

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CFN 1120541

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 11, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dennis Schoen, President
Home Health Products, Inc.
3890 Park Central Boulevard, North
Pompano Beach, Florida 33064

Dear Mr. Schoen:

This letter is in reference to "**VAPOHALER INHALANT**" and other products which are manufactured or marketed by your firm.

Because these products are labeled with statements which represent and suggest that they are intended to be used in the cure, mitigation, treatment, or prevention of diseases, they are drugs as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Since these products are offered for sale over-the-counter (OTC), they are required to comply with the general regulations and policies covering OTC drugs, as stated in Title 21, Code of Federal Regulations (CFR), Part 330, and specific OTC drug product monographs. If they fail to comply, the product is then considered a new drug as described in Section 201(p) of the Act, and may not be legally marketed in the United States unless it has an approved new drug application (NDA). We are unaware of any substantial scientific evidence which demonstrates that these drugs are generally recognized as safe and effective for the following conditions.

"VAPOHALER INHALANT"

This product contains six ingredients, including tincture benzoin, rectified beechwood creosote, and grain alcohol 90-95%, and is labeled "Decongestant***for the temporary relief of nasal congestion." Because the product is indicated to provide nasal congestion relief, it is subject to the final rule for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for

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OTC Human Use (21 CFR 341). This product fails to meet the requirements of the final rule, as the ingredients are not permitted for the indications listed.

"MYRRH TINCTURE STOMACHIC AND CARMINATIVE"

This product contains alcohol 86%, water, and myrrh tincture, and is labeled for oral use as a stomachic and carminative and for topical use for the relief of sore gum and sore mouth. The product is in violation of the final rule for Digestive Aid Drug Products for OTC Human Use (21 CFR 310.545(a)(8)), the final rule for Oral Health Care Drug Products for OTC Human Use (21 CFR 310.545(a)(14)), and the final rule for OTC Drugs Intended for Oral Ingestion that Contain Alcohol (21 CFR 328), since it contains more than 5% alcohol.

"NORMALAID HERBAL TONIC No. 2085 An Edgar Cayce Formulation"

This product contains pepsin, ginseng, 10-20% grain alcohol, and several other ingredients, and is labeled to help maintain normal conditions in the alimentary canal and as a protectant and digestant. The product is in violation of the final rule for Digestive Aid Drug Products for OTC Human Use (21 CFR 310.545(a)(8)) and the final rule for OTC Drugs Intended for Oral Ingestion that Contain Alcohol (21 CFR 328), since it contains more than 5% alcohol.

Because all of the above listed products are labeled for the treatment of disease conditions, they are misbranded within the meaning of Section 502(a) of the Act. Their labeling is considered false and misleading because they present and suggest that there is substantial scientific evidence to establish that the products are safe and effective for their intended uses when, in fact, such evidence does not exist.

They are further misbranded within the meaning of Section 502(f)(1) of the Act, because the labeling fails to bear adequate directions for the uses for which the products are being offered as defined in 21 CFR 201.5, and the conditions for which they are being offered are not amenable to self-diagnosis and treatment by the laity. Therefore, adequate directions for use cannot be written under which the layman can use these drugs safely and for which they are intended. Further, they are not exempt from this requirement under 21 CFR Part 201.115, since the articles are new drugs within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for such drugs.

Furthermore, during our inspection of your manufacturing facility located in Virginia Beach, Virginia, conducted November 10 - 17, 1997, our investigator documented deviations from the Current Good Manufacturing Practice (GMP) Regulations (Title 21, CFR, Parts 210 & 211). These deviations cause your products, Everclean Anti-Dandruff Shampoos, Psoriasis Cream, Psoriasis Medicated Scalp and Body Wash, Blemish Treatment Lotion, and Antifungal Lotion, to

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be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the controls used for the manufacture, processing, packing, or holding of these products are not in conformance with GMPs. The deviations are as follows:

1. Failure to have batch production records for each batch of drug product, including documentation that each significant step in the manufacture, processing, packing, or holding, was accomplished at the time of performance.
2. Failure to establish written procedures for the production and process control designed to assure that the deionized water used in the manufacture of the drug products has the identity, strength, quality, and purity it purports or is represented to possess.
3. Failure to establish adequate written complaint handling procedures and to have a written record of each complaint, to include the findings of the investigation and follow-up.
4. Failure to follow established written procedures designed to assure that correct labels and labeling are used, including identification of the drug products with a lot or control number that permits determination of the history of the manufacture and control of the batch.

At the conclusion of the inspection, a written list of inspectional observations, FDA-483 (enclosed), was issued to Mr. Vincent Biondo, Vice President.

The above list of violations is not intended to be an all-inclusive list of those that exist at your firm. It is your responsibility to ensure that the drug products you market meet all requirements of the Act and implementing regulations, including GMPs. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

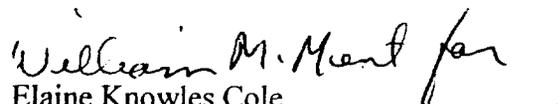
You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

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

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Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, Ext. 14.

Sincerely,


Elaine Knowles Cole
Director, Baltimore District

Enclosure

cc: Michael Ashkin, Chairman
The Darby Group
865 Merrick Avenue
Westbury, New York 11590

Vincent Biondo, Vice President
Home Health Products, Inc.
949 Seahawk Circle
Virginia Beach, Virginia 23454