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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, CA 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

June 14, 2007

W/L 13-07

Mr. Jack Carter, President
Crystal Reflections International, Inc.
170 N. La Canada Drive, Suite 80
Green Valley, Arizona 85614-3100

Dear Mr. Carter:

During an inspection of your firm located in Green Valley, Arizona on February 8, 9, 13, and 15, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures tinted contact lenses and theatrical contact lenses. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body. Additionally, Public Law 109-96 was enacted into law on November 9, 2005, deeming all contact lenses to be devices under section 201(h) of the Act. Your firm is a manufacturer because it designs, fabricates, assembles, or processes finished devices, per Title 21, Code of Federal Regulations (21 CFR), Part 820.3(o).

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at 21 CFR 820. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met, as required by 21 CFR 820.75(b). Specifically, no bioburden testing has been performed as required quarterly by your Quality Assurance Bioburden Testing procedure.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, your firm has not implemented a complaint handling procedure and has no records of complaints in your complaint file, but has records in other locations of product deficiencies that would be classified as complaints.
3. Failure to establish quality system procedures and instructions, and an outline of the structure of the documentation used in the quality system where appropriate, as required by 21 CFR 820.20(e). Specifically, your firm has not established quality system procedures. Additionally, the procedures observed and cited as unsigned and undated during our prior inspection of 2004 remained unsigned until after the initiation of this inspection.
4. Failure to establish and maintain procedures to control all documents, as required by 21 CFR 820.40. Specifically, the change control procedure, among others, remains unsigned and undated. Changes were observed having been made via the addition of "post-it" notes.
5. Failure to establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups, as required by 21 CFR 820.60. Specifically, no record accompanies each pair of lenses nor is a record created concurrent with each step of production.
6. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. Specifically, no audits have been performed since your firm began manufacturing in 2000.
7. Failure to establish and maintain procedures for finished device acceptance to ensure that each product run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). Specifically, no acceptance procedures for finished devices have been established and device history records do not include documentation of a final review to assure lenses are manufactured in accordance with device master records.

Our inspection also revealed that your theatrical lenses are being commercially distributed without marketing approval or clearance and that your tinted lenses, which have been cleared by FDA for prescription use only, are being commercially distributed without the order of a licensed physician. Therefore, the devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have approved

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applications for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or approved applications for investigational device exemptions (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The above stated devices are also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce these devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For devices requiring premarket approval, the notifications required by section 510(k) of the Act, 21 U.S.C. 360(k), are deemed satisfied when PMAs are pending before the agency. 21 C.F.R. 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your devices is described on the Internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information you submit and decide whether your products may be legally marketed.

The devices are also misbranded under section 502(f)(1) of the Act, [21 U.S.C. 352(f)(1)] in that their labeling fails to bear adequate directions for use as required by Title 21 Code of Federal Regulations (CFR) section 801.5 and the devices do not meet the requirements for an exemption from section 502(f)(1) under 21 CFR 801.109 and 801.110.

This letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations 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 money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those

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corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.
Your response should be sent to:

Pamela B. Schweikert
Director, Compliance Branch
United States Food and Drug Administration
19701 Fairchild
Irvine, California 92612.

If you have any questions about the content of this letter please contact Barbara Rincon, Compliance Officer at (949) 608-4439.

Sincerely,

Alonza E. Cruse
District Director