DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

March 3, 2003

Ref: 2003-DAL-WL-08

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Rudolph Johnson, Owner/Manager
Pride and Power, Inc.
P.O. Box 14727
3901 Old Spanish Trail
Houston, Texas 77021

Dear Mr. Johnson:

This letter is written in reference to the inspection of your facility conducted by our investigator on January 22-25, 2002 and to your firm's marketing of "Don't-B-Bald Hair and Scalp Treatment Medicated," "Don't-B-Bald Scalp Stimulate," and "BBD 1854 Dandruff Shampoo". Statements on the immediate containers of the products and on your Internet website, www.prideandpower.com, from which consumers can buy these products, indicate that the following products are useful in the treatment of various conditions as listed bellow:

"Don't-B-Bald Hair Care Treatment Medicated"

The immediate container of the product bears statements, "Don't-B-Bald," "Medicated," "Fights Dandruff," and "For Dry Itchy Scalp." Your Internet website, www.prideandpower.com, makes statements such as "The **DON'T-B-BALD** line of hair care products is designed for the customer who is having hair loss," "Hair loss comes from a variety of things that can cause a change to take place to the scalp ... Hair loss from stress, over processed hair, hair dyes, pulling from braids, cancer, etc. ... we all want a head full of healthy hair," "Our line has many natural ingredients that we believe help the process of keeping your hair healthy and aiding in growth," "Formulated for those with dry itchy scalp," and "Helps fight dandruff."

Based on the intended uses described, this product is considered a drug [(Section 201(g)

of the Federal Food, Drug, and Cosmetic Act (the Act)] and is subject to the final rule covering over-the-counter (OTC) hair grower and hair loss prevention drug products [Title 21, Code of Federal Regulations (21 CFR) Part 310.527]. Under this rule, no ingredients are generally recognized as safe and effective to grow or prevent hair loss. This product also is subject to the final rule covering OTC dandruff, seborrheic dermatitis, and psoriasis drug products (21 CFR 358.701 - .750). The product does not meet the requirements of this final rule. Specifically, it does not specify the active ingredient [21 CFR 358.710 (a)], and does not bear the appropriate warning statements and directions as required [21 CFR 358.750 (c) and (d)].

"Don't-B-Bald Scalp Stimulate"

The immediate container includes statements, "Don't-b-Bald Scalp Stimulate has been formulated to stimulate the scalp hair follicle, allowing the blood cells to circulate," and "Aids in relief of itchy, tight, dry scalp and dandruff." Based on the intended uses described, this product is considered a drug [Section 201(g) of the Act] and is subject to the final rule covering OTC hair grower and hair loss prevention drug products (21 CFR Part 310.527). Under that rule, no ingredients are generally recognized as safe and effective to grow or prevent hair loss. This product also is subject to the final rule covering OTC dandruff, seborrheic dermatitis, and psoriasis drug products (21 CFR 358.701 - .750). The product does not meet the requirements of this final rule. Specifically, it does not specify the active ingredient [(21 CFR 358.710 (a)], and does not bear appropriate warning statements and directions as required [21 CFR 358.750 (c) and (d)].

"BBD 1854 Dandruff Shampoo"

The immediate container of the product states "it treats dandruff, thereby helping eliminate the dryness and flakiness associated with it." Based on the intended use for treating dandruff problem, this product is considered a drug [Section 201(g) of the Act]. This product is subject to the final rule covering OTC dandruff, seborrheic dermatitis, and psoriasis drug products (21 CFR 358.701 - .750). The labeling does list "Zinc Omadine" as the active ingredient, a trade name for "pyrithione zinc." The active ingredient must be declared by the established name "pyrithione zinc" [Section 502 (e) (1) (A) (i) of the Act]. The labeling does not declare the percentage of pyrithione zinc, as required. The labeling of this product does not meet the requirements of this final rule. Specifically, the product does not bear the required declaration of active ingredient [21 CFR 358.710 (a) (2)], and the appropriate warning statements and directions, as required [21 CFR 358.750 (c) and (d)].

