



January 2, 2002

WARNING LETTER NO. 2002-NOL-19

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Jimmy N. Johnson, President
CASA Lab, Inc. (d.b.a. Walking Bird International, Inc.)
#2 Emu Lane
Silver Creek, Mississippi 39663

Dear Mr. Johnson:

During May 15 through 18, 2001, an investigator of the U.S. Food and Drug Administration (FDA) conducted an inspection of your pharmaceutical and cosmetic manufacturing facility, located at #2 Emu Lane, Silver Creek, Mississippi. The inspection was conducted to determine compliance with FDA's Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, *Code of Federal Regulations*, Parts 210 and 211 (21 CFR 210 & 211). Our investigator documented deviations from the regulations that cause your finished pharmaceuticals to be adulterated [Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act)]. The investigator found that your firm manufactures, labels, and distributes *Maxim Care Emu Oil Therapy Maxim Heal Wound Dressing*, *Maxim Heal Antiseptic Cream*, and other drug products. Our investigator also noted that Walking Bird International, Inc. (also known as WBI) is owned by you and is conducting business at your location.

This letter is specifically written in reference to the marketing of *Maxim Care Emu Oil Therapy Maxim Heal Wound Dressing* and *Maxim Heal Antiseptic Cream* by your firm. The labeling for the products, including accompanying brochures printed under the name of Walking Bird International, Inc. states or suggests that *Maxim Care Emu Oil Therapy Maxim Heal Wound Dressing* is useful for promoting hair growth and treating skin fungus, wounds, and ringworm, and that *Maxim Heal Antiseptic Cream* is useful in treating psoriasis, acne, and fungus diseases. Since your product labeling includes statements that these products are intended for use in the curing, mitigation, treatment, or prevention of diseases, or are intended to affect the structure or any function of the body of man, these products are drugs [Section 201(g) of the Act].

Based on the above noted labeling claims, these two products are in violation of the regulations and final rules found in 21 CFR 310.527 Hair Grower and Hair Loss Prevention Drug Products, 21 CFR 333.301 Topical Acne Drug Products, 21 CFR 333.201 Topical Antifungal Drug Products, and 21 CFR 358.701-750 OTC Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products. These two products fail to meet the requirements of the above mentioned final rules, and thus are “new drugs” [Section 201(p) of the Act] which may not be marketed since they are not subject to an approved New Drug Application [Sections 505(a) & (b) of the Act]. Furthermore, the products are misbranded [Section 502(o) of the Act] because they have not been drug listed as required [Section 510(j) of the Act and 21 CFR 207].

You should be aware that drugs must comply with all existing labeling requirements of Section 502 of the Act and in 21 CFR 210 & 211; they must be manufactured by a registered facility and listed with FDA (21 CFR 207); and, they must be manufactured, packaged, labeled, and stored according to CGMP's (21 CFR 210 & 211).

In addition, we found your products currently are being promoted on the Internet web site of <http://www.wbi-inc.com> for treating various diseases. Walking Bird International, Inc. is also known as WBI, and is a distributor for your products. The Internet web site of WBI, <http://www.wbi-inc.com>, promotes *Maxim Care Emu Oil Therapy Maxim Heal Wound Dressing*, *Maxim Heal Antiseptic Cream*, and products with statements which represent or suggest that these products are intended to be used in the cure, mitigation, treatment, or prevention of disease. Such claims on the Internet may cause these products to be misbranded.

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 previous inspection on November 9, 2000, you made a verbal commitment to correct observed deficiencies, which were identical to those documented on May 18, 2001. 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. Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,



Richard D. Debo
Acting District Director
New Orleans District

Enclosure: Form FDA 483

cc: Mr. Jimmy N. Johnson, President
Walking Bird International, Inc.
137 Crawford Road
Pinola, Mississippi 39149