



DEPARTMENT OF HEALTH AND HUMAN SERVICE

34653d

Food and Drug Administration
New Orleans District
Southeast Region
6500 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 804-253-4500
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April 21, 2004

WARNING LETTER NO. 2004-NOL-24

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Kenneth H. Grissett, President
Old Hickory Medicine Company, Inc.
410 Pearl Street
Andalusia, Alabama 36420

Dear Mr. Grissett:

On November 18, 19, and 20, 2003, an investigator of the U.S. Food and Drug Administration (FDA) conducted an inspection of your drug manufacturing facility, located at 410 Pearl Street, Andalusia, Alabama. The inspection was conducted to determine compliance with FDA's Current Good Manufacturing Practice (CGMP) for Finished Drugs, Title 21, *Code of Federal Regulations*, Parts 210 and 211 (21 CFR 210 and 211). Our investigator documented deviations from the regulations that cause your finished drugs to be adulterated and misbranded within the meaning of Sections 501(a)(2)(B), 502(c), and 502(f)(1) and (2) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, your firm is distributing unapproved new drugs in violation of 505(a) of the Act. The investigator found that your firm manufactures, labels, and distributes human drug products, including "Old Hickory Ear Drops," "Old Hickory Foot-O-Latum," "Old Hickory Athlete's Foot & Ringworm Remedy," and "Old Hickory Athlete's Foot & Ringworm Liquid."

Old Hickory Ear Drops

The label of this product bears claims, such as "For softening and aid of the removal of ear wax and to relieve the minor irritation caused by the wax accumulation." Based on these intended uses, the product is a drug as defined in Section 201(g) of the Act. Because this product claims that it is useful for the removal of earwax, it is subject to the final regulations covering over-the-counter (OTC) topical otic drug products found in 21 CFR 344 (Topical Otic Drug Products for Over-the-Counter Human Use). While the label includes a list of ingredients, there is no differentiation between active and inactive ingredients. This causes all the labeled ingredients to be active ingredients, but none of the listed ingredients is permitted as an active ingredient in an earwax removal aid (21 CFR 344.10). Further, the product's statement of identity, indications, warning, and directions that are listed on the label do not comply with the final regulations (21 CFR 344.50).

Old Hickory Foot-O-Latum

Because the product's label claims that it is effective to remove corns and calluses, it is a drug as defined in Section 201(g) of the Act, and it is subject to the final regulations for OTC corn and callus remover products (21 CFR 358, Subpart F). The product label does not distinguish between active and inactive ingredients. This causes all the labeled ingredients to be active ingredients. The formulation of this product does not comply with the final regulation because methyl salicylate and petrolatum are not permitted as active ingredients in OTC corn and callus remover products (21 CFR 358.510). Further, product's statement of identity, indications, warnings, and directions that are listed on the label do not comply with the final regulations [21 CFR 358.550(a) - (d)].

Old Hickory Athlete's Foot & Ringworm Remedy

Based on the claims on the product's label, such as "For relief of athlete's foot, ringworm, toe itch . . . [and] aids in removing soft corns and callouses," the product is a drug as defined in Section 201(g) of the Act. Because the label claims that the product is useful in treating athlete's foot and ringworm, it is subject to final regulations for topical OTC antifungal drug products (21 CFR 333, Subpart C). The product's label does not differentiate between active and inactive ingredients. This causes all labeled ingredients to be active ingredients. None of the listed ingredients is permitted as an active ingredient under the final regulations for topical OTC antifungal drug products (21 CFR 333.210). Further, the product's statement of identity, indications, warnings, and directions that are listed on the label do not comply with the final regulations [21 CFR 333.250(a) - (d)].

Because the product also claims to be effective as an OTC corn and callus remover, it is subject to the final regulations for OTC corn and callus remover drug products (21 CFR 358, Subpart F). The formulation of this product does not comply with these final regulations because benzoic acid and phenol are not permitted as active ingredients in an OTC corn and callus remover (21 CFR 358.510). Further, the product's statement of identity, indications, warnings, and directions that are listed on the label do not comply with the final regulations [21 CFR 358.550(a) - (d)].

Old Hickory Athlete's Foot & Ringworm Liquid

Based on the claims on the product's label, such as "For relief of athlete's foot, ringworm, toe itch, golf itch, and other fungus skin irritations also aids in removing soft corns and callouses," the product is a drug as defined in Section 201(g) of the Act. Because the product claims that it is useful in treating athlete's foot and ringworm, it is subject to final regulations for topical OTC antifungal drug products (21 CFR 333, Subpart C). The product's label does not differentiate between active and inactive ingredients. This causes all labeled ingredients to be active ingredients. None of the listed ingredients is permitted as an active ingredient under the final regulations for topical OTC antifungal drug products (21 CFR 333.210). Further, the product's statement of identity, indications, warnings, and directions that are listed on the label do not comply with the final regulations [21 CFR 333.250(a) - (d)].

Because the product also claims to be effective as an OTC corn and callus remover, it is subject to final regulations for OTC corn and callus remover drug products (21 CFR 358, Subpart F).

