



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d/6806

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-96-12

December 19, 1996

Mr. Bill Davis
International Sales Representative
Colloidal Products, Inc.
16101 N.E. 9th Avenue
No. Miami Beach, Florida 33162

Dear Mr. Davis:

We have obtained information that your firm distributes "CM SYSTEMS 2 GEL". The label states that this product is a topical pain relieving gel. A promotional flyer (labeling) distributed with your product contains claims for the treatment of diabetic neuropathy, shingles, herniated discs, headaches, retention of liquids, and "phantom pain", among others.

In general, based on the agency's general regulatory policy which governs over-the-counter (OTC) drug products, those products which are labeled as external analgesic drug products for OTC human use are subject to coverage under the ongoing review of OTC human drugs. However, we are not aware of any information which shows that your product or any other OTC drug product, with the same formulation and labeling, was marketed in the United States before December 4, 1975. We are not aware of any substantial scientific evidence which establishes that your product is generally recognized as safe and effective for its labeled uses cited above.

Based on its intended use stated in the labeling, CM SYSTEMS 2 GEL is a drug [section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (Act), and a new drug, section 201(p), of the Act]. This product may not be introduced into interstate commerce under section 505(a) of the Act since no approved new drug application is in effect for this drug. CM SYSTEMS 2 GEL is misbranded because the labeling fails to bear adequate directions for use for the conditions it is offered [section 502(f)(1) of the Act] and its label fails to declare the active ingredients [section 502(e) of the Act] in a manner that differentiates active ingredients as defined in Title 21, Code of Federal Regulations (CFR), Section 210(b)(7) from other, inactive ingredients in the product. Listing

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all the ingredients without such differentiation creates an impression of value for these ingredients greater than their actual role in the formulation [21 CFR 201.10(c)(4)]. Further, advertisements for CM SYSTEMS 2 GEL state that this product is "FDA Approved". This statement is false because this product is not approved; thus, it is misbranded [section 502(a) of the Act].

The above is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all drug products are in compliance with the Act. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, which may include seizure and/or injunction, without further notice. Other Federal Agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the awards of contracts.

You should notify this office in writing within fifteen (15) working days of this letter of the specific steps you have taken to correct these violations. If corrections cannot be completed within fifteen (15) days, state the reason for the delay, and the time frame within which corrections will be completed. You should notify this office when corrective actions are completed so that a verification inspection can be scheduled. In addition, the FDA will then withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications.

Your reply should be directed to Martin E. Katz, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, telephone no. (407) 648-6823, ext. 262.

Sincerely,



Douglas D. Tolen
Director, Florida District