



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Denver District Office  
Building 20 – Denver Federal Center  
P.O. Box 25087  
Denver, Colorado 80225-0087  
TELEPHONE: 303-236-3000

August 4, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Sam L. Jenkins  
President/Owner  
Dandy Day Corporation  
13608 Raleigh Street  
Broomfield, CO 80020

Ref #. -DEN-00-29

Dear Mr. Jenkins:

This letter is in reference to your firm's marketing and distribution of the products, CRAVE AWAY, THE ALOE PEARL, AID CREME, Dyna Rich, GAROLIC, and KLEAN & KLEAR. Labeling for these products contains therapeutic claims which cause the products to be drugs [section 201(g) of the Federal Food Drug, and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product containers but includes any promotional literature that you distribute in connection with your products. This includes product labels, brochures, newsletters, and audio and video cassette tapes. In addition, numerous claims are made for the ingredient Aloe Vera without referring to a specific product. These claims may apply to any of your products that contain Aloe Vera.

Products and objectionable claims include the following:

CRAVE AWAY: All references to diabetic or diabetes including: "I am a bad diabetic. My sugar, they can't regulate it, it goes up and down, up and down. I have headaches, can't sleep at night... I started taking CRAVE AWAY. I was almost at a 300 high on my blood sugar... My sugar started coming down from 300 to 250, 200, 150...124 that's where I'm at," hyperglycemia,

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hypoglycemia, reduce craving for alcohol, stop smoking by reducing the craving for nicotine, Attention Deficit Disorder, measles, fever, headache, diarrhea, dysentery, treat the effects of alcohol, alcohol abuse, high blood pressure, a combination of vitamins, minerals, and herbs which have been known to be deficient in people who have blood sugar - insulin imbalances, lowering of the blood sugar in people who were testing their blood sugar daily

**ALOE PEARL:** stomach disorders, arthritis, anti-inflammatory, cancer and tumors, heart attacks and strokes, infectious hepatitis, phlebitis, bleeding rectum, osteoarthritis, compared to Naprosyn, Bufferin and Tagamet, high blood pressure, allergies, bladder infections, bursitis, arthritic pain, colon pain, Sclera Derma, peptic and duodenal ulcers, dysentery, bladder and kidney infections, hearing impairments, pulmonary tuberculosis, inflammation, serves as a biochemical “bandage,” antihistamine, indigestion, insomnia, build resistance to ailments, kidney stones, angina, coronary thrombosis, manic depressive illnesses, heart attacks due to ruptured aorta

**AID CREME:** Demonstration showing AID CREME treating a hand burned from scalding water including the statement: “If you get a serious burn you need to go to the doctor immediately, but in the meantime before getting to the doctor, I highly recommend, that on any burn that requires doctors attention, you put AID CREME on it first,” “I had a mole on the side of my face...was irregular in shape and dark. I used AID CREME on it...it completely disappeared,” abrasions, stings, fever blisters, itching, bruises, cuts, wounds, headaches, insect bites, hemorrhoids, psoriasis, rashes, skin cancer, skin spots, sores, bed sores, scalds, ringworms, diaper rash, moles, eczema, warts, yeast infections, styes, radiation treatments, fungus, skin reaction to radiation therapy, dermatitis, cold sores, fever blisters, shingles, [burn] pain, dark spots on face...went away, acne, itching, allergies, sunburn, scars...went away, bee stings, growth on back, used on thousands of radiation oncology patients, ingrown toenail, rattlesnake bite, stye, strep throat

**Dyna Rich:** vomiting from chemotherapy, anti-inflammatory, cancer and tumors, heart attacks and strokes, infectious hepatitis, peptic and duodenal ulcers, dysentery, bladder and kidney infections, pulmonary tuberculosis, antibiotic, inflammation, arthritis, serves as a biochemical “bandage,” antihistamine, indigestion, insomnia, build resistance to ailments, kidney stones, angina, coronary thrombosis, manic depressive illnesses, heart attacks due to ruptured aorta, nose congestion, periodontosis, colitis, rheumatism, gingivitis, allergies, blood infections, amenorrhea

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**GAROLIC:** natural antibiotic, hypertension, favorable changes in blood coagulation (clotting), improvement in blood cholesterol levels which protects against heart disease, arteriosclerosis and coronary-artery diseases, antibiotic, antifungal, antibacterial, fevers, lung and respiratory ailments, infections, headaches, colds, yeast infections, cancer

**KLEAN & KLEAR:** removing skin impurities and rebuilding natural tissue, anti-(topical) bacterial, kills pain of any kind to skin infected by burns and cuts plus the healing process increases, poison ivy, itch, used on open heart patients... found superior repair dripping it on the leg incisions where they remove the veins to use in the by-pass surgery, ringworms and boils, ulcers, dermatitis exfoliativa, skin regeneration, atomic radiation burns, stimulate new healthy cells at least 10 times (10X) faster than normal, ulcers...cutaneous leishmaniasis (protozoan), dendritic keratitis (viral), acne, psoriasis, eczema, erysipelas, corns, calluses, baldness, diaper rash, scars, sunburn, acne vulgaris, anemia, nose congestion, periodontosis,

These products are "new drugs" [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act] and their labeling is false and misleading because it suggests that these products are safe and effective for their intended use, when in fact, this has not been established [section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. 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 implemented.

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Page 4 – Warning Letter  
August 4, 2000

Your reply should be directed to the attention of Shelly Maifarth, Compliance Officer, Food and Drug Administration at the attached letterhead address.

Sincerely,



Thomas A. Allison  
Acting District Director

cc:



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