



Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

May 14, 1998

**WARNING LETTER**

**VIA FACSIMILE AND  
FEDERAL EXPRESS**

**Ref: 98-DAL-WL-34**

Mr. Michael M. Barbour  
President & Chief Executive Officer  
Henley HealthCare, Inc.  
120 Industrial Blvd.  
Sugar Land, Texas 77478-3128

Dear Mr. Barbour:

We have recently received information that Henley HealthCare, Inc. is marketing LidoKain Anesthetic Strips, MediPad-H Plus Pads, MediGel-H Plus, MediPad-L Plus Pads, and Medigel-L Plus.

LidoKain Anesthetic Strips are formulated with lidocaine 4% as the active ingredient, and are labeled "LidoKain is used to relieve muscle and joint pain resulting from repetitive motion injuries, strains, arthritis, carpal tunnel syndrome, simple backache, tendonitis, bursitis, or bruises." The MediPad-L Plus Pads and MediGel-L Plus are formulated with lidocaine 4% and menthol 0.2% as the active ingredients, and are labeled for many indications including "to provide temporary relief of minor aches and pain associated with arthritis, backache, bruises, sprains, and sports injuries."

The MediPad-H Plus Pads and the MediGel-H Plus products are formulated with hydrocortisone 1% as the active ingredient, and are labeled for the treatment of numerous disease conditions including psoriatic arthritis, rheumatoid arthritis, systemic lupus erythematosus, severe psoriasis, and exfoliative dermatitis. The MediPad-H Plus Pads and the MediPad-L Plus Pads are described as adhesive pads which are covered with a plastic (occlusive) film, and are intended to be absorbed across the skin and into systemic circulation (transdermal). They are labeled as "an effective, easy to use, safe alternative to injections and oral medications."

These products are drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Based on their formulation and intended uses, these products are external analgesic drugs. The safety and efficacy of this class of OTC drugs is

currently being evaluated by the Food and Drug Administration under the Agency's OTC Drug Review. Pending the issuance of a final regulation, we would not object to the marketing of OTC drugs that are formulated and labeled in conformance with a proposed rule or were marketed in the United States prior to December 4, 1975, and do not present a danger to the health of the user. LidoKain Anesthetic Strips, MediPad-L, and MediGel-L are not formulated and labeled in accord with the proposed rule for external analgesic drug products published in the February 8, 1983 **Federal Register**. Further, we have no information which shows that these or any other similarly labeled and formulated OTC drug products were marketed in the United States prior to December 4, 1975.

In addition, the products formulated with hydrocortisone 1% as the active ingredient are not labeled in accord with the **Notice of Enforcement Policy** published in the August 30, 1991 **Federal Register**. Therefore, these products are subject to regulatory action under the provisions of regulation 21 CFR 330.13(b)(2) pertaining to the marketing of drugs containing active ingredients which have been permitted to switch from prescription only to OTC human use.

Based on their failure to meet the above described requirements, 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 they are not approved as stated in Section 505(b) of the Act. Further, the MediPads products are new drugs irrespective of the status of the ingredients or labeling, because they are transdermal. These drugs are also misbranded (as described in Section 502(f)(1)), because their labeling fails to bear adequate directions for use.

The above list of violations is not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to ensure that the drug products you distribute meet all the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

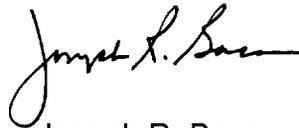
Please notify this office in writing within fifteen (15) working days of receipt of this letter, of specific actions you will take to correct these violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrections cannot be completed within fifteen (15) working days, please state the reason for the delay, and the time within which corrections will be completed.

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Henley HealthCare, Inc.

Your reply should be addressed to James Austin Templer, Compliance Officer, at the above letterhead address.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Joseph R. Baca".

Joseph R. Baca  
Dallas District Director