



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

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**Food and Drug Administration**  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-99-08

November 12, 1998

H. David Marcum  
President & Owner  
Derma-Tek Industries, Inc.  
362 Center Court  
Venice, Florida 34292

Dear Mr. Marcum:

During an inspection of your facility in Venice, Florida, on May 28, 1998 through June 4, 1998, Food and Drug Administration (FDA) Investigator Shari J. Hromyak determined that your firm manufactures various OTC human and animal drug products. These products are drugs as described in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act), since these products contain representations in their labeling that the products are useful in treating or preventing various disease conditions in man or other animals.

The product "Derma-Tek for Acne" is a product for topical application labeled to ease the pain and discomfort associated with acne. Based on its labeling, this product is subject to the final rule for topical acne drug products found in Title 21, Code of Federal Regulations (21 CFR), Part 333. The ingredients in these products are not listed among the acceptable active ingredients for OTC acne products in 21 CFR 333.310 and 320. Because of this, "Derma-Tek for Acne" is an unapproved new drug. The labeling for the product also fails to bear the warning statements required by 21 CFR 330.1(g) for topical OTC drugs or the directions for use required by 21 CFR 333.350(d)(1), and lacks the warnings required by 21 CFR 333.350(c). Therefore, "Derma-Tek for Acne" is misbranded.

The product "Derma-Tek for Athlete's Foot" is a product for topical application labeled to ease the pain and discomfort associated with athlete's foot fungus and jock itch. Based on its labeling, this product is subject to the final rule for topical antifungal drug products found in 21 CFR, Part 333.201-250. The ingredients in these products are not acceptable active ingredients in any OTC products for athlete's foot or jock itch. Because of this,

Mr. H. David Marcum

Page 2

November 12, 1998

"Derma-Tek for Athlete's Foot" is a drug. The labeling for the product also fails to bear the required warning statements for topical OTC drugs, lacks the warnings required by 21 CFR 333.250(c), and fails to bear the required directions for use. Therefore, "Derma-Tek for Athlete's Foot" is misbranded.

Additionally, the products "Derma-Tek for Psoriasis, and Psoriasis Liquid Spray" and "Derma-Tek Scalp Treatment" are products for topical application on the scalp or body. Based on its labeling, these products are subject to the final rule for Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis found in 21 CFR, Part 358.701-750. The ingredients in these products are not acceptable active ingredients in any OTC products for dandruff, seborrheic dermatitis or psoriasis. Because of this, these products are new drugs. The labeling for these products also fails to bear the required warning statements for topical OTC drugs, the warnings required by 21 CFR 358.750(c), and the required directions for use. Therefore, these products are also misbranded.

The following products are also considered drugs because of their names and/or the claims made for them:

Derma-Tek for Hemorrhoids

Derma-Tek for Eczema

Derma-Tek for Shingles

Shingles and Chicken Pox

Derma-Tek for Burns

Burns and Sunburns

Derma-Tek for Arthritis

Arthritis, Carpal Tunnel Syndrome, Tendinitis

Derma-Tek for Arthritis Liquid Spray

Arthritis, Carpal Tunnel Syndrome

Derma-Tek for Cold Sores

Cold Sores, Fever Blisters, Dry Chapped Lips

Derma-Tek Itch Relief Liquid Spray

Shingles, Chicken Pox, other Skin Irritations

Because labeling includes statements that these drugs are intended for use in the cure, mitigation, treatment, or prevention of disease conditions, these products are drugs as described in section 201(g) of the Act. Further, these drugs are new drugs [section 201(p) of the Act] which cannot be legally marketed in the U. S. since they are not subject to an approved New Drug Application (NDA) [section 505(b) of the Act].

Mr. H. David Marcum  
Page 3  
November 12, 1998

The drugs are also misbranded as described in section 502(a); their labeling is false and misleading, because it states that the drugs are safe and effective for their intended uses, when this has not been established.

The drugs are further misbranded (section 502) since their labeling fails to provide adequate directions for use and you have failed to subject proper listing information for them. Several drugs (Derma-Tek for Shingles, Athlete's Foot, Psoriasis, Psoriasis Liquid Spray, Arthritis Liquid Spray, Itch Relief Liquid Spray, and Cold Sores) are also misbranded [section 502(e)(1)(A)(ii)] since these drugs are labeled to contain alcohol, but fail to list the quantity, kind or proportion of the alcohol included.

The inspection further revealed that all these drugs are also adulterated within the meaning of section 501(a)(2)(B) of the Act in that they are drug products and the methods used in, or the facilities or controls used for their manufacturer, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs specified in CFR, Part 211 as follows:

Failure to perform finished product testing on each batch of the product manufactured or reprocessed before release for distribution, such testing to include identity and strength of each active ingredient;

Failure to establish finished product specifications for all products manufactured;

An ongoing, well-controlled stability program has not been established, nor have stability studies been performed on products;

Manufactured products lack expiration dates and they are not exempt from this requirement since appropriate data showing stability of products over a three year period is lacking;

Failure to establish and maintain master production records for products;

Failure to maintain adequate batch records for manufactured or reprocessed products;

Failure to establish component specifications;

Failure to establish a control system for the receipt, testing and approval of components, and drug containers and closures;

Mr. H. David Marcum

Page 4

November 12, 1998

Failure to establish or implement an adequate label control system;

Failure to establish cleaning procedures; and,

Failure to do validation studies on various systems, including but not limited to cleaning validation procedures.

It is your responsibility as a drug manufacturer to assure that all requirements of the good manufacturing practice (GMP) regulations pertaining to the manufactured lot (or, for reprocessed products, those requirements that pertain to reprocessing operations) are met. These include both finished product and stability testing, process validation, and assuring that all necessary records are prepared, are accurate, and are accessible both to you and the FDA. Your responsibility exists whether you have done the procedures or contracted a firm to do them, and cannot be relinquished.

These deficiencies are similar and, in some cases identical to deficiencies observed during the previous two inspections of Derma-Tek, Inc., Nicholasville, Kentucky, in September 1993 and June 1992, showing a continuing pattern of noncompliance with GMP regulations. We refer you to the list of Inspectional Observations (FDA-483) left with your firm at the close of the current inspection and the previous two inspections. A copy of the latest FDA-483 is attached for your convenience.

Other Federal agencies are routinely advised of Warning Letters issued so that they may consider this information when awarding contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the FDA in determining such corrections have been made, withdrawing its advisory to other Federal agencies, and resuming review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations, so a verification inspection can be scheduled

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

Mr. H. David Marcum

Page 5

November 12, 1998

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations and to prevent their

Mr. H. David Marcum

Page 5

November 12, 1998

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Martin E. Katz, Compliance Officer, Florida District, U. S. Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,



Douglas D. Tolen  
Director, Florida District

Enclosure  
Inspectional Observations (FDA-483)