



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 17, 2022

Mr. Mark Baker
Soft Lights Foundation
9450 SW Gemini Drive PMB 44671
Beaverton, OR 97008

Reference: COR22000194

Dear Mr. Mark Baker :

This is in response to your submission dated October 14, 2022, in which you provided information about an accidental radiation occurrence (ARO) involving General Optical Products, Non-Medical.

Thank you for providing this information to the Food and Drug Administration (FDA). Information from regulated industry and consumers is often very helpful to us in identifying problems with marketed products and possible violations of the laws that we enforce. We take such reports seriously, and we will evaluate this matter to determine what follow-up action is appropriate. The type and extent of any follow-up is dependent upon the nature of the problem, the possible impact on the public health, and the availability of our resources. If we have further questions, we will contact you.

While FDA does not provide information on ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request, once an investigation is closed. Requests for information may be online at the following address:

<http://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm>

If you have any questions, please contact the Director of the Division of Radiological Health, or the branch chief of your respective product area, as listed on the CDRH Management Directory, under the Office of In Vitro Diagnostics and Radiological Health, Division of Radiological Health.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm>

Please include a primary (and optional secondary) contact email address in all submissions (and/or cover letters) to facilitate electronic correspondence.

Sincerely yours,

Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health