

HF1-35
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

PS 12/19/97
702

CFN 1117263

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

December 2, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas L. Johnson, President
The Heritage Store, Inc.
314 Laskin Road
Virginia Beach, Virginia 23451

Dear Mr. Johnson:

This letter is in reference to "**De-Tense Herbal Tonic**" 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 for use 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). Further, we are unaware of any substantial scientific evidence which demonstrates that these drugs are generally recognized as safe and effective for the following conditions:

"De-Tense Herbal Tonic"

This product contains sarsaparilla root, wild cherry bark, burdock root, buchu leaves, and other ingredients, and is labeled for the treatment of hypertension.

"Atomidine"

This product contains 1% iodine trichloride, and is labeled to treat cuts, boils, surface infections, toothaches, sore throat, arthritis, asthma, baldness, bursitis, dermatitis, goiter, and hay fever. Based on its use to treat boils, it is in violation of the final rule (Title 21, Code of Federal Regulations (CFR), Part 310.531) for OTC drugs for the treatment of boils. Additionally, this product is marketed in violation of the final rules for OTC drugs to prevent hair loss or grow hair (21 CFR 310.527).

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"Castor Oil The Palma Christi"

This product contains castor oil, and is labeled for treating the immune system, increasing the production of lymphocytes and T-11 cells, and improving lymphatic circulation.

"ZILATONE LAXATIVE DIGESTIVE AID"

This product contains bile extract, cascara sagrada extract, pancreatin, phenolphthalein, pepsin, and capsicum, and is labeled as a laxative and digestive aid. As a laxative, "**ZILATONE LAXATIVE DIGESTIVE AID**" is in violation of the final rule for Laxative Drug Products for OTC Human Use (21 CFR 310.545(a)(12)). As a digestive aid, this product is in violation of the final rule for Digestive Aid Drug Products for OTC Human Use (21 CFR 310.545(a)(8)).

"Inspirol For Inhalation Therapy"

This product contains six ingredients, including tincture tolu balsam, oil eucalyptus, compound tincture benzoin, rectified creosote, and alcohol 93-95%, and is labeled "For All Types of Respiratory Problems," and as a stimulating expectorant and decongestant for all types of respiratory distress, including bronchitis, coughs, colds, hay fever, asthma, and sinusitis. This product is subject to the final rule for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use (21 CFR 341), and fails to meet the requirements of the final rule, as the ingredients are not permitted for the indications listed.

"CRUDOLEUM"

This product contains Pennsylvania Grade Crude Oil, and is labeled to cure dandruff and to grow hair on the scalp. The product is marketed in violation of the final rules for OTC drugs to prevent hair loss or grow hair (21 CFR 310.527), and OTC drugs to treat dandruff (21 CFR 358.701).

All of the above listed products are misbranded within the meaning of Section 502(a) of the Act, in that their labeling is false and misleading because they represent 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 they are being offered. They are not exempt from this requirement under 21 CFR 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.

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Additionally, the drugs are further misbranded pursuant to Section 502(f)(1), in that their labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5, since 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.

The articles are also drugs within the meaning of Section 201(g) which may not be introduced or delivered for introduction into interstate commerce under Section 505(a), since they 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.

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that the drug products you market 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 that they may take this information into account when considering the award of contracts.

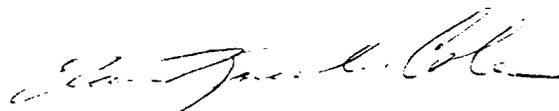
We acknowledge that Ms. Chris Jackson, Regulatory Affairs Director, has submitted a response to this office concerning our investigator's observations noted on Form FDA-483. We have determined that your response is adequate.

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.

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