures for production and process control designed to assure the drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100]. For example, your Standard Operating Procedures are incomplete such as Theoretical versus Actual Yield.

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 of the issuance of all Warning Letters about drugs and devices so 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 them may result in regulatory action without further notice.

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These actions include, but are not limited to, seizure and/or injunction against the manufacturer or distributor of these illegal products.

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

Also, labeling with your sunburn cream states "Alwyn SUNBURN CREAM is manufactured...in accordance with FDA Code of Federal Regulations (21 CFR Part 348, External Analgesic Drug Products For Over-the-Counter Human Use)." Your active ingredient, 0.1% menthol, is not an approved ingredient for 21 CFR Part 348. However, the active ingredient is acceptable for sunburn pain relief. In addition, the products referenced in 21 CFR Part 348 are male genital desensitizing agents, not sunburn creams.

Your reply should be sent to Compliance Officer Carrie A. Hoffman indicated on the letterhead.

Sincerely,


James A. Rahto
District Director
Minneapolis District

CAH/ccl