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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

September 26, 2002

Our Reference No. 1000123912

Karen L. Johnson, President
Softchrome, Inc.
2551 San Ramon Valley Blvd., Suite 101
San Ramon, CA 94583

WARNING LETTER

Dear Ms. Johnson:

During an inspection of Softchrome Inc., located at 2551 San Ramon Valley Blvd., San Ramon, on April 9, 15 and May 9, 2002, our investigator observed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). At that facility you manufacture and distribute the Softchrome In-Office Tint System, a device within the meaning of section 201(h) of the Act.

The Softchrome In-Office Tint System is adulterated under section 501(a)(4) of the act, in that it contains, for the purposes of coloring only, a color additive that is unsafe within the meaning of section 721 of the Act. A color additive used in a device that comes in direct contact with the body of man for a significant period of time, such as the Softchrome In-Office Tint System, is unsafe under section 721 unless the color additive and its use are in conformity with a regulation issued under section 721 or is exempted by the Secretary. Specifically, your device contains the color additives "Burcofix Scarlette E2GA" (Reactive Red 123), "Burcofix Brill Red EBA" (Reactive Red 124), and Navy Blue RGB" (Reactive Blue 250). These color additives are not listed in Title 21 Code of Federal Regulation, Part 73.3121 (21 CFR 73.3121) and are not exempt.

We have also reviewed the labeling and some promotional material distributed by Softchrome, Inc. pertaining to the Softchrome In-Office Tint System. This device was cleared for marketing pursuant to FDA premarket review of Softchrome's 510(k) submission K991995. The intended use of the device, as represented in the 510(k), is "...for daily wear to enhance and/or alter the apparent eye color..." and "... lens optical parameters remain the same as originally prescribed for the user prior to tinting."

The labeling and promotional materials for the Softchrome In-Office Tint System, including information contained on your website, www.softchrometinting.com promote the device for the enhancement of color recognition in individuals with red/green color deficiency. As described below, these statements have changed the device's intended use and have resulted in the product being misbranded and adulterated.

Softchrome's flyer, "Softchrome In-Office Tint System Makes The Difference" contains the statement, "Therapeutic Tinting Use the Red tint for color-vision enhancement". The recipes booklet that is included in the labeling of the devices has the statement, "RED FILTER LENSES, WHILE NOT A CURE, MAY AID IN COLOR-DEFICIENCY PROBLEMS BY ALLOWING THE WEARER TO DISTINGUISH MORE COLORS". The directions for use booklet contains the statement, "RED-FILTER LENS (Aid for Red/Green-Color Deficiency)". Your website also has the statement, "A red-filter lens worn on the non-dominant eye may be helpful as an aid for red-green color deficiency."

The Softchrome® In-Office Tint System for Soft Contact Lenses is misbranded under section 502(o) of the Act in that your firm has made a significant modification to the intended use of this device for color-vision enhancement, without providing a notice or other information respecting this modification to the device to the FDA as required by section 510(k) and 21 CFR Part 807.81(a)(3)(ii).

The intended use for color-vision enhancement also causes the Softchrome® In-Office Tint System for Soft Contact Lenses to be adulterated under 501(f)(1)(B) for failing to have an approved premarket approval application in effect under section 515(a) or an approved application for an investigational device exemption under 520(g) of the Act for that use. These approvals are required unless you have submitted a premarket notification submission that shows that the modified Softchrome® In-Office Tint System for Soft Contact Lenses is substantially equivalent to other devices that are legally marketed and you have been notified by FDA that you may market the modified Softchrome® In-Office Tint System for Soft Contact Lenses.

The Softchrome® In-Office Tint System for Soft Contact Lenses is misbranded within the meaning of section 502(a) and the requirements of 21 CFR 807.97 in that the labeling contains statements which represent and create an impression that FDA approved the device. For example, the instructions for use entitled "Softchrome® The In-Office Tinting System For Soft Contact Lenses" includes the statement "The Softchrome® System has received marketing approval from the United States Food and Drug Administration (FDA) which is your assurance of quality." In addition Softchrome's web site, www.softchrometinting.com, under Frequently Asked Questions includes the question and answer "Are the dyes & solutions used in the In-Office tinting System approved by the FDA for tinting soft contact lenses? Yes. Softchrome was given approval to market their lens-tinting products in September of 1999." These statements are misleading. The Softchrome System was cleared for marketing under section 510(k); FDA has not approved a PMA for the device.

Our investigation also found several significant current Quality System (QS) Regulation deviations. Many of these violations were corrected prior to the conclusion of the inspection. It is your responsibility, as a device manufacturer, to conduct periodic quality audits and identify and correct any and all violations of the quality system requirements. We will verify your corrective actions, and their implementation, during our next inspection.

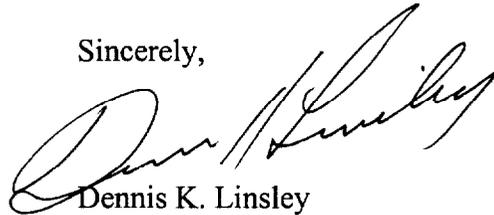
We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. It appears that the response is adequate with respect to your distribution of unlisted colors and deviations from the QS Regulation.

The above deficiencies should not be construed as an all-inclusive list of violations which may be in existence at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. 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.

Please notify this office in writing, within fifteen (15) days of receipt of this letter, stating the actions you have taken to correct these violations and to prevent future violations of the Act. If you fail to take such action, FDA is prepared to take further actions against your firm, such as seizure and/or injunction.

Please direct your response or questions regarding this matter to Russell A. Campbell, Compliance Officer, Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is fluid and cursive, with a large initial "D" and "L".

Dennis K. Linsley
Director
San Francisco District