DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M23267

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 13, 1998

Dr. Tei Fu Chen, CEO
Sunrider Manufacturing, L.P.
320 South 6th Avenue
City of Industry, CA 91746

WL – 8-9

Dear Dr. Chen:

During an inspection of your food, drug, and cosmetic manufacturing facilities on March 19 – 24, 1998, our investigator documented serious deviations from the Current Good Manufacturing Practice Regulations [Title 21, Code of Federal Regulations (CFR), Parts 210 & 211). These deviations cause your drug products to be adulterated within the meaning of Section 501 (a) (2) (B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or "the Act"). For example:

1. Your firm failed to reject drug products which did not meet established standards or specifications. Specifically, your company released for distribution at least two batches of Protective Emulsion SPF 25 (Lots #0178912 and 0171622), which had failed to meet release specifications for an active ingredient assay or viscosity. [CFR 211.165 (f)]

2. Your firm failed to reprocess lots using material that met appropriate standards, specifications, and other relevant criteria. Specifically, your firm reprocessed lots which failed to meet specifications by blending with lots that met specifications. This practice is not permitted under the FD&C Act. [CFR 211.165 (f)]

3. Your firm failed to establish and follow control procedures to monitor and validate the performance of manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Specifically, your firm failed to validate the manufacturing and rework processes to assure that your methods and procedures consistently

produce product which meets pre-determined specifications and quality characteristics. [CFR 211.110 (a)]

4. Your firm failed to establish and follow cleaning procedures intended to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of your drug products. Specifically, your company failed to validate current cleaning procedures to assure that no other product or cleaning agent residue contaminates your drug products. In addition, documentation of cleaning procedures performed by employees was inadequate and incomplete. [CFR 211.67]

5. Your firm failed to establish and document the accuracy, sensitivity, specificity, and reproducibility of test methods used for raw materials, in process, and finished product testing. Specifically, your company has not validated laboratory methods used on various tests used in testing raw materials and sunscreen finished product. In addition, system suitability testing is not performed on the HPLC testing performed on the drug products. [CFR 211.165 (e)]

In addition to the above, we have information that your firm is marketing "VITASPRAY DIETARY SUPPLEMENT". The label and the product catalog (labeling) state that it contains Vitamin C and essential B-complex vitamins B1, B2, B6, and B12. This labeling also states that "Vitamin B12 is best absorbed through the tongue membranes or injection because if it is ingested, gastrointestinal juices will break down the vitamin, thereby destroying its value...Just one spray under the tongue enables the vitamins, including over 100% of the recommended daily value (DV) of vitamin B12 to be absorbed into the body efficiently."

The Dietary Supplement Health and Education Act (DSHEA) became law on October 25, 1994. Section 201(ff) of the Federal Food, Drug and Cosmetic Act (Act) defines the term "dietary supplement" to be a product that is formulated with vitamins, minerals, or botanicals that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form. Consequently, your product "VITASPRAY DIETARY SUPPLEMENT" which is not intended for ingestion cannot meet the definition of "dietary supplement".

Since it is intended to affect the structure or function of the body of man and is not a dietary supplement, VITASPRAY DIETARY SUPPLEMENT is a drug as defined in section 201(g) of the Act, and is a new drug as defined in section 201(p) of the Act. Therefore, "VITASPRAY DIETARY SUPPLEMENT" may not be legally marketed in the United States since it is not approved (section 505 of the Act), and is misbranded (section 502(f)(1) of the Act) because the labeling fails to bear adequate directions for use.

You should be aware that the list of violations identified above is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulation and other applicable 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.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Although we received your 11/9/98 response to the FD-483, you should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations mentioned above, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. We will evaluate your 11/9 FD-483 response and notify you if we find it inadequate.

Your reply should be addressed to:

Patricia A. Gupta, Compliance Officer/Investigator
U.S. Food and Drug Administration
4605 East Elwood St., Ste. 402
Phoenix, AZ 85040

Sincerely,

Elaine C. Messa
District Director

cc: California DHS/Food and Drug Branch
Attn: Stuart E. Richardson, Jr.
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320