



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

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Stoneham, Massachusetts 02180
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WARNING LETTER

NWE-13-03W

April 9, 2003

Reissued April 17, 2003

VIA FEDEX

Jeffrey V. Kral, President
Selfworx.Com, LLC
51 Nonesuch River Plaza, Suite I
Scarborough, Maine 04074

Dear Mr. Kral:

This letter is in reference to your marketing of "Skin Zinc Spray" and "Skin Zinc Cream." Statements on the immediate container and the promotional material that accompanies these products states that the "Skin Zinc Spray" is useful in treating psoriasis, eczema, seborrheic dermatitis, and dandruff, and the "Skin Zinc Cream" is useful in treating psoriasis, eczema, and seborrheic dermatitis.

Based on the above claims, these products are drugs according to Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Over-the-counter (OTC) drugs for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis are subject to regulations at Title 21 Code of Federal Regulations Part 358 Subpart H (21 CFR 358 Subpart H). Regulation 21 CFR 358.710 lists the acceptable active ingredients and their concentration for products labeled for the control of dandruff, seborrheic dermatitis, or psoriasis. Regulation 21 CFR 358.750 states the acceptable labeling for products labeled for the control of dandruff, seborrheic dermatitis, or psoriasis. OTC drugs subject to this final rule must be formulated and labeled in accord with the final rule to be generally recognized as safe and effective and not misbranded.

"Skin Zinc Spray" is labeled to contain pyrrithione zinc 0.25% as the active ingredient, and its label states "Helps eliminate skin and scalp redness, scaling, itching, flaking and irritation associated with psoriasis, eczema, seborrheic dermatitis and dandruff." Regulations 21 CFR 358.710 and 21 CFR 358.750 set forth conditions when OTC drug products containing pyrrithione zinc between 0.1 and 0.25 percent are generally

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recognized as safe and effective when applied and left on the skin or scalp for the control of dandruff, and seborrheic dermatitis. Pyrithione zinc is not acceptable for the control of eczema or psoriasis.

"Skin Zinc Cream" is labeled to contain salicylic acid 2% as the active ingredient, and its label states "Helps eliminate Flaking, Itching, Irritation, Redness & Scaling associated with Psoriasis, Eczema & Seborrheic Dermatitis." Regulations 21 CFR 358.710 and 21 CFR 358.750 set forth conditions when OTC drug products containing salicylic acid between 1.8 and 3 percent are generally recognized as safe and effective and is not misbranded for the treatment of psoriasis and seborrheic dermatitis. Eczema is not an acceptable indication under this regulation.

Under the regulations cited above, OTC drugs containing pyrithione zinc as the active ingredient are not generally recognized as safe and effective for the treatment of psoriasis and eczema. Also, OTC drugs containing salicylic acid 2% as the active ingredient are not generally recognized as a safe and effective for the treatment for eczema. Therefore, Skin Zinc Spray and Skin Zinc Cream are new drugs within the meaning of 201(p) of the Act. Because neither of these two drugs is the subject of an FDA-approved new drug application, the marketing of these products violates section 505 of the Act.

This letter is not intended to be an all-inclusive review of all your labeling or your products your firm 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 these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

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 fifteen (15) working days, state the reason for the delay and the time within which the correction will be implemented.

OTC drugs such as yours that are subject to final regulations must now also comply with the Drug Facts Format Labeling requirements in 21 CFR 201.66. If you relabel and reformulate your products to comply with the regulations cited in this letter, these products must also meet the requirements of this regulation.

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You should address your response to Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180.

Sincerely,



Gail T. Costello
District Director
New England District

cc:

