



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
7200 Lake Ellenor Drive  
Orlando, FL 32809

WARNING LETTER

FLA-98-18

January 14, 1998

Dr. Johnny L. Johnson  
Owner and CEO  
The Aloe Man, Inc.  
18800 N.W. 2nd Avenue  
Suite 102-110  
Miami, Florida 33169

Dear Dr. Johnson:

During an inspection of your firm on August 20, 22, and 27, 1997, FDA Investigator Jennifer M. Donzanti found that your firm is manufacturing and marketing various products which are labeled and promoted for conditions which cause them to be drugs according to [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. We regard your promotional literature as labeling, since it makes therapeutic claims for the products.

Aloe Man products are considered drugs because claims made for them establish their intended use as a drug. Each of the listed products is followed by some examples of the drug claims found in the product labeling.

- **The Master Healer:** sugar diabetes, asthma, ulcers, broken bones, bronchitis, dissolves blood clots, valvular heart disease, varicose veins, cancer (slow or stops growth), powerful diuretic (congested heart failure [sic.]), lupus, bladder and kidney disease, pneumonia, high blood pressure, Immune builder - helps ailment as AIDS, HIV and other immune problems.
- **The Body Healer:** diarrhea, dysentery, prolapsus of the uterus or anus, gonorrhoea, prostatic enlargement, hernia, bleeding from lungs or stomach, aid in the elimination of venereal warts, helps stop bleeding cancer, ulcers, reduces or shrinks tumors.
- **Super Bright:** cataract, glaucoma, nearsightedness, farsightedness, detached retina, macular degeneration, blood behind the eyes.
- **Special Tea #232:** fibroid tumors, cyst in breast, Endometriosis, pelvic infection.

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- **Diasulin:** diabetes
- **Ole' Arthur:** partial paralysis, rheumatoid, bursitis, swelling, gout.
- **Maximum Desire:** impotence
- **Pros-Guard:** prostate enlargement, swelling of prostate urinary problems.
- **The Big "C":** fight circulating cancer cells, fight tumor growth, boils, ulcers, sores, warts, cysts, hard cancers, ringworms, blood clots, (sic) psoriasis, prostate problems, gangrene.
- **Formula C:** relief of leg cramps, Rejuvenates kidneys, help kidney problems, help bladder problems, help urine problems, frequent urine, unable to control urine, slow urine, pancreas.
- **G.A.P:** high blood pressure, diabetes and arthritis.

Further, we have no information that your products are generally recognized as safe and effective for the above referenced conditions and may not be legally marketed in the U. S. without approval of a new drug application [Section 505(b) of the Act].

These drugs are also misbranded [Section 502(a) of the Act] because their labeling is false and misleading and suggests that there is evidence that the drugs are safe and effective when this is not the case. These drugs are also misbranded [Section 502(f)(1) of the Act] because their labeling fails to bear adequate directions for use [Section 502(f)(1) of the Act].

Furthermore, drugs manufactured or repacked by your firm are also misbranded according to Section 502(o) of the Act since they are manufactured in a facility that is not registered with the FDA, as required by the Drug Registration and Listing Act (Section 510 of the Act), nor has the proper listing information been filed (21 CFR, Section 207).

Drug products manufactured by your firm, including Dr. Johnson's Body Healer, Master Healer, and Big "C" are also adulterated within the meaning of Section 501(a)(2)(B) of the Act in that they are drugs and the methods used in, and the facilities and controls used for, their manufacture, processing, packing or holding do not conform to or are not administered in conformity with current good manufacturing practice (GMP) regulations as specified in 21 CFR, Part 211, as follows:

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No component, in-process or finished product testing; no stability testing, nor is there an expiration date on the label; no reserve samples; no label controls; no master records and incomplete batch records; no written procedures for component handling, production and process control, prevention or control of microbiological contamination, the distribution of drug products, or cleaning/maintenance of equipment; no quality control unit and no written procedures describing the responsibilities and functions of such a unit; and, personnel lack the necessary training to adequately perform their duties.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. 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 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 seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include 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.

Your reply should be sent to the Food and Drug Administration, Florida District, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, Attn: Martin E. Katz, Compliance Officer, telephone no. (407) 684-6823, ext. 262.

Sincerely,



Edward R. Atkins  
Acting Director  
Florida District