The formulation of this product does not comply with the final regulations because alcohol and glycerine are not permitted as active ingredients in an OTC corn and callus remover (21 CFR 358.510). Further, the product's statement of identity, indications, warnings, and directions that are listed on the label do not comply with the final regulations [21 CFR 358.550(a) - (d)].

Because of their deviations from applicable regulations, "Old Hickory Ear Drops," "Old Hickory Foot-O-Latum," "Old Hickory Athlete's Foot & Ringworm Remedy," and "Old Hickory Athlete's Foot & Ringworm Liquid" are considered new drugs as defined in Section 201(p) of the Act. Therefore, under Section 505(a) of the Act, they may not be introduced or delivered into interstate commerce without approved new drug applications. These products also are misbranded under Section 502(f)(1) of the Act in that their directions for use deviate from the language of the applicable monographs. Likewise, the products are misbranded under Section 502(f)(2) of the Act for failure to bear required warnings.

In addition, each label for the above-mentioned products fails to comply with the regulations under 21 CFR 201.66 covering the format and content of OTC drug labeling. These regulations establish the criteria for ensuring that OTC drug labeling information is conspicuous at the time of purchase and use. See <http://www.fda.gov/cder/Offices/OTC/DrugFactsFinalRule.pdf>. The failure to comply with these regulations causes your OTC drug products to be misbranded under Section 502(c) of the Act.

You should be aware that all of your drug products must comply with all existing labeling requirements of Section 502 of the Act and manufactured, packaged, labeled, and stored according to CGMP's (21 CFR 210 & 211).

In addition to deviations from the requirements of the Act discussed above, our investigator documented deviations from the CGMP regulations. The deviations were listed on the enclosed Form FDA 483 which was discussed with you at the close of the inspection. The CGMP deviations documented during the inspection include, but are not limited to, the following:

- Your firm does not perform any finished product testing prior to release of drug products for distribution to determine satisfactory conformance to the final specifications, identity, and strength of each active ingredient [21 CFR 211.165(a)].
- Your firm has not performed any stability testing to support the three year expiration date you assign to your finished drug products [21 CFR 211.166 (a) and (b)].
- Your firm has not established written procedures to prevent objectionable microorganisms in your finished drug products [21 CFR 211.113(a)] and has not performed microbial testing on each batch of finished drug product [21 CFR 211.165(b)].
- Your firm has not conducted any assays or identity tests on components used in the manufacture of your drug products to assure the components meet required specifications [21 CFR 211.84(d)(1) and (2)].
- Your production batch records do not identify mixing times nor heating temperatures used to manufacture your drug products to assure uniformity and homogeneity [21 CFR 211.110(a)].

- Your firm's quality control unit does not have the responsibility for approving or rejecting all procedures or specifications impacting the identity, strength, quality, and purity of the product. For example, finished drug products are released for distribution without approval from a quality control unit and your written procedures are not reviewed and approved by a quality control unit [21 CFR 211.22].
- Your employees involved in the manufacturing of drug products have not been given CGMP training [21 CFR 211.25(a)].
- Your firm has not kept records documenting the maintenance and cleaning of equipment [21 CFR 211.67(c)]. In addition, you do not document on your batch records the number or code of equipment used in the manufacture of each batch of drug product [21 CFR 211.105(b)].
- A second person does not verify the addition of components to a batch of drug product [21 CFR 211.101(d)].
- Your firm stores drug components, removed from the original containers, in plastic containers that are not properly labeled with the strength and lot number of the component [21 CFR 211.101(b)].
- Your firm does not exercise strict control over labeling issued for use in drug product labeling operations [21 CFR 211.125(a)]. Also, your firm does not compare incoming drug product labels against a master label upon receipt and before use in packaging and labeling of your drug products [21 CFR 211.122(a)]. In addition, your firm does not include a specimen or copy of each finished drug product label in the master production and control records [21 CFR 211.186(b)(8)].
- Your firm has not calibrated the three weight scales and one thermometer used in the production of drug products [21 CFR 211.160(b)(4)].
- Your firm has no written procedures to address the distribution of finished drug products manufactured, stored, and distributed by your firm (21 CFR 211.150). Also, you do not have written procedures for recalls that describe a system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary [21 CFR 211.150(b)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It remains your responsibility to ensure adherence to all requirements of the Act and regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

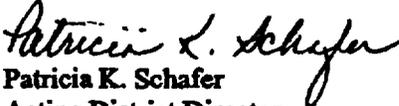
Until such corrections have been made, Federal agencies will be advised of the issuance of this warning letter, so they may take this information into account when considering the award of contracts. Additionally, pending product or methods approval applications or export approval requests may not be approved until the above violations are corrected.

We are aware that at the close of your inspection on November 20, 2003, you made a verbal commitment to correct observed deficiencies. You should notify this office in writing, within

fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, please state the reason for the delay and the time by which the corrections will be completed.

Address your reply to the U.S. Food and Drug Administration, Attention: Ms. Cynthia R. Crocker, Compliance Officer, 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. If you have any questions regarding any issue in this letter, please contact Ms. Crocker at (601) 965-4581.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483