



VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-69

July 12, 2001

Dr. Steve E. Rosen, President
Tend Skin International, Inc.
2090 SW 71st Terrace
Davie, FL 33317

Dear Dr. Rosen:

During an inspection of your firm on January 8, 9, 19 & 23, 2001, FDA investigator Courtney Hunt determined that your firm manufactures and distributes several over-the-counter (OTC) products including "Tend Skin," "Soft Cell," "Hard Top," and "Air Shave Gel." These OTC products are human drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Since these products are offered for sale OTC, they are required to comply with the general regulations and policies covering OTC drugs contained in Title 21 Code of Federal Regulations, Part 330 (21 CFR 330) and any specific drug product monographs.

"Tend Skin" is promoted and labeled for razor bumps and ingrown hair, but is also promoted for the treatment of acne, cold sores, athlete's foot, warts, pityriasis rosea and ringworm. "Tend Skin" contains, among other ingredients, acetylsalicylate (aspirin), which is not recognized as a safe and effective ingredient in an external analgesic OTC drug product (21 CFR 310.545(a)(10)(i)). Additionally, based on the above labeling claims, this product is in violation of other OTC final rules and final monographs as follows:

- For acne treatment claims, 21 CFR 333.301, 333.310, 333.320, 333.350
- For wart remover claims, 21 CFR 358.101, 358.110, 358.150
- For ringworm and athlete's foot claims, 21 CFR 333.201, 333.203, 333.210, 333.250
- For cold sore claims, 21 CFR 310.545(a)(10)(v)

"Soft Cell" is labeled for acne treatment and contains "isopropyl alcohol, water, propylene glycol, acetylsalicylic acid, cyclomethicone, glycerine" as ingredients. This product is subject to the final rule for topical acne drug products found in 21 (CFR) 333.301, 333.310, 333.320 and 333.350. The ingredients and labeling for this product do not comply with the final regulations.

Dr. Rosen
July 12, 2001
Page 2

Labeling for the product, "Hard Top", contains the statement that it can "clear up fungal and other infections on or at the perimeter of the nail". This statement demonstrates an intended use of "Hard Top" as a medication for treating nail infections, particularly fungus infections. Therefore, based on this intended use, "Hard Top" is subject to the regulations contained in 21 CFR 310.545(a)(22)(iii), which states that there are no active ingredients recognized for over-the-counter use in the treatment of fungal infections of the scalp and nails. Part (b) of that regulation states that any product labeled for these conditions is a new drug requiring approval of a new drug application before it can be marketed. The labeling for the product also fails to bear the warning statements required by 21 CFR 330.1(g) for topical OTC drugs, and is also misbranded.

The product "Air Shave Gel" is labeled to contain the ingredients "water, glycerine, polyquaternium 10, PEG-75 lanolin, dimethicone copolyol, polysorbate 20, PVP/VA copolymer, tetrasodium EDTA, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, chloroxylenol, and fragrance." This product has labeling claims for the treatment of psoriasis, i.e. "For those with severe psoriasis, razor bumps, or other skin disorders with severe crusting or surface roughness, Air Shave Gel is a blessing." Therefore, this product is subject to the final rule for drug products for the control of dandruff, seborrheic dermatitis, and psoriasis found in 21 CFR 358.701, 358.703, 358.710 (c) and 358.750. The ingredients and labeling for this product do not comply with the final regulations.

Based on the above, these products, "Tend Skin," "Soft Cell," "Hard Top," and "Air Shave Gel," are drugs [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and "new drugs" [Section 201(p) of the Act]. A "new drug" may not be marketed in the United States without an approved New Drug Application (NDA) [Section 505(a) of the Act].

The drugs are also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. The labeling is false and misleading as it suggests the products are safe and effective for their intended uses when, in fact, this has not been established [Section 502(a) of the Act].

The products are also misbranded because you have failed to register with the FDA as a drug manufacturer and have failed to list the drug products you manufacture [Section 502(o) of the Act].

Dr. Rosen
July 12, 2001
Page 3

Further, the above stated inspection revealed that the referenced drug products manufactured by you are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the controls used for processing, packaging or holding do not conform or are not operated or administered in conformity with the Good Manufacturing Practice (GMP) Regulations to assure that your drugs meet the requirements of the Act as specified in 21 CFR 211, as follows:

Failure to have a quality control unit that reviews all production and testing prior to release of a batch;

Failure to perform any system or process validation, or any in-process, finished product, or stability testing, including microbial quality;

Failure to establish finished product specifications;

Failure to establish or maintain production records, including master production records, standard operating procedures, validation documents, and cleaning procedures or records;

Inadequate batch records; and,

No procedures for handling consumer complaints.

This letter is not intended to be an all-inclusive review of all labeling and products your firm manufactures and/or distributes. 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 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 the seizure of illegal products and for an 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. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be implemented.

Dr. Rosen
July 12, 2001
Page 4

You should reply to Martin E. Katz, Compliance Officer, Food and Drug Administration,
555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4731.

Sincerely,



for Emma R. Singleton
Director, Florida District.