This product is labeled for use as a shampoo to be rinsed off after use. The product labeling fails to bear the required statement "For best results use at least twice a week or as directed by a doctor." (21 CFR 358.710(d)(1). Because the labeling fails to bear the

required directions and warnings statements, this product is misbranded. [Section 502(f)(1) and (2) of the Act.]

Based on the intended uses established by the claims cited above, these products are drugs as defined in Section 201(g) of the Act. Because these drugs do not meet each of the conditions contained in 21 CFR 330.1 and the applicable monographs cited above, they are not generally recognized as safe and effective. These products are new drugs [Section 201(p) of the Act] because there is no evidence that these products are generally recognized as safe and effective for their intended uses.

Under Section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Because none of your products is the subject of an approved NDA, your products may not be marketed in the United States and their continued distribution violates Section 505 of the Act.

During this same inspection, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (21 CFR Parts 210 & 211) for drugs. These deviations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Act. Examples include:

- Failure to establish and validate written procedures that describe the manufacturing processes for all drug products [21 CFR 211.110(a)].

- Failure to establish procedures that describe the responsibilities of the quality control unit on the acceptance or rejection of procedures, specifications, or any other criteria that may impact the identity, strength, purity, and quality of finished drug products [21 CFR 211.22(c)].

- Failure to perform finished product testing for the identity and strength of active ingredients and their conformance to established specifications for any of your drug products, such as those claiming to treat dandruff [21 CFR 211.165(a)].

- Failure to conduct training in current good manufacturing practices for employees involved in the manufacturing, packaging, and labeling of drug products [21 CFR 211.25(a)].

- Failure to establish and validate complete procedures that pertain to cleaning and sanitization of manufacturing and packaging equipment used during drug manufacturing [21 CFR 211.67(b)]. Your firm uses equipment that is not dedicated to the manufacture of drug products and there are no written or validated procedures that describe the cleaning of equipment before and after manufacturing drug products.

- Failure to determine acceptance or rejection of active ingredients and other incoming components used in the manufacture of drug products [21 CFR 211.84(d)(2)]. Testing is not performed for the identity, purity, or strength of incoming components nor are certificates of analysis obtained from component suppliers.

- Failure to maintain complete batch production and control records for each batch of drug products manufactured [21 CFR 211.188]. Production records do not include information pertaining to the identity and quantity of added ingredients, lot numbers of raw ingredients used, mixing times, equipment used, in-process and finished product testing criteria, or batch review and release signatures.

- Failure to maintain complete written procedures for master production records that pertain to manufactured batches of drug products [21 CFR 211.186(b)(9)]. Master production procedures lack detailed instructions for production, processing, and testing to ensure the quality and purity of drug products.

- Failure to determine and establish stability procedures, data, and expiration dates that assure drug products meet applicable standards of identity, strength, quality and purity during their time of use [21 CFR 211.137(a)]. Drug products are not identified or labeled with an expiration date and there is no data to support an expiration date greater than three (3) years.

- Failure to establish and validate written procedures describing the receipt, handling, storage, or examination of incoming labeling and packaging materials [21 CFR 211.122(a)].

- Failure to establish and maintain procedures that describe the handling of complaints, investigations into their cause, and necessary corrective actions to prevent future occurrences that relate to drug products [21 CFR 211.198(a)].

This letter does not represent a comprehensive review of all the products distributed by your firm or product labeling or promotional materials you may use. It is your responsibility to ensure that all products distributed by your firm meet the requirements of the Act and its implementing regulations.

We request that you notify this office in writing within 15 working days of receipt of this letter stating the action you will take to discontinue the marketing of these drug products or to otherwise bring them into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

Your reply should be directed to Brenda C. Baumert, Compliance Officer, at the address on the letterhead.

Sincerely,

Michael A. Chappell
Director, Dallas District

MAC: BCB