



November 15, 2002

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

Ref: 2003-DAL-WL-03

WARNING LETTER

FEDERAL EXPRESS

Mr. Jack H. McClung, President
Blue Stuff, Inc.
3750 N. I-44 Service Rd.
Oklahoma City, OK 73112

Dear Mr. McClung:

This letter is in reference to the inspection of your facility conducted by our investigator on September 25-26, 2001 and to your firm's marketing of several products identified below. Your promotional material, which includes product labels, newsletters, brochures, and your Internet web site at www.bluestuff.com, contains statements that represent or suggest that these products are intended to be used in the cure, mitigation, treatment, or prevention of disease. Such claims cause the products to be drugs under Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Products for which objectionable claims are being made include, but are not limited to, the following:

BLUE STUFF

"...arthritis pain, stiff joints & muscles, neck & back pain, and decreased injury, or surgery, recovery time..."; "...pain relief...arthritis...reduce inflammation..."; "emu oil acts as a transporting agent to rapidly carry all ingredients deep into the skin, where they immediately begin to work to reduce pain, inflammation, and swelling..."; "...improve many health problems such as allergies, asthma, emphysema, lung dysfunction, arthritis, headaches, skin problems, stomach and digestive tract problems, circulation, cell osmosis and absorption..."

According to the product label, BLUE STUFF contains "Whole Leaf Aloe Vera Concentrate, Purified Water, Carbomer-940, MSM, Willow Bark Extract, SD-Alcohol-40, Emu Oil, Sorbitol, Triethanolamine, Capsicum Oleoresin, Witch Hazel Extract, Menthol, Extracts of: (Blue Bottle, Roman Chamomile, Fever Few, St. John's Wort, Marigold, Limetree), Coriander Oil, Fragrance, Grape Seed Extract, FD&C Blue No. 2."

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SUPER BLUE STUFF

“...much more powerful with 700% more MSM than the original Blue Stuff...pain reliever...arthritis...”; “...targeting certain types of arthritis pain and stiffness...work to reduce pain, inflammation, and swelling...carpal tunnel...shingles...sciatic nerve pain...poison ivy, bee and wasp stings...spider bites...burns...earaches, and all types of headaches...relief from asthma attacks...”

According to the product label, SUPER BLUE STUFF contains “Whole Leaf Aloe Vera Concentrate, Purified Water, MSM, Amica Extract, Emu Oil, SD-Alcohol-40, Sorbitol, Menthol, Sodium Chondroitin Sulfate, Glucosamine Hcl, Capsicum Oleoresin, Nettle Extract, Coriander Oil, Kava Kava Extract, Extracts of: (Blue Bottle, Roman Chamomile, Marigold, Limetree), Willow Bark Extract, Witch Hazel Extract, Carbomer-940, Triethanolamine, Fragrance, Ascorbyl Palmitate, FD&C Blue No. 1.”

PURE EMU OIL

“...arthritis...sore muscles...minor sprains and bruises...joint inflammation and pain...faster healing for burn victims...”; “...burns...wounds...”

FOOT STUFF

“...removing dry skin...calluses...corns...”; “relieves foot pain...”

According to the product label, FOOT STUFF contains, “Whole Leaf Aloe Vera Concentrate, Purified Water, Emu Oil, MSM, SD-Alcohol-40, Sorbitol, Menthol, Capsicum Oleoresin, Witch Hazel Extract, Willow Bark Extract, Extracts of: (Blue Bottle, Roman Chamomile, Fever Few, St. John’s Wort, Marigold, Limetree), Coriander Oil...”.

In addition, FOOT STUFF does not meet the conditions of the Final Monograph for Corn and Callus Remover Drug Products for Over-the-Counter Use [Title 21 of the Code of Federal Regulations, Part 310.358 (21 CFR 310.358)] with respect to formulation and labeling.

