



March 31, 2017

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Shuren,

The American Optometric Association (AOA) represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation's family eye doctors and the leading authority on eye health, vision care, and patient safety issues. Doctors of optometry prescribe the majority of contact lenses for patients in the United States. Contact lenses are an effective, safe, and popular choice for vision correction. Because improper use can lead to injuries and infections, our member doctors are essential in mitigating this risk and ensuring that the use of contact lenses results in optimal vision. The AOA has an interest in ensuring that the contact lenses sold to patients are safe and effective.

On August 26, 2013, the Food and Drug Administration (FDA) Office of Compliance in the Center for Devices and Radiological Health issued a warning letter¹ to St. Shine Optical, a contact lens manufacturer, citing violations identified during an inspection of the firm located in Taipei Hsien, Taiwan. The FDA found that St. Shine Optical was using facilities or manufacturing process that were not in accordance with the Current Good Manufacturing Practice (cGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

Hubble Contacts is an online retailer of their own daily disposable contact lenses. Hubble Contacts uses St. Shine Optical as their contact lens manufacturer.² In describing the retailer's decision to partner with St. Shine Optical, Hubble notes, "After careful consideration, we chose St. Shine as our partner, an FDA-approved contact lens manufacturer with more than twenty years of experience. St. Shine produces billions of high-quality lenses, worn worldwide from New York to Tokyo. They use state-of-the-art injection molding to craft our lenses and perform a variety of tests and inspections to assure their high quality." The AOA would greatly appreciate an update from the FDA on St. Shine Optical and whether the company has made improvements to ensure compliance with Current Good Manufacturing Practice (cGMP) requirements.

Additionally, on Hubble's website, the company cites research which they note has found, "no significant differences between the comfort and visual sharpness of our contacts and the most popular brands in the U.S." The AOA has been unable to obtain a complete copy of this study for

¹ <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm366982.htm>

² <https://www.hubblecontacts.com/pages/contacts>

review. The AOA would greatly appreciate the FDA's assistance in obtaining any additional information from the study that would be useful to patients.

Thank you very much for your time. Please contact Kara Webb at kcwebb@aoa.org or 703-837-1018 with any additional information that you may be able to share.

Sincerely,

A handwritten signature in cursive script that reads "Andrea P. Thau, OD". The signature is written in black ink and is positioned above the typed name.

Andrea Thau, OD
President, American Optometric Association