



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

June 4, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Charles R. Briggs, O.D.
President/CEO
Sunsoft Corporation
6815 Academy Parkway West NE
Albuquerque, NM 87109

Ref # : DEN-99-09

PURGED

Dear Dr. Briggs:

During an inspection of your firm conducted between January 19 and February 1, 1999, Consumer Safety Officer Cynthia Jim determined your firm manufactures sterile soft contact lenses. These products are devices within the meaning of Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure of management to ensure that a Quality Policy is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20(a).
2. Failure to adequately validate, with a high degree of assurance, production processes where results cannot be fully verified by subsequent inspection and testing as required by 21 CFR 820.75(a). Specifically, numerous discrepancies were noted in [x x x x x ^ ^] [x x] process [x x x] study [x x x] yet the [x x x] summary recommends the lens design be transferred to production. These discrepancies included a typographical error in a standard operating procedure (SOP) which resulted in all [x x] lots of the first validation run failing due to small diameter; an ultraviolet light (UV) curing problem which

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resulted in 1 of 2 lots of the second validation run failing due to out of specification base curve readings; a lens curling problem attributed to unknown causes which resulted in all 2 lots of the 1 validation run being rejected; and torn lenses which resulted in 1 of 2 lots of the 1 validation run failing.

3. Failure to properly evaluate and investigate complaints involving possible failure of a device, its labeling, or packaging to meet its specifications as required by 21 CFR 820.198(c). Specifically, our review of Complaint Investigation forms from the month of 3/98 found several which were not investigated according to your own 1 2 Procedures. Deviations from your procedures included: testing lenses of the same lot as the complaint and finding the same problem yet remaining inventory was not pulled or rejected (1 2 3 4 5 6); testing lenses of the same lot as the complaint and confirming the lenses were off power yet reporting the lenses "read as labeled" (1 2 3 4 5 6 7 8 9); and testing only 1 lenses from the same lot as the complaint rather than the required 2 lenses (Complaints 1 2 3 4 5 6 7 8 9 10). Significantly, each of these inadequate investigations were signed off not only by the Complaint Technician but the Q.A. Manager as well.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

An example of permanent corrective action would be to more effectively address the observation on the FD-483 reporting mix-ups in several production runs which resulted in complaints of off power. Your investigations revealed that lenses were placed out of sequence during processing thus resulting in incorrect labeling. In your response to the FD-483, you stated that during 1998, 1 mixed lots were found by Sunsoft out of approximately 2 lots of Toric 15.0 lenses manufactured. You attributed these mixed lots to processing errors by the technicians. Further, your standard procedure when this occurs is to retrain the technician. However, under 21 CFR 820.100, Corrective and Preventive Action, you are required to not only investigate the cause of nonconformities related to products, but also identify the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems.

We acknowledge your response dated February 22, 1999, to the observations noted on the FD-483. We have reviewed your response and it appears to address most of the concerns. However, we have also carefully reviewed our inspectional history with your firm and note a significant and disturbing pattern. Since 1991, FDA has inspected your facility six times. Including the current inspection, multiple page FD-483's have been issued at the conclusion of five of the six inspections. Additionally, Warning Letters were issued following the May 1991 and June 1993 inspections. Following each of the inspections, corrections were promised, yet we continue to find significant, and in the case of 1 Study 2, fundamental deficiencies. Attached for your

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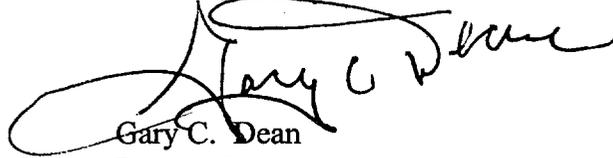
review and use are copies of the FD-483's mentioned above. Although you appear capable of bringing your firm into compliance, as evidenced by our November 1993 inspection which resulted in no FD-483 being issued, we are deeply concerned that we continue to find deviations from good manufacturing practices at your firm.

You should take prompt action to correct these and any other manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. 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.

Please notify this office in writing, within 15 days of receipt of this letter, of any additional steps you will be taking to achieve compliance which have not been previously reported to us.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: H. Tom Warwick, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary C. Dean". The signature is written in a cursive style with a large, sweeping initial "G".

Gary C. Dean
District Director

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Enclosures:
As Stated