ALOE STUFF (100% Whole Leaf Aloe Vera Juice Drink with EMU Oil) (listed on your website as "ALOE STUFF ORANGE FLAVOR & CRANBERRY FLAVOR"):

"antibiotic, pain inhibiting, . . . and scar reduction properties have been demonstrated by Scientific research studies"

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ESSENTIAL STUFF SOFT GEL CAPSULES (listed on your website as "ESSENTIAL STUFF GEL-CAPS"):

"help fight inflammation in shoulders, knees, and other joints, decreasing pain by at least 90%"

BLUE GREEN STUFF VEGETARIANCAPS (listed on your website as "BLUE GREEN STUFF"):

"greater resistance to cold and flu"

ESSENTIAL STUFF (A Blend of Essential Fatty Acids) (listed on your website as "ESSENTIAL STUFF LIQUID"):

"has been reported to reduce cholesterol, reduce the sugar count in diabetics, . . . reduce acid reflux and ulcer pain, . . . clear up eczema, psoriasis"

MSM STUFF:

"analgesic and anti-inflammatory . . . demonstrates the ability to alleviate chronic pain associated with systemic inflammatory disorders. . . helps speed healing of musculoskeletal injuries. . . eliminates free radicals in the body, reducing or eliminating allergies to pollens and certain foods. . . possible anti-cancer effects"

Based on the intended uses established by the claims quoted above, these products are drugs as defined in Section 201(g)(1)(B) of the Act. We are unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, these products are new drugs as described in Section 201(p) of the Act and may not be legally marketed in the United States since no new drug application (NDA) has been approved for any of these drugs as required by Section 505 of the Act.

Even if the products "Essential Stuff Soft Gel Capsules," "Essential Stuff (A Blend of Essential Fatty Acids)," and "Blue Green Stuff Vegetariancaps" did not contain disease claims in their labeling that cause them to be drugs and were instead marketed as dietary supplements or as foods, they would still violate other provisions of the Act.

The products "Essential Stuff Soft Gel Capsules" and "Blue Green Stuff Vegetariancaps" are misbranded within the meaning of Section 403(i)(1) and 403(s)(2)(B) of the Act in that the labels fail to identify the products using the term

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"dietary supplement" [21 CFR 101.3(g)], or other alternative descriptive term authorized by regulation.

The product "Essential Stuff Soft Gel Capsules" is misbranded under Section 403(q)(5)(F) of the Act in that the label fails to bear nutrition labeling as required under 21 CFR 101.36, and is not exempt from this requirement.

The product "Essential Stuff (A Blend of Essential Fatty Acids)" is misbranded under Section 403(q)(1) of the Act because the label fails to bear nutrition labeling as required under 21 CFR 101.9.

In addition, based on our review of your promotional materials, we have found that your firm's products for use with animals are adulterated under Section 501(a)(5) of the Act. The claims currently made for these products indicate that they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and therefore cause them to be drugs as defined under Section 201(g) of the Act. Some examples of drug claims are listed below:

"BLUE STUFF" line of animal products (including ANIMAL STUFF LOTION, DOG STUFF, and CAT STUFF):

"special treatment for injured animals and pets in pain"; "pain relief in 5 minutes"; "very effective on skin problems"; "relieve itching skin disorders as well as pain and inflammation"; "ensure a pain free life for your dog"; "heal open sores 10 times faster"; "relieve pain and inflammation"; "reduce incidences of, as well as reversal of, many skin disorders"; "reduce arthritis and joint pain in all animals"; "promote healing of ulcer conditions"

"ROYAL EQUINE" line of animal products, including WOUND AND HOOF DRESSING:

"quickly heal minor cuts, abrasions and burns with minimal scarring"; "ease muscle aches and joint pain"

The claims made clearly demonstrate your firm's intent to market and promote animal products for drug use. These products are not generally recognized as safe and effective for the labeled claims and are therefore new animal drugs under Section 201(v) of the Act. Because no new animal drug applications (NADAs) have been approved for these products, they are deemed unsafe under Section 512(a)(1). The products are thus adulterated under Section 501(a)(5).

This letter is not intended to be an all-inclusive review of your Internet web site nor all labeling and products your firm markets. The violations of the Act described above are

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not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We strongly suggest that you review all of your labeling for all of the products you are marketing, taking particular note of the types of claims that may cause your products to be unapproved and misbranded under the Act. 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 FDA without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office within fifteen (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 attention of Brenda C. Baumert, Compliance Officer, at the U.S. Food and Drug Administration at the attached letterhead address.

Sincerely,



Michael A. Chappell
Director, Dallas District

MAC:bc